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Contents

Federal Register

Vol. 84, No. 186

Wednesday, September 25, 2019

Agency for International Development
NOTICES
Meetings:
Board for International Food and Agricultural Development; Correction, 50371

Agricultural Marketing Service
RULES
Official United States Standards for Grain, 50293–50294
Softwood Lumber Research, Promotion, Consumer Education and Industry Information Order:
Change in Membership, Nominations, Procedures, and Continuance Referenda Period, 50294–50301
NOTICES
Opportunity for Designation:
South Carolina Area, 50371
Request for Renewal of a Recordkeeping Burden; Correction, 50371–50372

Agriculture Department
See Agricultural Marketing Service
See Food and Nutrition Service
See Forest Service
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 50372–50374

Centers for Disease Control and Prevention
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 50451–50453

Centers for Medicare & Medicaid Services
RULES
Medicaid Program:
State Disproportionate Share Hospital Allotment Reductions, 50308–50332
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 50453–50456

Commerce Department
See Foreign-Trade Zones Board
See International Trade Administration
See National Oceanic and Atmospheric Administration

Commodity Futures Trading Commission
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Swap Data Recordkeeping and Reporting Requirements, 50413–50414

Corporation for National and Community Service
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Application Package for AmeriCorps National Civilian Community Corps Member Experience Survey, 50414

Defense Acquisition Regulations System
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Defense Federal Acquisition Regulation Supplement; Quality Assurance, 50414–50415
Defense Federal Acquisition Regulation Supplement; Radio Frequency Identification Advance Shipment Notices, 50415–50416

Defense Department
See Defense Acquisition Regulations System
See Navy Department
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 50429–50430
Arms Sales, 50418–50441,
TRICARE:
Civilian Health and Medical Program of the Uniformed Services; Adoption of Medicare's Home Health Value-Based Purchasing Adjustments for Reimbursement under TRICARE's Home Health Prospective Payment System Demonstration, 50416–50418

Education Department
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Profiles of Selected Practices of Charter Schools, Charter Management Organizations, and Charter School Authorizers, 50443–50444
Agency Information Collection Activities; Proposals, Submissions, and Approvals;
Borrower Defenses Regulations, 50443
Submission of Data by State Educational Agencies:
Submission Dates for State Revenue and Expenditure Reports for Fiscal Year 2019, Revisions to those Reports, and Revisions to Prior Fiscal Year Reports, 50441–50443

Employment and Training Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Trade Adjustment Assistance Efforts to Improve Outcomes, 50475–50476
Federal-State Unemployment Compensation Program:
Federal Agencies with Adequate Safeguards and an Appropriate Method of Payment or Reimbursement to Satisfy Confidentiality the Requirements of Agency Rules, 50476–50477
Labor Surplus Area Classification, 50474–50475

Energy Department
See Federal Energy Regulatory Commission
NOTICES
Request for Information on Identifying Wells of Opportunity for Critical Geothermal Field Research Applications, 50444–50445

Environmental Protection Agency
RULES
Air Quality State Implementation Plans; Approvals and Promulgations:
Texas; Control of Air Pollution from Motor Vehicles, 50305–50307
Wisconsin; Title V Operation Permit Program; Withdrawal, 50307
National Oil and Hazardous Substances Pollution Contingency Plan:
National Priorities List: Partial Deletion of the Novak Sanitary Landfill Superfund Site, 50307–50308
PROPOSED RULES
Air Quality State Implementation Plans; Approvals and Promulgations:
Connecticut; Regional Haze Five Year Progress Report, 50363–50367
Indiana; Second Maintenance Plan for 1997 Ozone NAAQS, 50354–50363
National Emission Standards for Hazardous Air Pollutants:
Taconite Iron Ore Processing Residual Risk and Technology Review, 50660–50695
Review Process to Determine Whether the Waste Isolation Pilot Plant Continues to Comply with the Disposal Regulations and Compliance Criteria, 50367–50369
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Greenhouse Gas Reporting Program, 50447–50448
Significant New Alternatives Policy Program; Renewal, 50446–50447

Federal Aviation Administration
RULES
Airworthiness Directives:
Airbus SAS Airplanes, 50301–50303
Amendment of Class C Airspace:
Lafayette, LA, 50304–50305
PROPOSED RULES
Airworthiness Directives:
Airbus SAS Airplanes, 50339–50341
Dassault Aviation Airplanes, 50336–50339
Amendment of Air Traffic Service Routes V–82, V–217, and T–383:
Vicinity of Baudette, MN, 50344–50346
Amendment of Area Navigation Route:
Q–75 and Q–475, Northeast Corridor Atlantic Coast Routes; Northeastern United States, 50341–50344
Amendment of Class C Airspace:
Lansing, MI, 50346–50347
Amendment of VOR Federal Airway V–7:
Vicinity of Sheboygan, WI, 50347–50349
Flight Attendant Duty Period Limitations and Rest Requirements, 50349–50353

Federal Deposit Insurance Corporation
NOTICES
Meetings:
Advisory Committee on Community Banking, 50448–50449

Federal Energy Regulatory Commission
NOTICES
Combined Filings, 50445–50446
Institution of Section 206 Proceeding and Refund Date:
Idaho Power Co., 50445

Federal Maritime Commission
PROPOSED RULES
Interpretive Rule on Demurrage and Detention under the Shipping Act, 50369–50370

Federal Reserve System
NOTICES
Change in Bank Control:
Acquisitions of Shares of a Bank or Bank Holding Company, 50449
Formations of, Acquisitions by, and Mergers of Bank Holding Companies, 50449

Fish and Wildlife Service
RULES
Endangered and Threatened Wildlife and Plants:
Regulations for Interagency Cooperation, 50333
NOTICES
Endangered and Threatened Species:
Recovery Permit Application, 50471–50472
Incidental Take Permit Application and Proposed Habitat Conservation Plan:
Alabama Beach Mouse, Baldwin County, AL; Categorical Exclusion, 50470–50471

Food and Drug Administration
PROPOSED RULES
Premarket Tobacco Product Applications and Recordkeeping Requirements, 50566–50658
NOTICES
Guidance:
Recommendations for Sponsors of Medically Important Antimicrobial Drugs Approved for Use in Animals to Voluntarily Bring under Veterinary Oversight All Products That Continue to be Available Over-the-Counter, 50456–50457

Food and Nutrition Service
RULES
Delayed Implementation of Grains Ounce Equivalents in the Child and Adult Care Food Program, 50287–50293

Foreign-Trade Zones Board
NOTICES
Application for Subzone Expansion:
Hitachi Automotive Systems America, Inc., Harrodsburg, KY; Foreign-Trade Zone 29, Louisville, KY, 50375–50376
Proposed Production Activity:
DENSO Manufacturing Michigan, Inc. (Automotive HVAC and Engine Cooling Products); Foreign-Trade Zone 43, Battle Creek, MI, 50375
Reorganization under Alternate Site Framework:
Foreign-Trade Zone 262; Southaven, MS, 50374
Subzone Application:
Pueblo, Inc., Guaynabo, PR; Foreign-Trade Zone 61, San Juan, PR, 50374

Forest Service
PROPOSED RULES
Land Uses; Special Uses:
Procedures for Operating Plans and Agreements for Vegetation Management within and along Powerline Rights-of-Way, 50698–50702
Streamlining Processing of Communications Use Applications, 50703–50706

Government Ethics Office
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Modified Qualified Trust Model Certificates and Model Trust Documents, 50449–50451

Health and Human Services Department
See Centers for Disease Control and Prevention
See Centers for Medicare & Medicaid Services
See Food and Drug Administration
See National Institutes of Health
NOTICES
Assistant Secretary for Administration:
Delegation of Authority, 50457–50458
Meetings:
Advisory Council on Alzheimer's Research, Care, and Services, 50458–50459
Presidential Advisory Council on HIV/AIDS, 50458

Housing and Urban Development Department
NOTICES
Statutorily Mandated Designation of Difficult Development Areas and Qualified Census Tracts for 2020, 50465–50470

Interior Department
See Fish and Wildlife Service
See Land Management Bureau
See Reclamation Bureau

International Trade Administration
NOTICES
Antidumping or Countervailing Duty Investigations, Orders, or Reviews:
Certain Crystalline Silicon Photovoltaic Products from the People's Republic of China, 50386–50387
Determination of Sales at Less Than Fair Value:
Alloy and Certain Carbon Steel Threaded Rod from the People's Republic of China, 50379–50382
Carbon and Alloy Steel Threaded Rod from India, 50376–50379
Carbon and Alloy Steel Threaded Rod from Taiwan, 50382–50384
Scope Rulings, 50385–50386

International Trade Commission
NOTICES
Antidumping or Countervailing Duty Investigations, Orders, or Reviews:
Carbon and Certain Alloy Steel Wire Rod from Brazil, Indonesia, Mexico, Moldova, and Trinidad and Tobago, 50474
Investigations; Determinations, Modifications, and Rulings, etc.:
Circular Welded Carbon Quality Steel Line Pipe from China, 50473

Labor Department
See Employment and Training Administration
See Mine Safety and Health Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Claim for Reimbursement-Assisted Reemployment, 50478
Migrant and Seasonal Farmworker Monitoring Report and Complaint/Apparent Violation Form, 50479
State Training Provider Eligibility Collection, 50477–50478

Land Management Bureau
NOTICES
Environmental Impact Statements; Availability, etc.:
Coastal Plain Oil and Gas Leasing Program, Alaska, 50472–50473

Mine Safety and Health Administration
NOTICES
Meetings:
Escapeways and Refuges in Underground Metal and Nonmetal Mines, 50479–50480

National Institutes of Health
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Application and Impact of Clinical Research Training on Healthcare Professionals in Academia and Clinical Research (Office of the Director), 50460–50461
Meetings:
Center for Scientific Review, 50459–50460, 50463–50464
Eunice Kennedy Shriver National Institute of Child Health and Human Development, 50460
National Heart, Lung, and Blood Institute, 50461–50462
National Institute on Aging, 50462–50463

National Labor Relations Board
NOTICES
Meetings; Sunshine Act, 50480

National Oceanic and Atmospheric Administration
RULES
Endangered and Threatened Wildlife and Plants:
Regulations for Interagency Cooperation, 50333
Snapper-Grouper Fishery of the South Atlantic:
2019 Recreational Accountability Measure and Closure for South Atlantic Red Grouper, 50334–50335
2019 Recreational Accountability Measure and Closure for the South Atlantic Other Jacks Complex, 50333–50334
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Atlantic Large Whale Take Reduction Plan Regulations, 50409
Basic Requirements for Special Exception Permits and Authorizations to Take, Import, and Export Marine Mammals, Threatened and Endangered Species, etc., 50409–50412
Estuary Habitat Restoration Program Inventory, 50412
West Coast Region Groundfish Electronic Fish Ticket Program, 50408
Meetings:
Advisory Committee to the U.S. Section of the International Commission for the Conservation of Atlantic Tunas, 50407–50408
Marine Fisheries Advisory Committee, 50412–50413
Takes of Marine Mammals Incidental to Specified Activities:
Erickson Residence Marine Access Project in Juneau, AK, 50387–50407

Navy Department
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 50441

Nuclear Regulatory Commission
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Certificate of Disposition of Materials, 50480–50481
License Renewal:
Department of Energy Idaho Operations Office Three Mile Island Unit 2 Independent Spent Fuel Storage Installation, 50481–50483

Postal Regulatory Commission
PROPOSED RULES
Periodic Reporting, 50353–50354
NOTICES
New Postal Products, 50483

Postal Service
NOTICES
Meetings; Sunshine Act, 50483
Product Change:
First-Class Package Service Negotiated Service Agreement, 50483

Presidential Documents
PROCLAMATIONS
Special Observances:
National POW/MIA Recognition Day (Proc. 9930), 50707–50710

Reclamation Bureau
NOTICES
Charter Renewal:
Glen Canyon Dam Adaptive Management Work Group, 50473

Securities and Exchange Commission
NOTICES
Self-Regulatory Organizations; Proposed Rule Changes:
BOX Exchange, LLC, 50534–50541
Cboe BZX Exchange, Inc., 50501–50502
Cboe Exchange, Inc., 50490–50495, 50504–50521, 50529–50532, 50545–50558
Investors Exchange, LLC, 50485–50489
Long-Term Stock Exchange, Inc., 50525–50527
National Securities Clearing Corp., 50532–50534
New York Stock Exchange, LLC, 50502–50504
NYSE American, LLC, 50527–50528
NYSE Arca, Inc., 50543–50545
NYSE Chicago, Inc., 50484–50485
The Depository Trust Co., 50541–50543
The Nasdaq Stock Market, LLC, 50490, 50495–50501, 50521–50525

Small Business Administration
NOTICES
Major Disaster Declaration for Public Assistance Only:
Illinois, 50559
Louisiana, 50559
Privacy Act; Systems of Records, 50558–50559

State Department
NOTICES
Culturally Significant Objects Imported for Exhibition:
Berthe Morisot: Impressionist Original, 50560–50561
Marino Marini: Arcadian Nudes, 50560
The Pencil is a Key: Drawings by Incarcerated Artists, 50560
Meetings:
Advisory Committee on International Law, 50560

Surface Transportation Board
NOTICES
Charter Renewal:
National Grain Car Council, 50561–50562
Rail Energy Transportation Advisory Committee, 50561
Quarterly Rail Cost Adjustment Factor, 50561

Transportation Department
See Federal Aviation Administration

Veterans Affairs Department
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Department of Veterans Affairs Acquisition Regulation Clause 852.211–72, Technical Industry Standards, 50562
Loan Guaranty:
Assistance to Eligible Individuals in Acquiring Specially Adapted Housing; Cost-of-Construction Index, 50562–50563

Separate Parts In This Issue

Part II
Health and Human Services Department, Food and Drug Administration, 50566–50658

Part III
Environmental Protection Agency, 50660–50695

Part IV
Agriculture Department, Forest Service, 50698–50706

Part V
Presidential Documents, 50707–50710

Reader Aids

Consult the Reader Aids section at the end of this issue for phone numbers, online resources, finding aids, and notice of recently enacted public laws.

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CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

3 CFR

Proclamations:

9930 50709

7 CFR

210 50287
220 50287
226 50287
810 50293
1217 50294

14 CFR

39 50301
71 50304

Proposed Rules:

39 (2 documents) 50336, 50339
71 (4 documents) 50341, 50344, 50346, 50347
121 50349

21 CFR

Proposed Rules:

1100 50566
1107 50566
1114 50566

36 CFR

Proposed Rules:

251 (2 documents) 50698, 50703

39 CFR

Proposed Rules:

3050 50353

40 CFR

52 50305
70 50307
300 50307

Proposed Rules:

52 (2 documents) 50354, 50363
63 50660
191 50367
194 50367

42 CFR

447 50308

46 CFR

Proposed Rules:

545 50369

50 CFR

402 50333
622 (2 documents) 50333, 50334

Rules and Regulations

Federal Register

Vol. 84, No. 186

Wednesday, September 25, 2019

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

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DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Parts 210, 220, and 226

[FNS–2019–0005]

RIN 0584–AE65

Delayed Implementation of Grains Ounce Equivalents in the Child and Adult Care Food Program

AGENCY: Food and Nutrition Service (FNS), USDA.

ACTION: Final rule.

SUMMARY: This action delays, from October 1, 2019 until October 1, 2021, the implementation date of the ''ounce equivalents'' requirement for crediting grains served in the Child and Adult Care Food Program (CACFP). The final rule, *Child and Adult Care Food Program: Meal Pattern Revisions Related to the Healthy, Hunger-Free Kids Act of 2010,* published on April 25, 2016, specified that meal planners must use ounce equivalents to determine the amount of creditable grain served as part of a reimbursable meal or snack. A two-year extension allows more time for FNS to develop additional technical assistance materials and for State agencies and sponsoring organizations to provide training and technical assistance to support meal planners and assure compliance nationwide. This action is consistent with FNS' efforts to provide excellent customer service as we work with State and local partners to ensure high quality, nutritious meals for children and adult participants in CACFP. This action also applies to the crediting of grains served to infants and toddlers in the National School Lunch and School Breakfast Programs. In addition, this rule makes a technical correction to the application for free and reduced-price meals for adult CACFP participants.

DATES: Effective October 1, 2019.

FOR FURTHER INFORMATION CONTACT: Andrea Farmer, 703–305–2590, *andrea.farmer@usda.gov*.

SUPPLEMENTARY INFORMATION:

Background

This final rule delays the implementation date, from October 1, 2019 until October 1, 2021, of the requirement for crediting grains served in CACFP by ''ounce equivalents.'' Historically, meal planners at day care homes and centers in CACFP have credited grains served as part of a reimbursable meal or snack based on household measures, such as cups or ''servings'' of breads and other grain-based foods. The final rule, *Child and Adult Care Food Program: Meal Pattern Revisions Related to the Healthy, Hunger-Free Kids Act of 2010,* published at 81 FR 24347 on April 25, 2016, specified that grains must be credited using ounce equivalents instead.

To make compliance easier, particularly as State agencies and local partners were focused on implementing more significant aspects of the meal pattern rule, FNS initially delayed implementation of the ounce equivalents provision until October 1, 2019. However, even with the additional time, confusion among some meal planners convinced FNS that additional training and technical assistance is needed to support day care homes and centers with the tools they need to more easily implement this provision and assure compliance.

On July 1, 2019, FNS published a proposed rule, *Delayed Implementation of Grains Ounce Equivalents in the Child and Adult Care Food Program,* 84 FR 31227, that would allow State agencies, institutions, and day care homes and centers additional time to fully implement the crediting of grains by ounce equivalents by October 1, 2021. The rule proposed a two-year extension to allow adequate time for FNS to develop additional technical assistance materials and for State agencies and sponsoring organizations to use these materials to provide training and technical assistance to support meal planners and assure compliance nationwide. This action is consistent with FNS' efforts to provide excellent customer service as we work with State and local partners to ensure high quality, nutritious meals for children and adult participants in CACFP.

FNS received 679 written comments during the 30-day comment period, which ended on July 31, 2019. Of these, 311 were unique comments and the remainder (368) were form letters. The majority of respondents were child care providers, including both center-based and in-home based care. Comments were also received from State administering agencies, non-profit organizations, advocates, dietitians, academics, industry stakeholders, adult care providers, and members of the general public.

The vast majority of respondents (604) wrote in support of a delayed implementation. As such, FNS will move forward with the delay as proposed. Most supporters cited the need for training and technical assistance on ounce equivalents. Supporters also frequently stated that the immediate change would overwhelm meal planners at day care homes and centers who may still be adjusting to implementing the other requirements of the updated CACFP meal patterns. Meal planners in CACFP may lack experience with or access to the same types of resources, such as Child Nutrition labeled products or the Food Buying Guide Interactive Web-Based Tool, which have helped schools successfully implement ounce equivalents in the National School Lunch and School Breakfast Programs. Many respondents cited the need for more user-friendly resource materials on ounce equivalents from FNS and other sources.

Nineteen respondents wrote in opposition to the delay, including one State agency. They stated that day care home and center providers have had adequate time to adjust to using ounce equivalents or that the State agency had already successfully implemented training. FNS is encouraged that these respondents are ready for implementation and FNS supports early implementation of ounce equivalents crediting, as outlined in the paragraphs below.

Seventy-eight respondents expressed frustration with the requirement or asked that it be reevaluated. The most common concerns were a lack of time and equipment. Many of these commenters seemed to misunderstand the ounce equivalents requirement and

believed that all grain portions must be weighed using a kitchen scale, thus requiring new equipment and reducing staff time available for direct care of children or adults in the program. To clarify, the use of ounce equivalents to credit grains will not require all grain portions to be weighed. Among these 78 respondents, 42 simultaneously supported the delay. In addition, some respondents expressed their frustration with CACFP requirements in general, often citing documentation burdens or limited staff resources, without expressing an opinion on the proposed delay. FNS will continue to listen to stakeholder feedback and monitor implementation during the period of delay to assess the success of sponsoring organizations and program operators in applying the ounce equivalents requirement.

FNS recognizes the concerns of stakeholders about the need for additional transition time to prepare to credit grains in ounce equivalents. FNS is working to deliver technical assistance materials and tools that can help simplify the use of ounce equivalents in CACFP, including resources that allow providers planning and preparing meals to continue to use common household measures while meeting the new crediting requirements.

Some examples of the resources that will ease this transition include a training webinar, a revised *Crediting Handbook for the Child and Adult Care Food Program,* and standardized recipes. USDA is also updating the online *Food Buying Guide for Child Nutrition Programs*—which now contains the *Recipe Analysis Workbook* and the *Exhibit A Grains Tool*—that allows menu planners to easily determine grain contributions for commercial grain products. FNS is also working to develop additional *CACFP Meal Pattern Training Worksheets* that will simplify the use of ounce equivalents, and clarify the method for determining ounce equivalents for grains in the CACFP. These new tools will be available on USDA Team Nutrition's web page: *https://www.fns.usda.gov/tn.*

Although this rule requires full implementation of ounce equivalents by October 1, 2021, State agencies may implement the ounce equivalents requirements prior to October 1, 2021. FNS encourages State agencies and sponsoring organizations to implement ounce equivalents as soon as they are confident that day care homes and centers have the training and technical assistance they need to successfully achieve compliance. However, during the period of early implementation, State agencies and sponsoring organizations must provide technical assistance in lieu of fiscal action when they observe violations related to the ounce equivalents requirement. Prior to October 1, 2021, a violation based solely on this requirement may not result in a disallowance of Federal reimbursement of meals that are otherwise eligible, an assessment of an overclaim, a declaration of serious deficiency, or any other adverse action.

Accordingly, FNS delays full implementation of the ounce equivalents requirement in CACFP until October 1, 2021. This action also applies to the crediting of grains served to infants and toddlers in the National School Lunch and School Breakfast Programs. Corresponding changes are made to update the infant meal pattern tables at 7 CFR 210.10(o), 210.10(q), 220.8(p), and 226.20(c); preschool meal pattern tables at 7 CFR 210.10(o), 210.10(p), and 220.8(o); and meal pattern tables for children and adult participants at 7 CFR 226.20(c). FNS is revising the endnotes to these tables to state that, beginning on October 1, 2021, ounce equivalents will be used to determine the quantity of creditable grains. FNS is also removing endnotes, which delayed implementation of the minimum serving size of dry, cold whole grain-rich, enriched, or fortified ready-to-eat cereal, specified in some of the tables. Beginning on October 1, 2019, this information will no longer be needed.

FNS is also using this opportunity to correct a technical error that appears in the free and reduced-price meal application for adult CACFP participants at 7 CFR 226.23. Under section 9(d)(1) of the Richard B. Russell National School Lunch Act, 42 U.S.C. 1758(d)(1), only the adult household member who signs a household application for free and reduced-price lunches must provide the last four digits of his or her social security number, as a condition of eligibility. However, an error in the statement that must be included on the meal benefit form for adult participants requires the last four digits of the social security number of all adult household members, including the adult day care participant. Accordingly, this rule corrects the statement at 7 CFR 226.23(e)(1)(iii)(E) to require the last four digits of the social security number of only the adult household member who signs the meal benefit form.

Procedural Matters

Executive Orders 12866 and 13563

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

Regulatory Flexibility Act

The Regulatory Flexibility Act, 5 U.S.C. 601–612, requires Agencies to analyze the impact of rulemaking on small entities and consider alternatives that would minimize any significant impacts on a substantial number of small entities. The FNS Administrator has certified that this final rule will not have a significant economic impact on a substantial number of small entities. This rule allows meal planners additional time to receive training and technical assistance and additional time for State agencies and sponsoring organizations to facilitate implementation of the new requirement. While this rule will affect State agencies, sponsoring organizations, school food authorities, and day care homes and centers, any economic effect will not be significant.

Executive Order 13771

Executive Order 13771 directs agencies to reduce regulation and control regulatory costs and provides that the cost of planned regulations be prudently managed and controlled through a budgeting process. This final rule is not expected to be an Executive Order 13771 regulatory action because it is not significant under Executive Order 12866.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandate Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments, and the private sector. Under section 202 of UMRA, FNS generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local, or

tribal governments in the aggregate, or to the private sector, of $100 million or more in any one year. When such a statement is needed for a rule, section 205 of UMRA generally requires FNS to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, more cost-effective or least burdensome alternative that achieves the objectives of the rule. This final rule contains no Federal mandates, under the regulatory provisions of title II of UMRA, for State, local, and tribal governments, or the private sector, of $100 million or more in any one year. Therefore, this rule is not subject to the requirements of sections 202 and 205 of UMRA.

Executive Order 12372

CACFP is listed in the Assistance Listings under the Catalog of Federal Domestic Assistance Number 10.558. The National School Lunch Program and School Breakfast Program are listed under No. 20.555 and 10.553, respectively. They are subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. Since the Child Nutrition Programs are State-administered, FNS has formal and informal discussions with State and local officials, including representatives of Indian Tribal Organizations, on an ongoing basis regarding program requirements and operations. This provides FNS with the opportunity to receive regular input from State administrators and local program operators, which contributes to the development of feasible requirements.

Federalism Summary Impact Statement

Executive Order 13132 requires Federal agencies to consider the impact of their regulatory actions on State and local governments. Where such actions have federalism implications, agencies are directed to provide a statement for inclusion in the preamble to the regulations describing the agency's considerations in terms of the three categories called for under section 6(b)(2)(B) of Executive Order 13132. FNS has determined that this final rule does not have federalism implications. This rule does not impose substantial or direct compliance costs on State and local governments. Therefore, under section 6(b) of the Executive Order, a federalism summary is not required.

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule is not intended to have preemptive effect with respect to any State or local laws, regulations, or policies which conflict with its provisions or which would otherwise impede its full implementation. This rule is not intended to have retroactive effect. Prior to any judicial challenge to the application of the provisions of this rule, all applicable administrative procedures must be exhausted.

Civil Rights Impact Analysis

FNS has reviewed this final rule in accordance with USDA Regulation 4300–4, *Civil Rights Impact Analysis,* to identify and address any major civil rights impacts the rule might have on minorities, women, and persons with disabilities. After a careful review of the rule's intent and provisions, FNS has determined that this rule is not expected to limit or reduce the ability of protected classes of individuals to participate as program operators or as recipients of meal benefits. FNS also does not expect this rule to have any disparate impacts on program operators by protected classes of individuals.

Executive Order 13175

Executive Order 13175 requires Federal agencies to consult and coordinate with Tribes on a government-to-government basis on policies that have Tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Tribal representatives were informed about this rulemaking on June 27, 2019. FNS anticipates that this will have no significant cost and no major increase in regulatory burden on tribal organizations.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35 and 5 CFR 1320, requires OMB to approve all collections of information by a Federal agency before they can be implemented. Respondents are not required to respond to any collection of information unless it displays a current valid OMB control number. This final rule does not add any new information collection requirements.

E-Government Act Compliance

FNS is committed to complying with the E-Government Act, to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes. Online resources to aid in the implementation of ounce equivalents for grains in the CACFP include the online interactive *Food Buying Guide for Child Nutrition Programs,* the *Exhibit A Grains Tool,* and the *Recipe Analysis Workbook.*

List of Subjects

7 CFR Part 210

Grant programs—education, Grant Programs—health, Infants and children, Nutrition, Penalties, Reporting and recordkeeping requirements, School breakfast and lunch programs, Surplus agricultural commodities.

7 CFR Part 220

Grant programs—education, Grant Programs—health, Infants and children, Nutrition, Reporting and recordkeeping requirements, School breakfast and lunch programs.

7 CFR Part 226

Accounting, Aged, Day care, Food assistance programs, Grant programs, Grant programs—health, American Indians, Individuals with disabilities, Infants and children, Intergovernmental relations, Loan programs, Reporting and recordkeeping requirements, Surplus agricultural commodities.

Accordingly, 7 CFR parts 210, 220, and 226 are amended as follows:

PART 210—NATIONAL SCHOOL LUNCH PROGRAM

■ 1. The authority citation for part 210 continues to read as follows:

Authority: 42 U.S.C. 1751–1760, 1779.

■ 2. In § 210.10, revise the tables in paragraphs (o)(3)(ii), (o)(4)(ii), (p)(2), and (q)(2) to read as follows:

§ 210.10 Meal requirements for lunches and requirements for afterschool snacks.

* * * * *

(o) * * *

(3) * * *

(ii) * * *

PRESCHOOL SNACK MEAL PATTERN

Food components and food items [1]	Minimum quantities	
	Ages 1–2	Ages 3–5
Fluid Milk [2]	4 fluid ounces	4 fluid ounces.
Meat/meat alternates (edible portion as served):		
Lean meat, poultry, or fish	½ ounce	½ ounce.
Tofu, soy products, or alternate protein products.[3]	½ ounce	½ ounce.
Cheese	½ ounce	½ ounce.
Large egg	½	½.
Cooked dry beans or peas	⅛ cup	⅛ cup.
Peanut butter or soy nut butter or other nut or seed butters	1 Tbsp	1 Tbsp.
Yogurt, plain or flavored unsweetened or sweetened.[5]	2 ounces or ¼ cup	2 ounces or ¼ cup.
Peanuts, soy nuts, tree nuts, or seeds	½ ounce	½ ounce.
Vegetables [4]	½ cup	½ cup.
Fruits [4]	½ cup	½ cup.
Grains (oz eq): [6 7]		
Whole grain-rich or enriched bread	½ slice	½ slice.
Whole grain-rich or enriched bread product, such as biscuit, roll, or muffin	½ serving	½ serving.
Whole grain-rich, enriched, or fortified cooked breakfast cereal,[8] cereal grain, and/or pasta.	¼ cup	¼ cup.
Whole grain-rich, enriched, or fortified ready-to-eat cereal (dry, cold): [8]		
Flakes or rounds	½ cup	½ cup.
Puffed cereal	¾ cup	¾ cup.
Granola	⅛ cup	⅛ cup.

Endnotes:

[1] Select two of the five components for a reimbursable snack. Only one of the two components may be a beverage.

[2] Must be unflavored whole milk for children age one. Must be unflavored low-fat (1 percent) or unflavored fat-free (skim) milk for children two through five years old.

[3] Alternate protein products must meet the requirements in Appendix A to Part 226 of this chapter.

[4] Pasteurized full-strength juice may only be used to meet the vegetable or fruit requirement at one meal, including snack, per day.

[5] Yogurt must contain no more than 23 grams of total sugars per 6 ounces.

[6] At least one serving per day, across all eating occasions, must be whole grain-rich. Grain-based desserts do not count towards meeting the grains requirement.

[7] Beginning October 1, 2021, ounce equivalents are used to determine the quantity of creditable grains.

[8] Breakfast cereals must contain no more than 6 grams of sugar per dry ounce (no more than 21.2 grams sucrose and other sugars per 100 grams of dry cereal).

(4) * * *

(ii) * * *

INFANT SNACK MEAL PATTERN

Birth through 5 months	6 through 11 months
4–6 fluid ounces breastmilk [1] or formula.[2]	2–4 fluid ounces breastmilk [1] or formula; [2] and 0–½ slice bread;[3 4] or 0–2 crackers;[3 4] or 0–4 tablespoons infant cereal [2 3 4] or ready-to-eat breakfast cereal;[3 4 5 6] and 0–2 tablespoons vegetable or fruit, or a combination of both.[6 7]

[1] Breastmilk or formula, or portions of both, must be served; however, it is recommended that breastmilk be served in place of formula from birth through 11 months. For some breastfed infants who regularly consume less than the minimum amount of breastmilk per feeding, a serving of less than the minimum amount of breastmilk may be offered, with additional breastmilk offered at a later time if the infant will consume more.

[2] Infant formula and dry infant cereal must be iron-fortified.

[3] A serving of grains must be whole grain-rich, enriched meal, or enriched flour.

[4] Beginning October 1, 2021, ounce equivalents are used to determine the quantity of creditable grains.

[5] Breakfast cereals must contain no more than 6 grams of sugar per dry ounce (no more than 21.2 grams sucrose and other sugars per 100 grams of dry cereal).

[6] A serving of this component is required when the infant is developmentally ready to accept it.

[7] Fruit and vegetable juices must not be served.

* * * * *

(p) * * *

(2) * * *

PRESCHOOL LUNCH MEAL PATTERN

Food components and food items [1]	Minimum quantities	
	Ages 1–2	Ages 3–5
Fluid Milk [2]	4 fluid ounces	6 fluid ounces.
Meat/meat alternates (edible portion as served):		
Lean meat, poultry, or fish	1 ounce	1½ ounces.
Tofu, soy products, or alternate protein products [3]	1 ounce	1½ ounces.
Cheese	1 ounce	1½ ounces.
Large egg	½	¾.
Cooked dry beans or peas	¼ cup	⅜ cup.
Peanut butter or soy nut butter or other nut or seed butters	2 Tbsp	3 Tbsp.
Yogurt, plain or flavored unsweetened or sweetened [4]	4 ounces or ½ cup	6 ounces or ¾ cup.
The following may be used to meet no more than 50% of the requirement:	½ ounce = 50%	¾ ounce = 50%.
Peanuts, soy nuts, tree nuts, or seeds, as listed in program guidance, or an equivalent quantity of any combination of the above meat/meat alternates (1 ounce of nuts/seeds = 1 ounce of cooked lean meat, poultry, or fish).		
Vegetables [5]	⅛ cup	¼ cup.
Fruits [5 6]	⅛ cup	¼ cup.
Grains (oz eq): [7 8]		
Whole grain-rich or enriched bread	½ slice	½ slice.
Whole grain-rich or enriched bread product, such as biscuit, roll, muffin	½ serving	½ serving.
Whole grain-rich, enriched, or fortified cooked breakfast cereal[9], cereal grain, and/or pasta.	¼ cup	¼ cup.

Endnotes:

[1] Must serve all five components for a reimbursable meal.

[2] Must be unflavored whole milk for children age one. Must be unflavored low-fat (1 percent) or unflavored fat-free (skim) milk for children two through five years old.

[3] Alternate protein products must meet the requirements in Appendix A to Part 226 of this chapter.

[4] Yogurt must contain no more than 23 grams of total sugars per 6 ounces.

[5] Pasteurized full-strength juice may only be used to meet the vegetable or fruit requirement at one meal, including snack, per day.

[6] A vegetable may be used to meet the entire fruit requirement. When two vegetables are served at lunch or supper, two different kinds of vegetables must be served.

[7] At least one serving per day, across all eating occasions, must be whole grain-rich. Grain-based desserts do not count towards the grains requirement.

[8] Beginning October 1, 2021, ounce equivalents are used to determine the quantity of the creditable grain.

[9] Breakfast cereals must contain no more than 6 grams of sugar per dry ounce (no more than 21.2 grams sucrose and other sugars per 100 grams of dry cereal).

(q) * * * * *

(2) * * * * *

INFANT LUNCH MEAL PATTERN

Birth through 5 months	6 through 11 months
4–6 fluid ounces breastmilk [1] or formula [2]	6–8 fluid ounces breastmilk [1] or formula [2] and 0–4 tablespoons infant cereal [2 3] meat, fish, poultry, whole egg, cooked dry beans, or cooked dry peas; or 0–2 ounces of cheese; or 0–4 ounces (volume) of cottage cheese; or 0–4 ounces or ½ cup of yogurt; [4] or a combination of the above; [5] and 0–2 tablespoons vegetable or fruit, or a combination of both [5 6]

[1] Breastmilk or formula, or portions of both, must be served; however, it is recommended that breastmilk be served in place of formula from birth through 11 months. For some breastfed infants who regularly consume less than the minimum amount of breastmilk per feeding, a serving of less than the minimum amount of breastmilk may be offered, with additional breastmilk offered at a later time if the infant will consume more.

[2] Infant formula and dry infant cereal must be iron-fortified.

[3] Beginning October 1, 2021, ounce equivalents are used to determine the quantity of creditable grains.

[4] Yogurt must contain no more than 23 grams of total sugars per 6 ounces.

[5] A serving of this component is required when the infant is developmentally ready to accept it.

[6] Fruit and vegetable juices must not be served.

* * * * *

PART 220—SCHOOL BREAKFAST PROGRAM

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

Authority: 42 U.S.C. 1773, 1779, unless otherwise noted.

■ 4. In § 220.8, revise the tables in paragraphs (o)(2) and (p)(2), to read as follows:

§ 220.8 Meal requirements for breakfasts.

* * * * *

(o) * * *

(2) * * *

PRESCHOOL BREAKFAST MEAL PATTERN

Food components and food items[1]	Minimum quantities	
	Ages 1–2	Ages 3–5
Fluid Milk[2]	4 fluid ounces	6 fluid ounces.
Vegetables, fruits, or portions of both[3]	¼ cup	½ cup.
Grains (oz eq):[4 5 6]		
Whole grain-rich or enriched bread	½ slice	½ slice.
Whole grain-rich or enriched bread product, such as biscuit, roll, muffin	½ serving	½ serving.
Whole grain-rich, enriched, or fortified cooked breakfast cereal,[7] cereal grain, and/or pasta.	¼ cup	¼ cup.
Whole grain-rich, enriched, or fortified ready-to-eat breakfast cereal (dry, cold):[7]		
Flakes or rounds	½ cup	½ cup.
Puffed cereal	¾ cup	¾ cup.
Granola	⅛ cup	⅛ cup.

Endnotes:
[1] Must serve all three components for a reimbursable meal.
[2] Must be unflavored whole milk for children age one. Must be unflavored low-fat (1 percent) or unflavored fat-free (skim) milk for children two through five years old.
[3] Pasteurized full-strength juice may only be used to meet the vegetable or fruit requirement at one meal, including snack, per day.
[4] At least one serving per day, across all eating occasions, must be whole grain-rich. Grain-based desserts do not count towards meeting the grains requirement.
[5] Meat and meat alternates may be used to meet the entire grains requirement a maximum of three times a week. One ounce of meat and meat alternates is equal to one ounce equivalent of grains.
[6] Beginning October 1, 2021, ounce equivalents are used to determine the quantity of creditable grains.
[7] Breakfast cereals must contain no more than 6 grams of sugar per dry ounce (no more than 21.2 grams sucrose and other sugars per 100 grams of dry cereal).

(p) * * *

(2) * * *

INFANT BREAKFAST MEAL PATTERN

Birth through 5 months	6 through 11 months
4–6 fluid ounces breastmilk[1] or formula[2]	6–8 fluid ounces breastmilk[1] or formula;[2] and 0–4 tablespoons infant cereal[2 3] meat, fish, poultry, whole egg, cooked dry beans, or cooked dry peas; or 0–2 ounces of cheese; or 0–4 ounces (volume) of cottage cheese; or 0–4 ounces or ½ cup of yogurt;[4] or a combination of the above[5]; and 0–2 tablespoons vegetable or fruit, or a combination of both.[5 6]

[1] Breastmilk or formula, or portions of both, must be served; however, it is recommended that breastmilk be served in place of formula from birth through 11 months. For some breastfed infants who regularly consume less than the minimum amount of breastmilk per feeding, a serving of less than the minimum amount of breastmilk may be offered, with additional breastmilk offered at a later time if the infant will consume more.
[2] Infant formula and dry infant cereal must be iron-fortified.
[3] Beginning October 1, 2021, ounce equivalents are used to determine the quantity of creditable grains.
[4] Yogurt must contain no more than 23 grams of total sugars per 6 ounces.
[5] A serving of this component is required when the infant is developmentally ready to accept it.
[6] Fruit and vegetable juices must not be served.

* * * * *

PART 226—CHILD AND ADULT CARE FOOD PROGRAM

■ 5. The authority citation for 7 CFR part 226 continues to read as follows:

Authority: Secs. 9, 11, 14, 16, and 17, Richard B. Russell National School Lunch Act, as amended, 42 U.S.C. 1758, 1759a, 1762a, 1765 and 1766.

■ 6. In § 226.20:

■ a. Revise the table in paragraph (b)(5);

■ b. In the table to paragraph (c)(1), remove the date ''October 1, 2019'' in endnote 7 and add in its place ''October 1, 2021'', and remove endnote 9;

■ c. In the table to paragraph (c)(2), remove the date ''October 1, 2019'' in endnote 10 and add in its place ''October 1, 2021''; and

■ d. In the table to paragraph (c)(3), remove the date ''October 1, 2019'' in endnote 8 and add in its place ''October 1, 2021'', and remove endnote 10.

The revision reads as follows:

§ 226.20 Requirements for meals.

* * * * *

(b) * * *

(5) * * *

INFANT MEAL PATTERNS

Infants	Birth through 5 months	6 through 11 months
Breakfast, Lunch, or Supper	4–6 fluid ounces breastmilk [1] or formula [2].	6–8 fluid ounces breastmilk [1] or formula; [2] and 0–4 tablespoons infant cereal,[3] meat, fish, poultry, whole egg, cooked dry beans, or cooked dry peas; or 0–2 ounces of cheese; or 0–4 ounces (volume) of cottage cheese; or 0–4 ounces or ½ cup of yogurt; [4] or a combination of the above; [5] and 0–2 tablespoons vegetable or fruit, or a combination of both.[5 6]
Snack	4–6 fluid ounces breastmilk [1] or formula [2].	2–4 fluid ounces breastmilk [1] or formula [2]; and 0-½ slice bread; [3 7] or 0–2 crackers; [3 7] or 0–4 tablespoons infant cereal [2 3 7] or ready-to-eat breakfast cereal; [3 5 7 8] and 0–2 tablespoons vegetable or fruit, or a combination of both [5 6]

[1] Breastmilk or formula, or portions of both, must be served; however, it is recommended that breastmilk be served in place of formula from birth through 11 months. For some breastfed infants who regularly consume less than the minimum amount of breastmilk per feeding, a serving of less than the minimum amount of breastmilk may be offered, with additional breastmilk offered at a later time if the infant will consume more.
[2] Infant formula and dry infant cereal must be iron-fortified.
[3] Beginning October 1, 2021, ounce equivalents are used to determine the quantity of creditable grains.
[4] Yogurt must contain no more than 23 grams of total sugars per 6 ounces.
[5] A serving of this component is required when the infant is developmentally ready to accept it.
[6] Fruit and vegetable juices must not be served.
[7] A serving of grains must be whole grain-rich, enriched meal, or enriched flour.
[8] Breakfast cereals must contain no more than 6 grams of sugar per dry ounce (no more than 21.2 grams sucrose and other sugars per 100 grams of dry cereal).

* * * * *

■ 7. In § 226.23, revise the third sentence in paragraph (e)(1)(iii)(E) to read as follows:

§ 226.23 Free and reduced-price meals.

* * * * *

(e) * * *

(1) * * *

(iii) * * *

(E) * * * You must include the last four digits of the social security number of the adult household member who signs the meal benefit form.* * *

* * * * *

Dated: September 19, 2019.

Pamilyn Miller,

Administrator, Food and Nutrition Service.

[FR Doc. 2019–20808 Filed 9–24–19; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 810

[Doc No. AMS–FGIS–19–0033]

Official United States Standards for Grain

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final action.

SUMMARY: The United States Department of Agriculture's (USDA) Agricultural Marketing Service (AMS) will not pursue changes to the United States (U.S.) Standards for Corn and Soybeans under the United States Grain Standards Act (USGSA).

DATES: September 25, 2019.

FOR FURTHER INFORMATION CONTACT: Patrick McCluskey, USDA AMS; Telephone: (816) 659–8403; Email: *Patrick.J.McCluskey@ams.usda.gov.*

SUPPLEMENTARY INFORMATION: Section 4 of the USGSA (7 U.S.C. 76(a)) grants the Secretary of Agriculture the authority to establish standards for grain regarding kind, class, quality, and condition. AMS published two requests for information on June 29, 2018, in the **Federal Register** (83 FR 30591 and 83 FR 30592), wherein AMS invited interested parties to submit comments, ideas, and suggestions on all aspects of the official procedures and the U.S. Standards for Soybeans.

AMS received a total of six comments on the U.S. Standards for Soybeans. AMS received one comment from a stakeholder requesting the comment period for the U.S. Standards for Soybeans be extended. AMS reopened the comment period in a **Federal Register** publication on October 2, 2018.

AMS received a total of six comments on the U.S. Standards for Soybeans. Two comments were not germane to the rulemaking and accordingly AMS will not take action based on the comments.

AMS received one comment from stakeholders representing grain handlers and exporters requesting the comment period for the U.S. Standards for Soybeans be extended and accordingly, the comment period was reopened on October 2, 2018. During the re-opened comment period, the same commenter group joined with soy processors recommending that AMS withdraw the Request for Information. AMS considers this to mean the commenters request no changes to the soybean standards.

One commenter recommended revising the standard to include a minimum protein content, and to establish a maximum limit of three percent of gluten containing grains in U.S. #1 and U.S. #2 soybeans. Protein content specifications in grain and oilseed commerce are typically handled contractually. Likewise, a maximum limit for gluten containing grains at the contracted grade can be a contract term. Accordingly, AMS will not take action based on this comment.

One commenter made three recommendations: First, that AMS change the table of Grades and Grade Requirements in the soybean Regulations to match the same table in Grain Inspection Handbook II, Chapter 10, Soybeans. AMS observes that the table of Grades and Grade Requirements is correct in both the Regulations and the Handbook, with only differences in format. AMS prefers the format of the table in the Regulations and AMS will format the layout of the table in the Handbook to match the Regulations.

Second, the commenter asked AMS to remove ''germ damage'' from the definition of Damaged Kernels in the Regulations, stating: ''There is not a germ location on a soybean, instead the area where the sprout protruded from the soybean is called the ''hilum.'' AMS agrees that there is no ''germ'' in soybeans. However, the hilum is not where a sprout emerges from the seedcoat, rather, the hilum is the point of attachment of the seed to the pod. AMS has no instruction, however, for assessing germ damage in soybeans, thus AMS inspectors never assesses germ damage. Third, the commenter recommend AMS change the term ''Interpretive Line Picture'' to ''Interpretive Line Print.'' AMS agrees that a technical correction would be appropriate to clarify the regulations on germ inspection and ''Interpretative Line Picture.'' AMS plans a subsequent rulemaking to addresses technical corrections throughout the Regulations.

Accordingly, AMS will not pursue amendment of the U.S. Standards for Soybeans and the U.S. Standards for Corn at this time.

Authority: USGSA (7 U.S.C. 71–87k).

Dated: September 16, 2019.

Bruce Summers,

Administrator, Agricultural Marketing Service.

[FR Doc. 2019–20295 Filed 9–24–19; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1217

[Document Number AMS–SC–19–0015]

Softwood Lumber Research, Promotion, Consumer Education and Industry Information Order; Change in Membership, Nominations, Procedures, and Continuance Referenda Period

AGENCY: Agricultural Marketing Service.

ACTION: Final rule.

SUMMARY: This rule changes the membership, nominations, procedures, and continuance referenda period for the Softwood Lumber Board (Board) established under the Softwood Lumber Research, Promotion, Consumer Education and Industry Information Order (Order). The Board administers the Order with oversight by the U.S. Department of Agriculture (USDA). This action will also make administrative changes to other provisions of the Order.

DATES: *Effective Date:* October 25, 2019.

FOR FURTHER INFORMATION CONTACT: Andrea Ricci, Marketing Specialist, Promotion and Economics Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, Room 1406–S, Washington, DC 20250; telephone: (202) 572–1442; facsimile (202) 205–2800; or electronic mail: *Andrea.Ricci@usda.gov.*

SUPPLEMENTARY INFORMATION: This rule affecting 7 CFR part 1217 (the Softwood Lumber Research, Promotion, Consumer Education and Industry Information (Order)) is authorized under the Commodity Promotion, Research, and Information Act of 1996 (1996 Act) (7 U.S.C. 7411–7425).

Executive Orders 12866, 13563, and 13771

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules and promoting flexibility. This action falls within a category of regulatory actions that the Office of Management and Budget (OMB) exempted from Executive Order 12866 review. Additionally, because this rule does not meet the definition of a significant regulatory action it does not trigger the requirements contained in Executive Order 13771. See OMB's Memorandum titled ''Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017, titled 'Reducing Regulation and Controlling Regulatory Costs''' (February 2, 2017).

Executive Order 13175

This action has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this regulation would not have substantial and direct effects on Tribal governments and would not have significant Tribal implications.

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect. Section 524 of the 1996 Act (7 U.S.C. 7423) provides that it shall not affect or preempt any other Federal or State law authorizing promotion or research relating to an agricultural commodity.

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not a major rule, as defined by 5 U.S.C. 804(2).

Under section 519 of the 1996 Act (7 U.S.C. 7418), a person subject to an order may file a written petition with USDA stating that an order, any provision of an order, or any obligation imposed in connection with an order, is not established in accordance with the law, and request a modification of an order or an exemption from an order. Any petition filed challenging an order, any provision of an order, or any obligation imposed in connection with an order, shall be filed within two years after the effective date of an order, provision, or obligation subject to challenge in the petition. The petitioner will have the opportunity for a hearing on the petition. Thereafter, USDA will issue a ruling on the petition. The 1996 Act provides that the district court of the United States for any district in which the petitioner resides or conducts business shall have the jurisdiction to review a final ruling on the petition, if the petitioner files a complaint for that purpose not later than 20 days after the date of the entry of USDA's final ruling.

Background

This rule changes the Board's membership, nominations, procedures, and continuance referenda period under the Order. The Board administers the Order with oversight by USDA. Under the Order, assessments are collected from manufacturers and importers and used for projects to promote softwood lumber within the United States. This rule reduces the number of Board members from 19 to 14, revises the nomination procedures, and revises the quorum and voting procedures. This rule also revises the time frame for periodic continuance referenda from five to seven years. Finally, this rule makes clarifying and conforming changes to other provisions of the Order. All of these changes will help facilitate program operations and were recommended to the Secretary by the Board at its November 28, 2018 meeting.

Board Membership and Geographical Distribution

Pursuant to § 1217.40(b), the Board is composed of 18 or 19 members, depending upon whether an additional importer member is appointed to the Board. Seats on the Board are apportioned based on the volume of softwood lumber manufactured and shipped within the United States by

domestic manufacturers and the volume of softwood lumber imported into the United States. Seats are also apportioned based on size of operation within each geographic region as specified herein. Large manufacturers are those who account for the top two-thirds of the total annual volume of assessable softwood lumber and small manufacturers are those who account for the remaining one-third of the total annual volume of assessable softwood lumber, based on a three-year average.

Table 1 shows the current structure of the Board. Of the 19 total Board seats, 12 are held by domestic manufacturers and seven are held by importers, six of whom are Canadian. Of the 12 domestic manufacturers, six represent the U.S. South (two large and four small), five represent the U.S. West (four large and one small), and one represents the Northeast and Lake States. Of the six Canadian importers, four represent Canada West (three large and one small) and two represent Canada East (one large and one small). An additional importer member may be appointed to represent all other importing countries other than Canada.

Table 1. Current Board structure						
	Domestic manufacturers					Total Board seats
Region	U.S. South		U.S. West		U.S. NE & Lake	
Size	Large	Small	Large	Small	Any size	
Seats	2	4	4	1	1	
Region Totals	6		5		1	
Grand Total	12					
	Importers					
Region	Canada West		Canada East		Other importers	
Size	Large	Small	Large	Small	Any size	
Seats	3	1	1	1	1	
Region Totals	4		2		1	
Grand Total	7					19

Section 1217.40(c)(1) requires that, in each five-year period, the Board review, based on a three-year average, the geographical distribution of the volume of softwood lumber manufactured and shipped within the United States by domestic manufacturers and the volume of softwood lumber imported into the United States. Section 1217.40(c)(2) requires that the Board also review, based on a three-year average, the distribution of the size of operations within each region. Section 1217.40(c)(3) specifies that, if warranted, the Board may recommend to the Secretary the reapportionment of its membership to reflect changes in the geographical distribution of the volume of softwood lumber manufactured and shipped within the United States by domestic manufacturers and the volume of softwood lumber imported into the United States. The number of Board members may also be changed. Any changes in Board composition shall be implemented by the Secretary through rulemaking.

Pursuant to § 1217.40, the Board evaluated the geographic distribution of softwood lumber by region, based on a three-year average (2015–2017). The Board utilized data from Forest Economic Advisors [1] to evaluate the regional distribution of assessable softwood lumber. The results of this evaluation are shown in Table 2. Based on a three-year average (2015–2017), the volume of assessed softwood lumber was largest in the U.S. South and U.S. West regions, at 36 percent and 30 percent, respectively, of the total assessed volume over all regions. Canada West followed with 20 percent of the total assessed volume. In these three regions, assessed volume by large entities made up the majority of assessed regional volume. In all other regions, assessed volume by small entities was either equal to or greater than the assessed volume by large entities.

[1] Forest Economic Advisors, LLC. FEA is an owner-operated company comprised of experienced and informed analysts covering the forest products industry. FEA applies rigorous economic analysis and delivers actionable information though their third-party forecasts and monthly advisors.

Table 2. Three-year average of assessed softwood lumber volume by regions (2015-2017)										
	Domestic manufacturers									Total assessed volume (bbf)
Region	U.S. South			U.S. West			U.S. NE & Lake			
Size	Large	Small	Total	Large	Small	Total	Large	Small	Total	
Assessed volume (bbf)	9.42	4.49	13.91	7.69	4.06	11.75	0.32	0.55	0.87	
Portion of Total	68%	32%	36%	65%	35%	30%	37%	63%	2%	
	Importers									
Region	Canada West			Canada East			Outside Canada			
Size	Large	Small	Total	Large	Small	Total	Large	Small	Total	
Assessed volume (bbf)	6.14	1.76	7.90	2.01	2.00	4.01	0	0.34	0.34	38.78
Portion of Total	78%	22%	20%	50%	50%	10%	0%	100%	1%	100%
Sources: Softwood Lumber Board; Forest Economic Advisors.										

From this evaluation, the Board recommended revising the Board membership from 19 current seats to 14 seats for the 2021 term of office, of which six members must represent large manufacturers or importers, four must represent small manufacturers or importers, and four may represent any size manufacturers or importers. Of the four representing any size manufacturer or importer, at least two of these members must represent small manufacturers or importers. The Board recommended adding more flexibility to the Order in terms of certain seats being open to representatives of any size manufacturer or importer. This will allow the Board to better adjust in the future to shifts in the size of operations within a region.

The Board also took into consideration the consolidation in the softwood lumber industry since the inception of the Order. The Board has indicated that the number of companies eligible to be represented on the Board has declined. According to the Board, there were about 290 entities eligible to be represented on the Board in 2013, and about 210 entities in 2018. The Board has faced challenges securing enough nominees for membership on the Board. This compelled the Board to consider a reduction in Board membership.

The Board seats are revised as follows: Ten domestic manufacturers seats, of which five members must be from the U.S. South Region (two large, two small, and one manufacturer of any size), four members must be from the U.S. West Region (two large, one small, and one manufacturer of any size), and one member from the Northeast and Lake States Region. Importers will have four seats on the Board (two large, one small, and one importer of any size) with a minimum of two from Canada West Region, a minimum of one from Canada East Region and the remaining member may be from Canada West, Canada East or offshore Regions. Table 3 illustrates this categorization of seats in the revised Board structure.

Table 3. Proposed Board structure										
	Domestic manufacturers									Total Board seats
Region	U.S. South			U.S. West			U.S. NE & Lake			
Size	Large	Small	Any size	Large	Small	Any size	Any size			
Seats	2	2	1	2	1	1	1			
Region Totals	5			4			1			
Grand Total	10									
	Importers									
	Region						Size			
	Canada West		Canada East		Any region		Large	Small	Any size	
Seats	2		1		1		2	1	1	
Grand Total	4									14

As the Board conducted the evaluation pursuant to § 1217.40, it also made a recommendation to align § 1217.40(a) and (c)(1) and (3) with section 515(b)(3) of the 1996 Act. (7 U.S.C. 7414(b)(3)). Section 1217.40(a) clarifies that the Board shall be apportioned based on the volume of softwood lumber *production* that is manufactured and shipped within the United States by domestic manufacturers. Section 1217.40(c)(1) and (3), respectively, specify that the Board shall review, based on a three-year average, the geographical distribution of the volume of softwood lumber *produced* and shipped within the United States by domestic manufacturers, and that the Board shall make recommendations to revise its structure based on this review.

Additionally, the Board recommended that U.S. Board members reside in the region they represent. This will ensure that entities from outside the U.S. that own softwood lumber entities within the U.S. could represent a U.S. region on the Board only if the individual seeking nomination resides in the respective region. The Board will review the USDA Advisory Committee on Research and Promotion Background Information Form AD–755 to determine in which Region each nominee resides.

According to the Board, this action should make the reduced number of seats easier to fill and reflect the current distribution of the industry.

The Board recommended a transitional approach to reduce the Board from 19 members to 14 members over a three-year period. The 2019

Board currently has 19 members. The 2020 Board will have 16 members consisting of five domestic manufacturer members representing the U.S. South Region (two large and three small), five representing the U.S. West Region (four large and one small) and one representing the Northeast and Lake States. Of the five Canadian importers (three large and two small), there will be three from the Canada West Region and two from the Canada East Region. The non-Canadian importer seat will not be filled in 2020 (when the current member reaches tenure).

The 2021 Board will have 14 members consisting of five domestic manufacturer members representing the U.S. South Region (two large, two small and one manufacturer of any size), four members representing the U.S. West Region (two large, one small and one manufacturer of any size) and one representing the Northeast and Lake States. Of the four Canadian importers (two large, one small and one importer of any size), there will be two from the Canada West Region and one from the Canada East Region. The remaining member may be from Canada West, Canada East or offshore Regions.

Nomination Procedures

Section 1217.41 establishes the procedures for the conduct of nominations to obtain Board nominees for appointment by the Secretary. The Board recommended to remove the procedures in § 1217.41(a) regarding the initial nominations to select the nominees for the initial Board in 2011. Section 1217.41(b) establishes an election process for nominations. In order to secure more nominees for Board seats, the Board recommended removing the election process from its nomination procedures.

The nomination procedure provides that the Board conduct outreach and solicit nominees who are interested in serving on the Board. A nominee could seek nomination to the Board for all seats for which he or she is qualified. The Board will evaluate all nominees and submit one recommended candidate for each open seat and one additional nominee for each open seat to the Secretary for consideration. Other qualified persons interested in serving in the open seats but not recommended by the Board will be designated as other nominees for consideration by the Secretary. From the nominations made, the Secretary would appoint members of the Board.

Finally, the Board recommended a clarification to § 1217.41(b)(7) that specifies no two members shall be employed by a single corporation, company, partnership, or any other legal entity, includes subsidiaries and affiliates thereof. Section 1217.41 will be revised accordingly.

Quorum and Voting Procedures

Section 1217.44 specifies the quorum and voting procedures for the Board based on the current 19 Board members. The Board's recommendation is to revise these provisions from specific number requirements needed for a quorum and for votes to a general term ''majority'' that could apply to any size Board. Thus, the Board recommended these conforming changes to complement the reduction in Board membership. Section 1217.44 will be revised accordingly.

Continuance Referenda Period

Section 1217.81(b) specifies that the Secretary conduct a referendum of the industry for the purpose of ascertaining whether manufacturers for the U.S. market favor the continuation of the Order. The first continuance referendum was held in 2018, and 78 percent of the voters representing 94 percent of the volume voted supported continuance of the Order. The Board recommended that the period between referenda be extended from five to seven years for the purpose of efficiency. The Board would incur costs associated with referenda once every seven years rather than every five years. The Order would still permit referenda to be held at the request of the Board; at the request of 10 percent or more of the number of persons eligible to vote in a referendum; and at any time as determined by the Secretary, pursuant to § 1217.81(b)(3), (4) and (5), respectively. Section 1217.81(b) will be revised accordingly.

This rule also makes minor changes to §§ 1217.52(h) and 1217.101(l), by updating the Harmonized Tariff Schedule (HTS) number codes. The HTS number codes are periodically updated by the United States Internal Trade Commission. Finally, this rule changes the OMB control number assigned to the previously approved information collection referenced in §§ 1217.88 and 1217.108 from 0581–0264 to 0581–0093, the correct control number assigned by OMB.

Final Regulatory Flexibility Act Analysis

In accordance with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), AMS is required to examine the impact of the rule on small entities. Accordingly, AMS has considered the economic impact of this action on such entities.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions so that small businesses will not be disproportionately burdened. The Small Business Administration (SBA) defines, in 13 CFR part 121, small agricultural service firms (domestic manufacturers and importers) as those having annual receipts of no more than $7.5 million.[2] The Random Lengths yearly average framing lumber composite price was $460 per thousand board feet in 2018.[3] Dividing the $7.5 million threshold that defines an agricultural service firm as small by this price results in a maximum threshold of 16.3 million board feet (mmbf) of softwood lumber per year that a domestic manufacturer or importer may ship to be considered a small entity for purposes of the RFA. Table 4 shows the number of entities and the amount of volume they represent that may be categorized as small or large based on the SBA definition.

[2] SBA does have a small business size standard for ''Sawmills'' of 500 employees (see *https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf*). Based on USDA's understanding of the lumber industry, using this criterion would be impractical as sawmills often use contractors rather than employees to operate and, therefore, many mills would fall under this criterion while being, in reality, a large business. Therefore, USDA used agricultural service firm as a more appropriate criterion for this analysis.

[3] Random Lengths Publications, Inc.; *www.randomlengths.com.*

Table 4. Domestic manufacturers and importers by SBA size standards, 2018						
	Domestic manufacturers		Importers		Totals	
	Entities	Volume (MMBF)	Entities	Volume (MMBF)	Entities	Volume (MMBF)
Small	178	1,156	753	919	931	2,074
Large	334	33,642	118	39,572	452	73,214
Total	512	34,798	871	40,491	1,383	75,288
Sources: Forest Economic Advisors; Customs and Border Protection.						

As shown in Table 4, there were a total of 1,383 domestic manufacturers and importers of softwood lumber based on 2018 data. Of these, 931 entities, or 67 percent, shipped or imported less than 16.3 mmbf and would be small entities under the SBA definition. These 931 entities domestically manufactured or imported 2.07 billion board feet (bbf) in 2018, less than 3 percent of total volume. The reduction in Board seats and other administrative changes will not disproportionately burden small domestic manufacturers and importers of softwood lumber.

This rule revises the Board's membership, nominations, procedure, and continuance referenda period provisions under the Order. Section 1217.40 is revised to reduce the number of Board members from 19 to 14 and reflects the diversity of the industry in terms of geographical distribution and size of operation. An additional change to this section requires that U.S. Board members reside in the region they represent. Section 1217.41 is revised by eliminating the election process in the nomination procedures. In § 1217.44 the quorum and voting procedures for the Board are revised to complement the reduction in Board membership. Section 1217.81 is revised to instruct that subsequent continuance referenda to be conducted every seven years rather than five. These changes were recommended by the Board and are authorized under §§ 1217.40(c)(3), 1217.41(b)(8), 1217.46(b), and 1217.87 of the Order and section 515(b)(3) of the 1996 Act.

Regarding the economic impact of this rule on affected entities, these changes are administrative in nature and would have no economic impact on entities covered under the program. These changes will help in securing nominees to fill seats on the Board, address the concerns of the softwood lumber industry not securing enough nominees to be submitted to the Secretary for selection, make conforming changes necessary to complement the reduction in Board membership, and improve efficiency regarding continuance referenda.

The Board's Industry Relations and Governance Committee (Committee) reviewed various alternatives to the Board's current 19-member make-up. The Committee considered a 12 and 13-member Board. The committee also considered maintaining the status quo at 19 members. Regarding the referenda period, one option the Board considered was to maintain the status quo. However, the Board recommended changing the period from five to seven years to improve the operating efficiency of the Board.

Reporting and Recordkeeping Requirements

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Order's information collection and recordkeeping requirements have been approved previously under OMB control number 0581–0093. This rule does not result in a change to the information collection and recordkeeping requirements previously approved and does not impose additional reporting requirements or recordkeeping burden on domestic manufacturers and importers of softwood lumber.

As with all Federal promotion programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public-sector agencies. USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule.

Regarding outreach efforts, the actions were discussed by the Board's Industry Relations and Governance Committee at meetings on May 30, 2018, August 15, 2018, and October 26, 2018. The full Board discussed outreach efforts at meetings on May 31, 2018, August 15, 2018. The Board then made its recommendation to the Secretary on November 28, 2018. All of the Board's meetings, including meetings held via teleconference, are open to the public and interested persons are invited to participate and express their views.

A proposed rule concerning this action was published in the **Federal Register** on June 26, 2019 (84 FR 30040). A 30-day comment period ending July 26, 2019, was provided to allow interested persons to submit comments.

Analysis of Comments

Fifteen comments were received in response to the proposed rule. Thirteen comments supported all the Board recommended changes. Two comments were considered outside the scope of this action. In summary, most commenters agreed that reducing the size of the Board is appropriate due to industry consolidation, resulting in fewer individuals eligible to serve. One commenter noted that the reduced size would allow the Board to administer the program more efficiently and would help streamline business operations. In addition, one commenter supported the proposed approach to the geographic distribution, stating that it allows for fair and appropriate representation of all segments of the industry. Thirteen commenters supported the proposed change to the nomination procedures noting that allowing the Board to conduct outreach and recommend nominees to the Secretary is a more acceptable process for the industry. Lastly, the commenters agreed that extending the period between conducting continuance referenda from five to seven years was in the best interest of the program. It not only reduces the cost to the industry and provides a more efficient process, but it allows the Board to focus on its program areas of research and promotion of softwood lumber.

After consideration of all relevant material presented, including the information and recommendations submitted by the Board, the comments received, and other available information, it is hereby found that this rule, as hereinafter set forth, is consistent with and will effectuate the purposes of the 1996 Act.

List of Subjects in 7 CFR Part 1217

Administrative practice and procedure, Advertising, Consumer information, Marketing agreements, Reporting and recordkeeping requirements, Softwood Lumber promotion.

For the reasons set forth in the preamble, 7 CFR part 1217 is amended as follows:

PART 1217—SOFTWOOD LUMBER RESEARCH, PROMOTION, CONSUMER EDUCATION AND INDUSTRY INFORMATION ORDER

■ 1. The authority citation for 7 CFR part 1217 continues to read as follows:

Authority: 7 U.S.C. 7411–7425; 7 U.S.C. 7401.

■ 2. Revise § 1217.40 to read as follows:

§ 1217.40 Establishment and membership.

(a) *Establishment of the Board.* There is hereby established a Softwood Lumber Board to administer the terms and provisions of the Order and promote the use of softwood lumber. The Board shall be composed of manufacturers for the U.S. market who manufacture and domestically ship or import 15 million board feet or more of softwood lumber in the United States during a fiscal period. Seats on the Board shall be apportioned based on the volume of softwood lumber production that is manufactured and shipped within the United States by domestic manufacturers and the volume of softwood lumber imported into the United States. Seats on the Board shall also be apportioned based on size of operation within each geographic region, as specified in paragraphs (b)(1)(i) and (ii) and (b)(2) and (3) of this section. For purposes of this section, ''large'' means manufacturers for the U.S. market who account for the top two-thirds of the total annual volume of assessable softwood lumber and ''small'' means those who account for the remaining one-third of the total annual volume of assessable softwood lumber. If there are no eligible nominees for a large or small seat within a region, that seat may be filled by a nominee representing an eligible manufacturer for the U.S. market of any size. Should the size of a manufacturer for the U.S. market change during a member's term of office, that member may serve for the remainder of the term.

(b) *Composition of the Board.* The 2020 Board shall be composed of 16 members. The 2021 Board and each subsequent Board shall be composed of 14 members. The Board shall be established as follows:

(1) *Domestic manufacturers.* For the 2020 Board, 11 members shall represent domestic manufacturers and for the 2021 Board and each subsequent Board, ten members shall represent domestic manufacturers who reside in the following three regions:

(i) Five members shall reside in the U.S. South Region, which consists of the states of Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, and West Virginia. For the 2020 Board, of these five members, two must represent large and three must represent small domestic manufacturers. For the 2021 Board and each subsequent Board of these five members, two must represent large, two must represent small, and one may represent domestic manufacturers of any size;

(ii) Five members shall reside in the U.S. West Region for the 2020 Board, and for the 2021 Board and each subsequent Board, four members shall reside in the U.S. West Region, which consists of the states of Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, Nevada, New Mexico, North Dakota, Oregon, South Dakota, Utah, Washington, and Wyoming. For the 2020 Board, of these five members, four must represent large and one must represent small domestic manufacturers. For the 2021 Board and each subsequent Board, of the four members, two must represent large, one must represent small, and one may represent domestic manufacturers of any size; and

(iii) One member shall reside in the Northeast and Lake States Region, which consists of the states of Connecticut, Delaware, Illinois, Indiana, Iowa, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Nebraska, New Hampshire, New Jersey, New York, Ohio, Pennsylvania, Rhode Island, Vermont, Wisconsin and all other parts of the United States not listed in paragraph (b)(1)(i), (ii), or (iii) of this section. This member may represent domestic manufacturers of any size.

(iv) For the 2021 Board, four members may represent a manufacturer for the U.S. market of any size.

(2) *Importers for the 2020 Board.* Five members shall be importers from the following two regions:

(i) Three members must import softwood lumber from the Canadian West Region, which consists of the provinces of British Columbia and Alberta. Of these three members, two must represent large and one must represent small importers; and

(ii) Two members must import softwood lumber from the Canadian East Region, which consists of the Canadian territories and all other Canadian provinces not listed in paragraph (b)(2)(i) of this section that import softwood lumber into the United States. Of these two members, one must represent large and one must represent small importers.

(3) *Importers for the 2021 Board and each subsequent Board.* Four members shall represent importers. Of these four members, two must represent large, one must represent small, and one may represent importers of any size. At least three of these members must import softwood lumber from the following regions:

(i) Two members must import softwood lumber from the Canadian West Region, as defined in paragraph (b)(2)(i) of this section; and

(ii) One member must import softwood lumber from the Canadian East Region, as defined in paragraph (b)(2)(ii) of this section.

(c) *Periodic review.* In each five-year period, but not more frequently than once in each three-year period, the Board shall:

(1) Review, based on a three-year average, the geographical distribution of the volume of softwood lumber production that is manufactured and shipped within the United States by domestic manufacturers and the volume of softwood lumber imported into the United States; and

(2) Review, based on a three-year average, the distribution of the size of operations within each region; and

(3) If warranted, recommend to the Secretary the reapportionment of the Board membership to reflect changes in the geographical distribution of the volume of softwood lumber production that is manufactured and shipped within the United States by domestic manufacturers and the volume of softwood lumber imported into the United States. The distribution of volumes between regions and the distribution of the size of operations within regions shall also be considered. The number of Board members may also be changed. Any changes in Board composition shall be implemented by the Secretary through rulemaking.

■ 3. Revise § 1217.41 to read as follows:

§ 1217.41 Nominations and appointments.

Nominations shall be conducted as follows:

(a) The Board shall conduct outreach to all segments of the softwood lumber industry. Softwood lumber domestic manufacturers and importers may submit nominations to the Board. Nominees must domestically manufacture and/or import 15 million board feet or more of softwood lumber per fiscal year;

(b) Domestic manufacturers and importer nominees may provide the Board a short background statement outlining their qualifications to serve on the Board;

(c) Nominees may seek nomination to the Board for all open or vacant seats for which the nominees are eligible;

(d) The Board will evaluate all eligible nominees and submit the name of one

nominee for each open seat and the name of one additional nominee for each open seat to the Secretary. Other qualified persons interested in serving in the open seats but not recommended by the Board will be designated by the Board as additional nominees for consideration by the Secretary;

(e) The Board must submit nominations to the Secretary at least six months before the new Board term begins. From the nominations submitted by the Board, the Secretary shall select the members of the Board;

(f) No two members shall be employed by a single corporation, company, partnership, or any other legal entity. This includes subsidiaries and affiliates thereof; and

(g) The Board may recommend to the Secretary modifications to its nomination procedures as it deems appropriate. Any such modifications shall be implemented through rulemaking by the Secretary.

■ 4. Revise § 1217.44 to read as follows:

§ 1217.44 Procedure.

(a) A majority of Board members (exclusive of vacant seats) will constitute a quorum so long as at least two of the members present are importer members and five of the members present are domestic manufacturers. If participation by telephone or other means is permitted, members participating by such means shall count as present in determining quorum or other voting requirements set forth in this section.

(b) All votes at meetings of the Board, executive committee, and other committees will be cast in person or by electronic voting or other means as the Board and Secretary deem appropriate to allow members participating by telephone or other electronic means to cast votes. Voting by proxy will not be allowed.

(c) Each member of the Board will be entitled to one vote on any matter put to the Board and the motion will carry if supported by a majority of Board members (exclusive of vacant seats), except for recommendations to change the assessment rate or to adopt a budget, both of which require affirmation by at least a majority of Board members plus two (exclusive of vacant seats).

(d) The Board must give members and the Secretary timely notice of all Board, executive committee, and other committee meetings.

(e) In lieu of voting at a properly convened meeting, and when, in the opinion of the Board's chairperson, such action is considered necessary, the Board may take action by mail, telephone, electronic mail, facsimile, or any other means of communication. Any action taken under this procedure is valid only if:

(1) All members and the Secretary are notified, and the members are provided the opportunity to vote;

(2) A majority of Board members (exclusive of vacant seats) vote in favor of the action (unless a vote of a majority of Board members plus two (exclusive of vacant seats) is required under the Order); and

(3) All votes are promptly confirmed in writing and recorded in the Board minutes.

■ 5. Revise § 1217.52(h) to read as follows:

§ 1217.52 Assessments.

* * * * *

(h) The HTSUS categories and assessment rates on imported softwood lumber are listed in the following table. A factor shall be used to determine the equivalent volume of softwood lumber in thousand board feet. The factor used to convert one cubic meter to one thousand board feet is 0.423776001. Accordingly, the assessment rate per cubic meter is as follows.

TABLE 1 TO PARAGRAPH (H)

Softwood lumber (by HTSUS No.)	Assessment ($/cubic meter)
4407.11.00	0.1483
4407.12.00	0.1483
4407.19.05	0.1483
4407.19.06	0.1483
4407.19.10	0.1483
4409.10.05	0.1483
4409.10.10	0.1483
4409.10.20	0.1483
4409.10.90	0.1483
4418.99.10	0.1483

* * * * *

■ 6. In § 1217.81, revise paragraphs (b)(1) and (2) to read as follows:

§ 1217.81 Referenda.

* * * * *

(b) * * *

(1) For the purpose of ascertaining whether manufacturers for the U.S. market favor the continuation, suspension, or termination of the Order;

(2) No later than seven years after the Order becomes effective and every seven years thereafter, to determine whether softwood lumber manufacturers for the U.S. market favor the continuation of the Order. The Order shall continue if it is favored by a majority of domestic manufacturers and importers voting in the referendum who also represent a majority of the volume of softwood lumber represented in the referendum who, during a representative period determined by the Secretary, have been engaged in the domestic manufacturing or importation of softwood lumber;

* * * * *

■ 7. Revise § 1217.88 to read as follows:

§ 1217.88 OMB Control numbers.

The control numbers assigned to the information collection requirements by the Office of Management and Budget pursuant to the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, are OMB control number 0505–0001 (Board nominee background statement) and OMB control number 0581–0093.

■ 8. Revise § 1217.101(l) to read as follows:

§ 1217.101 Definitions.

* * * * *

(l) *Softwood lumber* means and includes softwood lumber and products manufactured from softwood as described in section 804(a) within Title VIII (Softwood Lumber Act of 2008 or SLA of 2008) of the Tariff Act of 1930 (19 U.S.C. 1202–1677g), as amended by section 3301 of the Food, Conservation and Energy Act of 2008 (Pub. L. 110–246, enacted June 18, 2008) and categorized in the following Harmonized Tariff Schedule of the United States (HTSUS) numbers—4407.11.00, 4407.12.00, 4407.19.05, 4407.19.06, 4407.19.10, 4409.10.05, 4409.10.10, 4409.10.20, 4409.10.90, and 4418.99.10. Domestic product that cannot be categorized in the referenced HTSUS numbers if it were an import is not covered under the Order. Further, softwood lumber originating in the United States that is exported to another country and shipped back to the United States is also covered under the Order, provided it can be categorized in the referenced HTSUS numbers. Additionally, articles brought into the United States temporarily and for which an exemption is claimed under subchapter XIII of chapter 98 of the HTSUS are exempted from the SLA of 2008 and are not covered under the Order.

* * * * *

■ 9. Revise § 1217.108 to read as follows:

§ 1217.108 OMB control number.

The control number assigned to the information collection requirement in this subpart by the Office of Management and Budget pursuant to the Paperwork Reduction Act of 1995, 4 U.S.C. is OMB control number 0581–0093.

Dated: September 16, 2019.

Bruce Summers,

Administrator.

[FR Doc. 2019–20291 Filed 9–24–19; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2019–0402; Product Identifier 2019–NM–008–AD; Amendment 39–19731; AD 2019–18–04]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2005–17–14, which applied to all Airbus SAS Model A300 series airplanes; Model A300 B4–600, B4–600R, and F4–600R series airplanes, and Model A300 C4–605R Variant F airplanes (collectively called Model A300–600 series airplanes); and Model A310 series airplanes. AD 2005–17–14 required repetitive tests to detect desynchronization of the rudder servo actuators, and adjustment or replacement of the spring rods of the rudder servo actuators, if necessary. AD 2005–17–14 also required repetitive tests/inspections/analyses of the rudder servo actuators, and related investigative/corrective actions if necessary. This AD retains some requirements of AD 2005–17–14 and revises the inspection procedures and compliance times, as specified in a European Aviation Safety Agency (EASA) AD, which is incorporated by reference. This AD was prompted by reports of desynchronization of the rudder servo actuators. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective October 30, 2019.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of October 30, 2019.

ADDRESSES: For the material incorporated by reference (IBR) in this AD, contact the EASA, at Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 89990 1000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this IBR material on the EASA website at *https://ad.easa.europa.eu.* You may view this IBR material at the FAA, Transport Standards 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 on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0402.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0402; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3225.

SUPPLEMENTARY INFORMATION:

Discussion

The EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2019–0017, dated January 29, 2019 (''EASA AD 2019–0017'') (also referred to as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for all Airbus SAS Model A300 series airplanes, Model A300–600 series airplanes, and Model A310 series airplanes.

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2005–17–14, Amendment 39–14235 (70 FR 50157, August 26, 2005) (''AD 2005–17–14''). AD 2005–17–14 applied to all Airbus SAS Model A300 series airplanes, Model A300–600 series airplanes, and Model A310 series airplanes. The NPRM published in the **Federal Register** on June 10, 2019 (84 FR 26781). The NPRM was prompted by reports of desynchronization of the rudder servo actuators. The NPRM proposed to require repetitive inspections of the rudder servo actuators and related investigative/corrective actions. The FAA is issuing this AD to address desynchronization of one of the three rudder servo actuators, which, if combined with an engine failure, could result in the loss of the related hydraulic system and could cause the loss of one of the two synchronized actuators. This condition could create additional fatigue loading and possible cracking of the attachment fittings and could result in the inability of the remaining synchronized actuator to maintain the commanded rudder deflection, leading to reduced controllability of the airplane. See the MCAI for additional background information.

Comments

The FAA gave the public the opportunity to participate in developing this final rule. The FAA has considered the comments received. The Air Line Pilots Association, International (ALPA), and FedEx expressed support for the NPRM.

Conclusion

The FAA reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this final rule as proposed, except for minor editorial changes. The FAA has determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for addressing the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

Related IBR Material Under 1 CFR Part 51

EASA AD 2019–0017 describes procedures for repetitive inspections of the rudder servo actuators and related investigative/corrective actions. Related investigative actions include repetitive inspections of fin box and rudder servo controls. Corrective actions include repair. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

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

ESTIMATED COSTS FOR REQUIRED ACTIONS *

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Retained actions from AD 2005–17–14	1 work-hour × $85 per hour = $85	$0	$85	$11,305
New actions	2 work-hours × $85 per hour = $170	0	170	22,610

* Table does not include estimated costs for reporting.

The FAA estimates that it would take about 1 work-hour per product to comply with the reporting requirement in this AD. The average labor rate is $85 per hour. Based on these figures, the FAA estimates the cost of reporting the inspection results on U.S. operators to be $11,305, or $85 per product.

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

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Labor cost	Parts cost	Cost per product
34 work-hours × $85 per hour = $2,890	$0	$2,890

The FAA has received no definitive data that would enable the agency to provide cost estimates for the on-condition repair specified in this 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 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 control number for the collection of information required by this AD is 2120–0056. The paperwork cost associated with this AD has been detailed in the Costs of Compliance section of this document and includes time for reviewing instructions, as well as completing and reviewing the collection of information. Therefore, all reporting associated with this AD is mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at 800 Independence Ave. SW, Washington, DC 20591, ATTN: Information Collection Clearance Officer, AES–200.

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.

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes and associated appliances to the Director of the System Oversight Division.

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

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 removing Airworthiness Directive (AD) 2005–17–14, Amendment 39–14235 (70 FR 50157, August 26, 2005), and adding the following new AD:

2019–18–04 Airbus SAS: Amendment 39–19731; Docket No. FAA–2019–0402; Product Identifier 2019–NM–008–AD.

(a) Effective Date

This AD is effective October 30, 2019.

(b) Affected ADs

This AD replaces AD 2005–17–14, Amendment 39–14235 (70 FR 50157, August 26, 2005) (''AD 2005–17–14'').

(c) Applicability

This AD applies to the Airbus SAS airplanes, certificated in any category, specified in paragraphs (c)(1) through (3) of this AD, as identified in European Aviation Safety Agency (EASA) AD 2019–0017, dated January 29, 2019 (''EASA AD 2019–0017'').

(1) Model A300 B2–1A, B2–1C, B2K–3C, B2–203, B4–2C, B4–103, and B4–203 airplanes.

(2) Model A300 B4–601, B4–603, B4–620, B4–622, B4–605R, B4–622R, F4–605R and F4–622R airplanes, and Model A300 C4–605R Variant F airplanes.

(3) Model A310–203, –204, –221, –222, –304, –322, –324, and –325 airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 27, Flight controls; 55, Stabilizers.

(e) Reason

This AD was prompted by reports of desynchronization of the rudder servo actuators. The FAA is issuing this AD to address desynchronization of one of the three rudder servo actuators, which, if combined with an engine failure, could result in the loss of the related hydraulic system and could cause the loss of one of the two synchronized actuators. This condition could create additional fatigue loading and possible cracking of the attachment fittings and could result in the inability of the remaining synchronized actuator to maintain the commanded rudder deflection, leading to reduced controllability 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 2019–0017.

(h) Exceptions to EASA AD 2019–0017

(1) For purposes of determining compliance with the requirements of this AD: Where EASA AD 2019–0017 refers to its effective date, this AD requires using the effective date of this AD.

(2) For purposes of determining compliance with the requirements of this AD: Where paragraph (1) of EASA AD 2019–0017 specifies ''after the last inspection as previously required by DGAC France AD F–2004–092,'' this AD requires using ''after the most recent inspection done as specified in Airbus Service Bulletin A300–27–0188, Revision 2, dated October 1, 1997; A300–27–6036, Revision 2, dated October 1, 1997; A300–55–0044, dated October 22, 1996; A300–55–6023, dated October 22, 1996; A310–27–2082, Revision 2, dated October 1, 1997; or A310–55–2026, dated October 22, 1996.''

(3) For purposes of determining compliance with the requirements of this AD: Where paragraph (1) of EASA AD 2019–0017 refers to ''the 03 July 2004,'' this AD requires using ''September 30, 2005'' (the effective date of AD 2005–17–14).

(4) For purposes of determining compliance with the requirements of this AD: Where paragraph (4) of EASA AD 2019–0017 refers to ''during any inspection as required by paragraph (2) of this [EASA] AD,'' this AD requires using ''during any inspection as required by paragraph (2) or (3) of this [EASA] AD.''

(5) Where any service information referenced in EASA AD 2019–0017 specifies reporting, this AD requires reporting all inspection results at the applicable time specified in paragraph (h)(5)(i) or (ii) of this AD. If operators have reported findings as part of obtaining any corrective actions approved by Airbus SAS's EASA Design Organization Approval (DOA), operators are not required to report those findings as specified in this paragraph.

(i) If the inspection was done on or after the effective date of this AD: Submit the report within 30 days after the inspection.

(ii) If the inspection was done before the effective date of this AD: Submit the report within 30 days after the effective date of this AD.

(6) The ''Remarks'' section of EASA AD 2019–0017 does not apply to this AD.

(i) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Section, Transport Standards 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 International Section, send it to the attention of the person identified in paragraph (j) of this AD. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or EASA; or Airbus SAS's EASA 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 2019–0017 that contains RC procedures and tests: Except as required by paragraph (i)(2) of this AD, RC procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are 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 procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(4) *Paperwork Reduction Act Burden Statement:* 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 be approximately 1 hour per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave. SW, Washington, DC 20591, Attn: Information Collection Clearance Officer, AES–200.

(j) Related Information

For more information about this AD, contact Dan Rodina, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3225.

(k) Material Incorporated by Reference

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

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

(i) European Aviation Safety Agency (EASA) AD 2019–0017, dated January 29, 2019.

(ii) [Reserved]

(3) For EASA AD 2019–0017, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 89990 6017; 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.*

(4) You may view this EASA AD at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. EASA AD 2019–0017 may be found in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0402.

(5) You may view this material that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fedreg.legal@nara.gov,* or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Des Moines, Washington, on September 3, 2019.

Suzanne Masterson,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–20755 Filed 9–24–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2019–0676 Airspace Docket No. 19–AWA–3]

RIN 2120–AA66

Amendment of Class C Airspace; Lafayette, LA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action modifies the Lafayette, LA, Class C airspace area by amending the legal description to contain the current airport name and updated airport reference point (ARP) information. Additionally, minor administrative edits to the legal description title and Chart Supplement reference are made for readability. This action does not change the boundaries, altitudes, or operating requirements of the Class C airspace area.

DATES: Effective date 0901 UTC, December 5, 2019. The Director of the **Federal Register** approves this incorporation by reference action under Title 1 Code of Federal Regulations part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.11D, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *http://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. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11D at NARA, email *fedreg.legal@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: Colby Abbott, Airspace Policy Group, Office of Airspace Services, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

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 updates the airport name and ARP geographic coordinates for the Lafayette Regional Airport/Paul Fournet Field that is contained in the Lafayette, LA, Class C airspace description.

History

Class C airspace areas are designed to improve air safety by reducing the risk of midair collisions in high volume airport terminal areas and to enhance the management of air traffic operations in that area. During a recent review of the Lafayette Regional Airport/Paul Fournet Field, LA, Class C airspace area description, the FAA identified that the airport's name and ARP geographic coordinates were incorrect. This action updates the airport name and ARP geographic coordinates to coincide with the FAA's aeronautical database information. There are no changes to routing or air traffic control procedures resulting from this action.

Class C airspace designations are published in paragraph 4000 of FAA Order 7400.11D, dated August 8, 2019, and effective September 15, 2019, which is incorporated by reference in 14 CFR part 71.1. The Class C airspace designation listed in this document will be published subsequently in the Order.

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

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.11D, Airspace Designations and Reporting Points, dated August 8, 2019, and effective September 15, 2019. FAA Order 7400.11D is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11D lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This action amends Title 14 Code of Federal Regulations (14 CFR) part 71 by amending the Lafayette Regional Airport, LA, airspace area description. The airport formerly known as ''Lafayette Regional Airport'' is renamed ''Lafayette Regional Airport/Paul Fournet Field'' and the ARP geographic position for the airport is changed from ''lat. 30°12′19″ N, long. 91°59′15″ W'' to ''lat. 30°12′18″ N, long. 91°59′16″ W.'' These amendments to the airport name and ARP geographic coordinates reflect the current information in the FAA's aeronautical database. Additionally, minor administrative edits to the legal description title and Chart Supplement reference were made for readability.

This is an administrative change and does not affect the boundaries, altitudes, or operating requirements of the airspace, therefore, notice and public procedure under 5 U.S.C. 553(b) is unnecessary.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that 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, and its agency implementing regulations in FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' regarding categorical exclusions for procedural actions at paragraph 5–6.5a, which categorically excludes from full environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points. Since this action does not change the boundaries, altitudes, or operating requirements of the Class C airspace area, and only amends the legal description to contain the current airport name of Lafayette Regional Airport/Paul Fournet Field, LA, and updated ARP information, this airspace action is not expected to cause any potentially significant environmental impacts. In accordance with FAAO

1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, this action has been reviewed for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis, and it is determined that 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 7400.11D, Airspace Designations and Reporting Points, dated August 8, 2019, effective September 15, 2019, is amended as follows:

Paragraph 4000 Class C Airspace.

* * * * *

ASW LA C Lafayette, LA

Lafayette Regional Airport/Paul Fournet Field, LA
(Lat. 30°12′18″ N, long. 91°59′16″ W)

That airspace extending upward from the surface to and including 4,000 feet MSL within a 5-mile radius of the Lafayette Regional Airport/Paul Fournet Field, and that airspace extending upward from 1,300 feet MSL to 4,000 feet MSL within a 10-mile radius of the airport. This Class C airspace area is effective during the specific days and times of operation of Lafayette Tower and Approach Control Facility as established in advance by a Notice to Airmen. The effective dates and times will thereafter be continuously published in the Chart Supplement.

Issued in Washington, DC, on September 18, 2019.

Scott M. Rosenbloom,

Acting Manager, Airspace Policy Group.

[FR Doc. 2019–20689 Filed 9–24–19; 8:45 am]

BILLING CODE 4910–13–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R06–OAR–2018–0811; FRL–9999–03–Region 6]

Air Plan Approval; Texas; Control of Air Pollution From Motor Vehicles

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Pursuant to the Federal Clean Air Act (CAA or the Act), the Environmental Protection Agency (EPA) is approving revisions to the Texas State Implementation Plan (SIP) submitted by the Texas Commission on Environmental Quality (TCEQ or State). The revisions remove rules from the Texas SIP that address the Low Income Repair Assistance Program (LIRAP) for certain participating counties.

DATES: This final rule is effective on October 25, 2019.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R06–OAR–2018–0811. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information 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 electronically through *https://www.regulations.gov* or in hard copy at the EPA Region 6 Office, 1201 Elm Street, Suite 500, Dallas, Texas 75270.

FOR FURTHER INFORMATION CONTACT: Carrie Paige, EPA Region 6 Office, Infrastructure and Ozone Section, 1201 Elm Street, Suite 500, Dallas, TX 75270, 214–665–6521, *paige.carrie@epa.gov.* To inspect the hard copy materials, please schedule an appointment with Ms. Paige or Mr. Bill Deese at 214–665–7253.

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

I. Background

The background for this action is discussed in detail in our June 6, 2019 direct final rule and proposal (*see* 84 FR 26349 and 84 FR 26379, respectively). In the direct final rule, we approved the State's submittal to remove from the Texas SIP rules that address motor vehicle anti-tampering requirements and the LIRAP for participating Early Action Compact (EAC) counties.

The direct final rule and proposal stated that if any relevant adverse comments were received by the end of the public comment period on July 8, 2019, the direct final rule would be withdrawn, and we would respond to the comments in a subsequent final action. Relevant adverse comments pertaining to the removal of LIRAP for participating EAC counties from the SIP were received during the comment period and the direct final rule was partially withdrawn on August 13, 2019 (84 FR 39976). The partial withdrawal only withdrew the portions of the direct final rule that addressed the removal of LIRAP for participating EAC counties from the SIP since we did not receive relevant adverse comments on the removal of the motor vehicle anti-tampering requirements from the SIP. Our June 6, 2019 proposal provides the basis for this final rule.

We received one comment in support of our direct final rule and one relevant adverse comment. The comments are posted in the docket for this action. Our responses to the comments are provided below.

II. Response to Comments

Comment: The TCEQ expresses support of the EPA's approval of the SIP revision and corresponding removal of the associated State rules from the Texas SIP.

Response: We acknowledge the TCEQ's support of our direct final rule.

Comment: We received one relevant adverse comment from an anonymous source (''Commenter''). Commenter expresses concern that removal of the LIRAP program from the SIP would result in the State ending the program entirely. Commenter states that EPA should analyze the removal of this program based on the ability of motorists to come into compliance with the Inspection and Maintenance (I/M) program. Commenter states that if low income assistance programs are cut, motorists who are unable to afford repairs will defer or forgo repairs, resulting in lower compliance rates and thus, affecting emission reductions relied upon for the I/M program. Commenter states that Texas has several ozone nonattainment areas and therefore, EPA should run various Motor Vehicle Emission Simulator (MOVES) model scenarios to analyze whether removal of a low-income assistance program will affect compliance rates with the I/M program.

Response: EPA appreciates the Commenter's concerns. As mentioned in

our direct final rule at 84 FR 26349, the Texas SIP rules at 30 TAC 114, Section 114.86 apply only to the LIRAP for EAC[1] Counties (EAC LIRAP) who chose to voluntarily participate in the program.[2] The EAC counties were not required by the CAA nor federal regulations to implement an I/M program, but as participants in the EAC, Travis and Williamson Counties chose to implement an I/M program distinct from the State's SIP-approved I/M program in Chapter 114, Subchapter B applicable to nonattainment areas (*see* 70 FR 45542, August 8, 2005). The I/M program rules remain in the SIP. The LIRAP program assists low income vehicle owners in paying for repairs if their vehicle fails the I/M test. A person, however, must meet the I/M requirements for repair regardless of whether they receive funding assistance. Furthermore, motor vehicle operators cannot operate, or allow the operation of, a motor vehicle registered in an EAC county that does not comply with the requirements listed in Section 114.82(a).[3] Under these requirements, vehicles are required to undergo an annual vehicle safety inspection in order to be registered, and must comply with the applicable vehicle emissions I/M requirements in order to pass the inspection. The above requirements apply regardless of whether the vehicle operator is eligible for financial assistance under the EAC LIRAP. As such, the removal of the EAC LIRAP will not result in an increase in emissions. Since the LIRAP is not a CAA requirement, and its removal will not interfere with the area's ability to maintain the NAAQS, we find that the SIP revision meets the applicable 110(l) requirements. The Austin, Texas area, which includes Travis and Williamson Counties, is designated as attainment for all four of the ozone NAAQS and the 2016–2018 ozone design value for the Austin area continues to meet the 2015 ozone NAAQS.[4]

As mentioned in our direct final rule, the Federal I/M rules that apply to ozone nonattainment areas do not require states to implement a LIRAP-type program. The LIRAP rules found at 30 TAC 114 Subchapter C, Division 2 adopted by TCEQ create a voluntary program in the I/M areas in Texas ozone nonattainment areas, and are not, nor have they ever been, part of the Texas SIP. To the extent that the comment refers to the nonattainment LIRAP rules, we note that the nonattainment LIRAP rules are outside of the scope of this rulemaking. Eligible counties may choose to voluntarily participate in the Texas LIRAP.

EPA disagrees that we should analyze whether removal of a low-income assistance program for two counties in the EAC program will affect compliance rates with the I/M program because motor vehicle operators must comply with I/M program requirements for repairs whether they receive financial assistance from LIRAP or not.

III. Final Action

Pursuant to the CAA, the EPA is approving a revision to the Texas SIP submitted by the TCEQ on November 20, 2018. The revision removes the LIRAP for Participating EAC Counties at 30 TAC 114, Section 114.86, from the Texas SIP.

IV. Incorporation by Reference

In this document, EPA is amending regulatory text that includes incorporation by reference. As described in the amendments to 40 CFR part 52 set forth below, EPA is removing provisions from Table (c) ''EPA Approved Regulations in the Texas SIP'' in the Texas State Implementation Plan (SIP), which is incorporated by reference in accordance with the requirements of 1 CFR part 51.

V. Statutory and Executive Order Reviews

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

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, described in the Unfunded Mandates Reform Act of 1995 (Public Law 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).

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

[1] The EAC program was developed to allow communities an opportunity to reduce concentrations of ground level ozone sooner than required by the CAA. The program was designed for areas that approached or monitored exceedances of the 1997 8-hour ozone standard and were in attainment for the 1979 1-hour ozone standard. Areas that adopted EACs were required, among other criteria, to attain the 1997 8-hour ozone standard by December 31, 2007. For more on the EAC, see *https://archive.epa.gov/airquality/eac/web/html/basic.html.*

[2] The counties are free to opt out of the program at any time. See SIP submittal at pg. 3–1.

[3] This provision was approved by EPA and effective September 7, 2005 (see 70 FR 45542, August 8, 2005).

[4] See 56 FR 56694, page 56837, November 6, 1991; 69 FR 23858 (pages 23868 and 23938), April 30, 2004; 77 FR 30088, page 30151, May 21, 2012; and 82 FR 54232, page 54279, November 16, 2017. The area's compliance with the 8-hour ozone standard is posted at: *https://www.tceq.texas.gov/cgi-bin/compliance/monops/8hr_attainment.pl.*

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 November 25, 2019. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Ozone, Volatile organic compounds.

Dated: September 16, 2019.

David Gray,

Acting Regional Administrator, Region 6.

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 SS—Texas

§ 52.2270 [Amended]

■ 2. In § 52.2270, the table in paragraph (c) is amended by removing the entry for ''Section 114.86'' under ''Chapter 114 (Reg 4)—Control of Air Pollution from Motor Vehicles.''

[FR Doc. 2019–20313 Filed 9–24–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 70

[EPA–R05–OAR–2018–0285; FRL–10000–39–Region 5]

Air Plan Approval; Wisconsin; Title V Operation Permit Program; Withdrawal of Direct Final Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Withdrawal of direct final rule.

SUMMARY: Due to the receipt of an adverse comment, the Environmental Protection Agency (EPA) is withdrawing the July 31, 2019 direct final rule approving updates and revisions to the Wisconsin Title V Operating Permit Program. The revisions were submitted to update the title V program for the first time since the final approval of the program in 2001 and to change the permit fee schedule for subject facilities. The revisions consist of amendments to Chapter Natural Resources (NR) 407 Wisconsin Administrative Code, operation permits, Chapter NR 410 Wisconsin Administrative Code, permit fees, and Wisconsin statute 285.69, fee structure.

DATES: The direct final rule published at 84 FR 37104 on July 31, 2019, is withdrawn effective September 25, 2019.

FOR FURTHER INFORMATION CONTACT: Susan Kraj, Environmental Engineer, Air Permits Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 353–2654, *kraj.susan@epa.gov*.

SUPPLEMENTARY INFORMATION: In the direct final rule, EPA stated that if adverse comments were submitted by August 30, 2019, the rule would be withdrawn and not take effect. EPA received an adverse comment prior to the close of the comment period and, therefore, is withdrawing the direct final rule. EPA will address the comment in a subsequent final action based upon the proposed action also published on July 31, 2019 (84 FR 37194). EPA will not institute a second comment period on this action.

List of Subjects in 40 CFR Part 70

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Operation permits, Reporting and recordkeeping requirements.

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

Dated: September 11, 2019.

Cheryl L Newton,

Acting Regional Administrator, Region 5.

PART 70—STATE OPERATING PERMIT PROGRAMS

■ Accordingly, the amendment to appendix A to part 70 published in the **Federal Register** on July 31, 2019, (84 FR 37104) on page 37107 is withdrawn effective September 25, 2019.

[FR Doc. 2019–20863 Filed 9–24–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–HQ–SFUND–1989–0011; FRL–10000–36–Region 3]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List: Partial Deletion of the Novak Sanitary Landfill Superfund Site

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) Region 3 announces the partial deletion of the Novak Sanitary Landfill Superfund Site (Site) located in South Whitehall Township, Pennsylvania, from the National Priorities List (NPL). The NPL, promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is an appendix of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). The EPA and the Commonwealth of Pennsylvania, through the Pennsylvania Department of Environmental Protection (PADEP), have determined that all appropriate response actions to address the groundwater portion of the Site, other than monitoring, operations and maintenance, and Five-Year Reviews (FYRs), have been completed. However, this deletion does not preclude future actions under Superfund. This partial deletion pertains only to the groundwater portion of the Site. The landfill and landfill gas components of the Site will remain on the NPL and are not being considered for deletion as part of this action.

DATES: This action is effective September 25, 2019.

ADDRESSES: *Docket:* EPA has established a docket for this action under Docket Identification No. EPA–HQ–SFUND–

1989–0011. All documents in the docket are listed on the *http://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *i.e.,* Confidential Business Information 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 electronically through *http://www.regulations.gov* or in hard copy at the site information repositories. Locations, contacts, phone numbers and viewing hours are:

USEPA Region III Administrative Records Room, 1650 Arch Street—6th Floor, Philadelphia, Pennsylvania 19103–2029, 215–814–3157. Business Hours: Monday through Friday, 8:00 a.m.–4:30 p.m.; by appointment only.

Local Repository: Parkland Community Library, 4422 Walbert Avenue, Allentown, Pennsylvania 18104, 610–398–1361. Business Hours: Monday through Thursday 9 a.m.–9 p.m.; Friday 9 a.m.–6 p.m.; Saturday 9 a.m.–1 p.m.; closed Sunday.

FOR FURTHER INFORMATION CONTACT: Rombel Arquines, Remedial Project Manager, U.S. Environmental Protection Agency, Region III, (3SD21), 1650 Arch Street, Philadelphia, PA 19103, 215–814–3182, email *arquines.rombel@epa.gov*.

SUPPLEMENTARY INFORMATION: The potion of the site to be deleted from the NPL is the groundwater of the Novak Sanitary Landfill Superfund Site, South Whitehall Township, Lehigh County, Pennsylvania. A Notice of Intent for Partial Deletion for this Site was published in the **Federal Register** (84 FR 38905) on August 8, 2019.

The closing date for comments on the Notice of Intent for Partial Deletion was September 9, 2019. No public comments were received.

EPA maintains the NPL as the list of sites that appear to present a significant risk to public health, welfare, or the environment. Deletion from the NPL does not preclude further remedial action. Whenever there is a significant release from a site deleted from the NPL, the deleted site may be restored to the NPL without application of the hazard ranking system. Deletion of a site from the NPL does not affect responsible party liability in the unlikely event that future conditions warrant further actions.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous waste, Hazardous substances, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Dated: September 17, 2019.

Cosmo Servidio,

Regional Administrator, Region III.

For reasons set out in the preamble, 40 CFR part 300 is amended as follows:

PART 300—NATIONAL OIL AND HAZARDOUS SUBSTANCES POLLUTION CONTINGENCY PLAN

■ 1. The authority citation for part 300 continues to read as follows:

Authority: 33 U.S.C. 1321(d); 42 U.S.C. 9601–9657; E.O. 13626, 77 FR 56749, 3 CFR, 2013 Comp., p. 306; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

■ 2. Table 1 of appendix B to part 300 is amended by revising the entry for ''PA, Novak Sanitary Landfill'' to read as follows:

Appendix B to Part 300—National Priorities List

TABLE 1—GENERAL SUPERFUND SECTION

State	Site name	City/county	Notes [a]
* * *	* * *	* * *	
PA	Novak Sanitary Landfill	South Whitehall Township	P
* * *	* * *	* * *	

[a] = Based on issuance of health advisory by Agency for Toxic Substances and Disease Registry (if scored, HRS score need not be greater than or equal to 28.50).

* * * * * * *

P = Sites with partial deletion(s).

* * * * *

[FR Doc. 2019–20681 Filed 9–24–19; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 447

[CMS–2394–F]

RIN 0938–AS63

Medicaid Program; State Disproportionate Share Hospital Allotment Reductions

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: The statute requires aggregate reductions to state Medicaid Disproportionate Share Hospital (DSH) allotments annually beginning with fiscal year (FY) 2020. This final rule delineates the methodology to implement the annual allotment reductions.

DATES: These regulations are effective on November 25, 2019.

FOR FURTHER INFORMATION CONTACT: Stuart Goldstein, (410) 786–0694 and Richard Cuno, (410) 786–1111.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Purpose

Section 2551 of the Patient Protection and Affordable Care Act of 2010 *(Pub. L. 111–148, enacted March 23, 2010), as amended by the* Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152, enacted March 30,

2010)) (the ACA) amended section 1923(f) of the Act by setting forth aggregate reductions to state DSH allotments annually from FY 2014 through FY 2020. In the September 18, 2013 **Federal Register** (78 FR 57293), we published the ''Medicaid Program; State Disproportionate Share Hospital Allotment Reductions'' final rule (herein referred to as the ''2013 DSH allotment reduction final rule''). In the 2013 DSH allotment reduction final rule, we finalized a DSH Health Reform Methodology (DHRM), as required by statute, to implement annual allotment reductions that would have been in place only for FY 2014 and FY 2015. Prior to the implementation of allotment reductions, legislation was signed into law delaying the start of the reductions.[1] Subsequent legislation delayed the start of these reductions, modified the reduction amounts, and extended the fiscal years subject to reductions.[2] Under current law, annual allotment reductions start in FY 2020 and run through FY 2025. In July 28, 2017 **Federal Register** (82 FR 35155), we published the ''Medicaid Program; State Disproportionate Share Hospital Allotment Reductions'' proposed rule (herein referred to as the ''the July 2017 proposed rule''), in which we proposed to establish a DHRM applicable for all fiscal years subject to allotment reduction that would account for relevant data that was unavailable to CMS during prior rulemaking for DSH allotment reductions originally set to take place for FY 2014 and FY 2015. In this final rule, we are finalizing the DHRM as proposed, with limited exceptions identified below.

B. Summary of the Major Provisions

The statute as amended by the ACA, directs the Secretary of Health and Human Services (the Secretary) to implement the annual DSH allotment reductions using a DHRM. This final rule amends 42 CFR 447.294 by establishing the DHRM for FY 2020 and subsequent fiscal years, which incorporates factors identified in the statute. We are finalizing § 447.294(a) and (e) to remove language referring to specific federal fiscal years (FY 2014 and FY 2015) when calculating annual state DSH allotment reductions. We are finalizing § 447.294(b) to add the definition of ''Total hospital cost.'' We are modifying this definition from the proposed in order to give the term the same meaning as it is defined in § 447.299(c)(20). We believe that cross-referencing the existing provision is clearer, less likely to result in any confusion or ambiguity, and is not intended to be a substantive difference in meaning from that of the proposed definition. This rule finalizes § 447.294(d) to clarify state data submission requirements by simplifying the language and removing language related to the submission of data for previous state plan rate years (SPRY) already provided to CMS. We are finalizing § 447.294(e)(3)(i) to utilize total estimated Medicaid service expenditures in the calculation of the Low DSH adjustment factor (LDF) for the applicable year. In this rule, we are finalizing revisions to § 447.294(e)(5)(i) through (iii) to adjust the weighting of statutorily defined factors required to be included in the DHRM. Additionally, this rule finalizes revisions to § 447.294 to revise paragraph (f) by removing references to specific fiscal years in regulation.

C. Impacts

The DHRM will generate a state-specific DSH allotment reduction amount for each fiscal year in accordance with the requirements specified in section 1923(f)(7) of the Act. The total of all DSH allotment reduction amounts in a specific fiscal year will equal the aggregate annual reduction amount identified in the statute for that year. To determine the effective annual DSH allotment for each state, the state-specific annual DSH allotment reduction amount will be applied to the unreduced DSH allotment amount for the state.

II. Background

A. Introduction

In anticipation of lower uninsured rates and lower levels of hospital uncompensated care, the ACA modified the amounts of funding available to states under the Medicaid program to address the situation of hospitals that serve a disproportionate share of low-income patients, and therefore, may have uncompensated care costs. Under sections 1902(a)(13)(A)(iv) and 1923 of the Act, states are required to make payments to qualifying DSHs (DSH payments). Section 2551 of the ACA amended section 1923(f) of the Act, by adding paragraph (7), to provide for aggregate reductions in federal funding under the Medicaid program for such DSH payments for the 50 states and the District of Columbia. DSH allotments are not provided for the five US territories.

Section 1923(f)(7)(A)(i) of the Act requires that the Secretary implement the aggregate reductions in federal funding for DSH payments through reductions in annual state allotments of federal funding for DSH payments (state DSH allotments), and accompanying reductions in payments to each state. Since 1998, the amount of federal funding for DSH payments for each state has been limited to an annual state DSH allotment in accordance with section 1923(f) of the Act. The addition of section 1923(f)(7) of the Act requires the use of a DHRM to determine the percentage reduction in annual state DSH allotments to achieve the required aggregate annual reduction in federal DSH funding. The statutory reductions apply to all states and the District of Columbia, except the State of Tennessee. Under section 1923(f)(6)(A)(vi) of the Act, notwithstanding any other provision of section 1923(f) of the Act, or any other provision of law, the DSH allotment for Tennessee is established at $53.1 million per year for FY 2015 through FY 2025. Therefore, Tennessee's DSH allotment is not subject to reduction under section 1923(f)(7) of the Act. For purposes of this rule, references to the reduction for ''each state'' means ''each state subject to a DSH allotment reduction'' (that is, the 50 states and the District of Columbia, except, for periods before FY 2026, Tennessee).

Section 1923(f)(7)(B) of the Act establishes the following factors that must be considered in the development of the DHRM. The methodology must:

- Impose a smaller percentage reduction on low DSH States;
- Impose the largest percentage reductions on:
  - ++ States that have the lowest percentages of uninsured individuals during the most recent year for which such data are available;
  - ++ States that do not target their DSH payments on hospitals with high volumes of Medicaid inpatients;
  - ++ States that do not target their DSH payments on hospitals with high levels of uncompensated care; and
- Take into account the extent to which the DSH allotment for a state was included in the budget neutrality calculation for a coverage expansion approved under section 1115 of the Act as of July 31, 2009.

In section II.B. of the July 2017 proposed rule, we described the principles we intended to apply when calculating the annual DSH allotment reduction amounts for each state through the DHRM.

[1] Bipartisan Budget Act of 2013 (Pub. L. 113–67), enacted on December 26, 2013.

[2] Protecting Access to Medicare Act of 2014 (Pub. L. 113–93), enacted April 1, 2014; Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10), enacted April 16, 2015; and the Bipartisan Budget Act of 2018 (Pub. L. 115–123), enacted February 9, 2018.

B. Legislative History and Overview

The Omnibus Budget Reconciliation Act of 1981 (OBRA'81) (Pub. L. 97–35, enacted on August 13, 1981) amended section 1902(a)(13) of the Act to require that Medicaid payment rates for hospitals take into account the situation of hospitals that serve a disproportionate share of low-income patients with special needs. Over the more than 35 years since this requirement was first enacted, the Congress has set forth in section 1923 of the Act payment targets and limits to implement the requirement and to ensure greater oversight, transparency, and targeting of funding to hospitals.

To qualify as a DSH under section 1923(b) of the Act, a hospital must meet two minimum qualifying criteria in section 1923(d) of the Act. The first criterion is that the hospital has at least two obstetricians who have staff privileges at the hospital and who have agreed to provide obstetric services to Medicaid beneficiaries. This criterion does not apply to hospitals in which the inpatients are predominantly individuals under 18 years of age or hospitals that do not offer nonemergency obstetric services to the general public as of December 22, 1987. The second criterion is that the hospital has a Medicaid inpatient utilization rate (MIUR) of at least 1 percent.

Under section 1923(b) of the Act, a hospital meeting the minimum qualifying criteria in section 1923(d) of the Act is deemed as a DSH if the hospital's MIUR is at least one standard deviation above the mean MIUR in the state for hospitals receiving Medicaid payments, or if the hospital's low-income utilization rate (LIUR) exceeds 25 percent. States have the option to define DSHs under the state plan using alternative qualifying criteria as long as the qualifying methodology comports with the deeming requirements of section 1923(b) of the Act. Subject to certain federal payment limits, states are afforded flexibility in setting DSH state plan payment methodologies to the extent that these methodologies are consistent with section 1923(c) of the Act.

Section 1923(f) of the Act limits federal financial participation (FFP) for total statewide DSH payments made to eligible hospitals in each federal FY to the amount specified in an annual DSH allotment for each state. Although there have been some special rules for calculating DSH allotments for particular years or sets of years, section 1923(f)(3) of the Act establishes a general rule that state DSH allotments are calculated on an annual basis in an amount equal to the DSH allotment for the preceding FY increased by the percentage change in the consumer price index for all urban consumers for the previous FY. The annual allotment, after the consumer price index increase, is limited to the greater of the DSH allotment for the previous year or 12 percent of the total amount of Medicaid expenditures under the state plan during the FY. Allotment amounts were originally established in the Medicaid Voluntary Contribution and Provider Specific Tax Amendments of 1991 based on each state's historical DSH spending.

Section 1923(g) of the Act also limits DSH payments by imposing a hospital-specific limit on DSH payments. Specifically, a DSH payment must not exceed a hospital's uncompensated care costs for that year (that is, it must not exceed the costs of providing inpatient hospital and outpatient hospital services to Medicaid patients and the uninsured, minus payments received by the hospital by or on the behalf of those patients). FFP is not available for DSH payments that exceed the hospital-specific limit.

The statute, as amended by the ACA, required annual aggregate reductions in federal DSH funding from FY 2014 through FY 2020. However, subsequent legislation extended the reductions, modified the amount of the reductions, and delayed the start of the reductions, which now begin in FY 2020. The most recent related amendments to the statute were through the Bipartisan Budget Act of 2018 (Pub. L. 115–123, enacted February 9, 2018) (BBA 18). Currently, the aggregate annual reductions are set to begin in FY 2020, and the annual reduction amounts are specified in section 1923(f)(7)(A)(ii) of the Act:

- $4,000,000,000 for FY 2020.
- $8,000,000,000 for FY 2021.
- $8,000,000,000 for FY 2022.
- $8,000,000,000 for FY 2023.
- $8,000,000,000 for FY 2024.
- $8,000,000,000 for FY 2025.

To implement these annual reductions, the statute requires that the Secretary reduce annual state DSH allotments, and payments to states, based on a DHRM specified in section 1923(f)(7)(B) of the Act. The proposed DHRM relied on five statutorily-identified factors collectively to determine a state-specific DSH allotment reduction amount to be applied to the allotment that is calculated under section 1923(f) of the Act prior to the reductions under section 1923(f)(7) of the Act.

In the May 15, 2013 **Federal Register** (78 FR 28551), we published the ''Medicaid Program; State Disproportionate Share Hospital Allotment Reductions'' proposed rule. The rule proposed a DHRM that relied on the statutory factors and solicited comments regarding whether state decisions to extend Medicaid coverage to low-income adults under section 1902(a)(10)(A)(i)(VIII) of the Act (the Medicaid expansion population) should be accounted for in the reduction methodology. We received several comments in support of accounting for Medicaid coverage expansion and numerous comments in opposition.

In the September 18, 2013 **Federal Register** (78 FR 57293), we published the ''Medicaid Program; State Disproportionate Share Hospital Allotment Reductions'' final rule (herein referred to as the ''2013 DSH allotment reduction final rule''). In the 2013 DSH allotment reduction final rule, we decided to finalize a DHRM that would be in place only for FY 2014 and FY 2015 to allow time for revaluation of the methodology with improved and more recent data and information about the impact of the ACA on levels of coverage and uncompensated care. As a result of our reevaluation, we subsequently proposed to modify the DHRM factor weights and to use improved data sources where possible.

III. Summary of the Provisions of the July 2017 Proposed Rule and Responses to Public Comments

In the July 2017 proposed rule, we proposed to amend § 447.294 by establishing the DHRM for FY 2018 and subsequent fiscal years, incorporating factors identified in the statute. We received approximately 140 public comments on the proposed rule from organizations, individuals, health care providers, advocacy groups, and states. In the sections that follow, we describe each proposed provision, summarize any public comments received on each provision, and provide our responses to the comments.

A. General Comments

In addition to the comments we received on the July 2017 proposed rule's discussion of specific aspects of the State DSH Allotment Reductions (which we address later in this final rule), commenters also submitted the following more general observations on the reductions. The following is a discussion of these comments.

Comment: Many commenters urged delaying the implementation of the annual aggregate reductions to State DSH allotments. The commenters provided various reasons for the requested delay.

Response: The statute directs the Secretary to develop a DHRM to implement annual Medicaid DSH allotment reductions. Various legislation, including most recently the BBA 18, delayed the start of the reductions until FY 2020. We have no flexibility administratively to delay the start of the statutory reductions.

Comment: Multiple commenters expressed concern that unreduced DSH allotments under section 1923(f) of the Act are inequitable. Some of these commenters recommended modifications to the method for determining the unreduced allotments and some commenters indicated a belief that the proposed DHRM would exacerbate the alleged inequities of the unreduced allotments.

Response: Section 1923(f)(7) of the Act specifies the five factors for the DHRM, but does not authorize modifications to the statutory formula for calculating unreduced state DSH allotments under section 1923(f) of the Act. While the statute does not direct the Secretary to modify the formula for unreduced DSH allotments through the DHRM, the DHRM does take into account the size of the existing state DSH allotments in determining annual allotment reduction amounts. Most notably, the Low DSH Adjustment Factor (LDF) requires the imposition of smaller percentage reductions on low DSH states that historically have received lower DSH allotments relative to their total Medicaid expenditures than non-low DSH states.

Comment: One commenter inquired as to when the reduced 2018 DSH allotments will be available as cuts were to begin October 1, 2017.

Response: The BBA 18 delayed the start of annual DSH allotment reductions until FY 2020, which begins on October 1, 2019. We intend to make final FY 2020 reduction amounts available to states once finalized data necessary to calculate these reductions are available, which CMS anticipates will be on or before October 1, 2019.

Comment: A number of commenters expressed concern that the DSH allotment reductions will cause financial distress to hospitals.

Response: We understand the commenters' concerns. However, the statute requires annual aggregate reductions in DSH allotments starting in FY 2020 and the use of a DHRM to determine the percentage reduction in annual state DSH allotments to achieve the required aggregate annual reduction amounts. We are finalizing a DHRM that is consistent with statutory direction and does not affect the considerable flexibility afforded states in setting DSH state plan payment methodologies to the extent that these methodologies are consistent with section 1923(c) of the Act and all other applicable statutes and regulations.

Comment: One commenter stated that those affected by drug addiction and mental health issues will be hurt by the DSH reductions.

Response: We recognize the importance of health care services for substance use disorders and behavioral health issues. However, section 1923(f)(7)(A)(i) of the Act requires the Secretary implement aggregate reductions in federal funding for DSH payments through reductions in annual state DSH allotments. Moreover, these statutorily-required annual state DSH allotment reductions do not directly affect payment rates for services, including services related to substance use disorders or behavioral health, or otherwise directly affect reimbursement to providers that do not receive DSH payments.

Comment: A few commenters suggested that CMS finalize the rule for a limited period of time to allow for reevaluation and refinement to strengthen the DHRM in future years.

Response: We recognize the importance of the DHRM to states, hospitals, and other stakeholders. Therefore, we will monitor and reevaluate the DHRM and its application throughout implementation. If necessary, we will undertake future rulemaking to make modifications to the DHRM.

Comment: Multiple commenters suggested that the DHRM does not take into consideration that Medicaid reimbursement rates are considerably lower than private insurance.

Response: Section 1923(f)(7) of the Act specifies the five factors for the DHRM, but does not direct the Secretary to consider specifically the levels of Medicaid reimbursement rates as compared to private insurers. However, the DHRM does consider Medicaid coverage and payment levels by imposing the largest percentage DSH allotment reductions on states that do not target their DSH payments on hospitals with high volumes of Medicaid inpatients and states that do not target their DSH payments on hospitals with high levels of uncompensated care, which includes Medicaid shortfall.

Comment: Some commenters expressed concern that the Congress passed Medicaid DSH allotments reductions expecting that hospitals would care for fewer uninsured patients as a result of health care coverage expansion related to the ACA. Commenters also stated that projected increases in coverage have not been fully realized for a variety of reasons and some noted that some providers in Medicaid expansion states are still experiencing significant losses for serving Medicaid beneficiaries. Some commenters also expressed concern that increases in the number of insured individuals has not decreased the need for DSH payments.

Response: We appreciate the comments, but the statute directs the Secretary to develop a DHRM to implement annual Medicaid allotment reductions. We have no administrative flexibility to delay the start of the statutory reductions or to reduce the aggregate reduction amounts specified in statute. We believe that the final DHRM distributes DSH allotment reduction amounts among the states in an equitable manner, consistent with statutory requirements.

Comment: Several commenters stated that the hospital industry greatly opposes CMS' policy for the treatment of third party payments when calculating the hospital-specific DSH limit, stating it is a misinterpretation of the Medicaid statute.

Response: CMS' policy regarding the treatment of third party payments when calculating the hospital-specific DSH limit is outside the scope of this rule.

Comment: A few commenters indicated there are unresolved legal questions related to the DSH audit process that are the subject of pending litigation; therefore, CMS should delay finalizing the DSH reduction methodology. One commenter expressed concern that the DSH audit and reporting data may not be consistent with federal Medicaid law.

Some commenters recommended that CMS delay the final rule until stakeholders have had ample opportunity to replicate and evaluate the proposed DHRM and that CMS should provide requisite data sets and sufficient technical information before issuing a final rule. The commenters requested that if that is not possible, then CMS should finalize the DHRM for FY 2018 only and provide an adequate comment period, requisite data sets, and refined technical information with a proposed rule for FY 2019. The commenters noted that, given the complexity of the DHRM and the destabilizing effect that statutorily-required annual state DSH allotment reductions may have on safety net hospitals, a longer comment period and more transparency would be warranted.

Response: We do not believe that there is any need to delay finalizing the July 2017 proposed rule. The statute

directs the Secretary to develop a DHRM to implement annual Medicaid DSH allotment reductions, and the intent of this rule is to provide the methodology used to calculate the statutorily-required Medicaid DSH allotment reductions. While a number of issues related to Medicaid DSH payment calculations currently are the subject of litigation, the statutorily-required allotment reductions and the DHRM are not among them, and we are bound by statute to adopt a rule to implement the DSH reductions. With this final rule, we are doing so according to our view of the best interpretation of the DSH statute and will utilize the most recent data available to us that is consistent with applicable laws and regulations.

The BBA 18 delayed the start of the reductions until FY 2020. Accordingly, concerns with respect to how a DHRM might have applied with respect to prior fiscal years, including FY 2018 and FY 2019, are moot. We have no flexibility to delay the start of the statutory reductions. Finally, we intend to publish a separate DHRM technical guide that provides information regarding the DHRM calculation and associated data sources in order to be fully transparent with states and other stakeholders.

Comment: Several commenters expressed concern with the 30-day comment period and the availability of data used in the illustrative model during the comment period and noted that a 60-day comment period would have been more appropriate. Another commenter suggested a second comment period prior to when the DSH allotment reductions for FY 2018 are published to allow states to accurately estimate the impact of the proposed methodology on the state.

Response: We believe the 30-day comment period was appropriate and are not providing an additional comment period. Section 1923(f)(7)(B) of the Act, establishing the five factors that must be considered in the development of the DHRM, was enacted in statute in 2010. Additionally, we signaled our intent to pursue a similar methodology in future rulemaking when publishing the final 2013 DSH allotment reduction rule.

Comment: One commenter indicated that research has shown that residents of Medicaid expansion states are less likely to experience financial barriers to healthcare access than residents of states that have not expanded Medicaid coverage.

Response: This comment is outside the scope of this rule.

Comment: One commenter encouraged CMS to consider that Medicaid is the single largest payer to children's hospitals and suggested that the regulation will impose a greater burden to these hospitals, which already face significant financial challenges due to inadequate Medicaid reimbursement rates. Another commenter expressed concern that the reductions will have a negative impact on hospitals in the commenter's state, given that there is not a sufficient number of privately insured patients to offset losses from Medicare and Medicaid, which pay significantly less than private insurers.

Response: We appreciate the important role that children's hospitals play in serving Medicaid beneficiaries. This rule provides the methodology used to calculate the statutorily-required Medicaid DSH allotment reductions and does not affect the flexibility afforded to states when setting DSH state plan payment methodologies, to the extent that these methodologies are consistent with section 1923(c) of the Act and all other applicable laws and regulations. States retain flexibility to direct Medicaid DSH payments to qualifying hospitals in the state, including children's hospitals, in the manner the state determines most appropriate under the conditions in the state. In addition, we are finalizing a DHRM that would equitably allocate the statutorily-required annual reductions based on the factors specified in section 1923(f)(7) of the Act. Changes to Medicare and non-DSH Medicaid payment rates are outside the scope of this rule.

Comment: One commenter stated that the statute requiring DSH allotment reductions is unethical, particularly in that it would reduce payments to hospitals.

Response: We appreciate the concerns that the rule may have an impact on hospitals. However, the statute as amended by the ACA and subsequent legislation directs the Secretary to implement annual DSH allotment reductions using a DHRM, which is specified in this final rule.

Comment: One commenter noted their work for an institution that served mostly Medicaid patients and that the institution may not be able to continue to provide services to all individuals if DSH payments are reduced. Additionally, the commenter expressed concern that future Congressional action in health care might result in additional uninsured or underinsured patients.

Response: We appreciate the important role that DSHs play in providing health care to low-income individuals and vulnerable populations. The statute specifies the annual amount of aggregate DSH allotment reductions and directs the Secretary to develop a methodology which takes into consideration the required statutory factors for allocating a reduction amount to each state. This final rule does not affect state flexibility to develop methodologies as described in section 1923(c) of the Act for payments to qualifying hospitals, provided the methodology complies with all applicable statutory and regulatory requirements.

Comment: One commenter recommended that CMS carve out most non-DSH supplemental payments made to inpatient hospitals and add the funding into the state's DSH allotment, to better support essential hospitals by ensuring payments flow through one central distribution program.

Response: Non-DSH Medicaid supplemental payments and the method for calculating unreduced DSH allotments in section 1923(f) of the Act are outside the scope of this rule.

Comment: One commenter suggested CMS consider that Medicaid is about to embark on a new phase of payment and delivery reform, and the DSH reductions could disrupt those efforts.

Response: This rule does not address potential future payment and delivery reform, and does not affect state's flexibility under section 1923 of the Act to establish DSH payment methodologies.

Comment: Many commenters recommended that CMS mitigate the impact of reductions on specific hospital types, including rural hospitals, safety net hospitals, critical access hospitals, and academic medical centers. One commenter recommended that CMS mitigate reductions based on community needs to ensure individuals have access to care and that DSH funding is available for medically necessary services. Another commenter expressed concern for low and moderate income families having access to care and suggested that hospitals be required to meet basis standards related to charity care, billing, and collections to receive DSH payments.

Response: This rule only addresses the aggregate DSH allotment reductions under section 1923(f)(7) of the Act. The statutory requirements for DSH payment methodologies are specified in section 1923(c) of the Act and are outside of the scope of this rule. However, we believe that the DHRM reduces DSH allotments, at the state level, in an equitable manner that is consistent with the statute. Accordingly, we designed the DHRM to preserve the considerable flexibility afforded states in setting DSH state plan payment methodologies, to the extent that these methodologies are consistent with section 1923(c) of the Act and all

other applicable statutes and regulations.

Comment: One commenter recommended that CMS consider Medicaid shortfalls, charity care, and bad debt in the distribution of funds from uncompensated care pools approved under section 1115 demonstrations. In addition, the commenter recommended that CMS consider all lines of a hospital's business in the DHRM for hospitals experiencing negative margins to better account for the overall financial situation of hospitals.

Response: This regulation does not address the distribution of payments under section 1115 demonstrations; it only addresses the statutorily-required Medicaid DSH allotment reductions. Changes affecting the distribution of payments under section 1115 demonstrations are outside the scope of this rule. Additionally, the hospital-specific limit under section 1923(g) of the Act only considers costs incurred for furnishing hospital services to individuals who are either Medicaid beneficiaries or uninsured. Consistent with the DSH statute's overall focus on these populations, the statutory DHRM targeting factors also require smaller reductions be imposed on states that target their DSH payments to hospitals with high volumes of Medicaid inpatients and high levels of uncompensated care (excluding bad debt). As such, we did not propose and are not finalizing consideration of other lines of a hospital's business for purposes of the statutorily-required Medicaid DSH allotment reductions.

Comment: Many commenters expressed concerns regarding the possibility of revisions to or repeal of the ACA and recommended that the DHRM include a provision for reversal of reductions if future legislation affecting section 1923(f)(7) of the Act is enacted.

Response: We appreciate the commenters' concerns but are statutorily-bound to implement the DSH allotment reductions beginning with FY 2020. This final rule does not prevent CMS from following future statutory provisions, including any revisions to the applicable statute pertaining to Medicaid DSH allotment reductions. We will undertake future rulemaking as may be necessary to ensure that the regulations continue to implement statutory requirements appropriately.

Comment: We received several comments related to the Medicare Inpatient Prospective Payment System (IPPS) rules.

Response: Comments on the Medicare IPPS rules are outside the scope of this rule.

Comment: One commenter expressed concern that the proposed methodology will exacerbate current inequalities in Medicare IPPS and jeopardize the existence of hospitals already experiencing negative margins.

Response: The Medicaid and the Medicare programs are distinct programs authorized under different titles of the statute and the Medicare and Medicaid DSH rules have somewhat different purposes and statutory directives. Section 1923(f)(7)(B) of the Act establishes five factors that must be considered in the development of the DHRM. While we appreciate the commenter's concern, considerations related to the Medicare IPPS are not included in the factors Congress has specified to be considered in the DHRM. However, states will continue to have considerable flexibility in setting DSH state plan payment methodologies, to the extent that these methodologies are consistent with section 1923(c) of the Act and all other applicable statutes and regulations.

Comment: One commenter expressed concern that California's estimated DSH reductions are more than double those estimated in the proposed rule released in 2013.

Response: The aggregate DSH allotment reductions shown for FY 2018, as included in the illustrative model included in the July 2017 proposed rule, were greater for all states (except Tennessee) than the aggregate DSH allotment reduction amounts in the illustrative example for the 2013 DSH allotment reduction proposed rule. This was the result of the magnitude of the reductions shown in the illustrative example in the July 2017 proposed rule, which were $2 billion, while the reductions shown in the 2013 proposed rule were $500 million. Additionally, the state-specific DSH allotment reductions included in both proposed rules were part of illustrative examples to show how the DHRM would work, and were not estimated reduction amounts. Under current law FY 2018 would not be subject to annual allotment reductions which will now begin in FY 2020 and run through FY 2025.

Comment: One commenter questioned whether state-specific DSH allotment reductions for each fiscal year will increase proportionately as the annual aggregate DSH allotment reductions increase.

Response: Each state's annual DSH allotment reduction will be determined annually based on the DHRM.

Comment: One commenter stated that 50 percent of all hospitals are DSH and expresses concern that the reductions may be unevenly allocated.

Response: We believe that the DHRM will determine state DSH allotment reductions in an equitable manner consistent with statutory requirements. States will continue to have considerable flexibility in setting DSH state plan payment methodologies, to the extent that these methodologies are consistent with section 1923(c) of the Act and all other applicable statutes and regulations.

B. DHRM Data Sources

The statute establishes parameters regarding data and data sources for specific factors in the development of the DHRM. In the July 2017 proposed rule, we proposed that the DHRM would rely, wherever possible, on data sources and metrics that are consistent with the statute, transparent, and readily available to CMS, states, and the public, such as: DSH MIUR data; Medicaid DSH data reported as required by section 1923(j) of the Act; United States Census Bureau (Census Bureau) data; existing state DSH allotments; and Form CMS–64 Medicaid Budget and Expenditure System (MBES) data. We proposed to utilize the most recent year available for all data sources and proposed to align the state plan rate year (SPRY) of data sources whenever possible. Selected data sources are discussed in greater detail below, including our responses to comments regarding particular data sources.

1. MIUR Data

To ensure that all hospitals are properly deemed disproportionate share in accordance with section 1923(b) of the Act, states must determine the mean MIUR for hospitals receiving Medicaid payments in the state and the value of one standard deviation above the mean. States are currently required to provide this data to CMS annually under § 447.294(d) (CMS–R–266, Office of Management and Budget (OMB) 0938–0746). We proposed to utilize MIUR data from the year that corresponds to the DSH audit SPRY used in the calculation of each state's DSH allotment reduction.

2. Medicaid DSH Audit and Reporting Data

We also proposed to rely on data derived from Medicaid DSH audit (CMS–R–266, OMB 0938–0746) and reporting data (CMS–R–266, OMB 0938–0746). The data is reported by states as required by section 1923(j) of the Act and the ''Medicaid

Disproportionate Share Hospital Payments'' final rule published on December 19, 2008 (73 FR 77904) (and herein referred to as the 2008 DSH audit final rule) requiring state reports and audits to ensure the appropriate use of Medicaid DSH payments and compliance with the hospital-specific DSH limit imposed at section 1923(g) of the Act. This is the only comprehensive data source for DSH hospitals that identifies hospital-specific DSH payments and uncompensated care costs in a manner consistent with Medicaid DSH program requirements.[3]

To date, we have received rich, comprehensive audit and reporting data from each state that makes Medicaid DSH payments. To facilitate the provision of high quality data, we provided explicit parameters in the 2008 DSH audit final rule and associated policy guidance for calculating and reporting data elements. As the data elements are based on hospital costs reports and are subject to audit, the data elements are not due to CMS until the end of the calendar year 3 years following the end of each SPRY. Additionally, state submitted audit and reporting data is subject to detailed CMS review to ensure quality and accuracy and requires significant resources to compile and prepare for use in the DHRM. This means that the data used for the methodology may not be the most recently submitted data, but instead the most recent data available to us in usable form. For the reductions scheduled for FY 2020, we anticipate utilizing SPRY 2015 DSH audit and reporting data, which was due to CMS from states on December 31, 2018. We considered utilizing alternative uncompensated care cost data and Medicaid utilization data from sources such as the Medicare Form CMS–2552 (OMB 0938–0050), which we explained in more detail in the 2013 DSH allotment reduction final rule. The DSH audit and reporting data, however, remains the only comprehensive reported data available that is consistent with Medicaid program requirements.

3. United States Census Bureau Data

As required by the statute, the DHRM must impose the largest percentage DSH allotment reductions on the states that have the lowest percentages of uninsured individuals. Although other sources of this information could be considered for this purpose, the statute explicitly refers to the use of data from the Census Bureau for determining the percentage of uninsured for each state. As with the 2013 DSH allotment reduction final rule, we identified and considered two Census Bureau data sources for this purpose: The American Community Survey (ACS); and the Annual Social and Economic Supplement to the Current Population Survey (CPS). In consultation with the Census Bureau, we proposed to use the data from the ACS for the following reasons. First, the ACS is the largest household survey in the United States; in that regard, the annual sample size for the ACS is over 30 times larger than that for the CPS—about 3 million for the ACS versus 100,000 for the CPS. The ACS is conducted continuously each month throughout the year, with the sample for each month being roughly 1/12th of the annual total, while the CPS is conducted in the first 4 months following the end of the survey year.

Finally, although the definition of uninsured and insured status is the same for the ACS and the CPS, the CPS considers the respondents as uninsured if they are uninsured at any time during the year whereas the ACS makes this determination based on whether the respondent has coverage at the time of the interview, which are conducted at various times throughout the year. For these reasons, and with the recommendation of the Census Bureau, we determined that the ACS is the appropriate source for establishing the percentage of uninsured for each state for purpose of the DHRM.

We received a number of public comments on our proposals regarding DHRM data sources in the July 2017 proposed rule. A discussion of these comments, with our responses, appears below.

Comment: One commenter expressed support for the DSH audit and reporting data being the source for uncompensated care cost data for the DHRM.

Response: We thank the commenter for the support for the proposal and are finalizing the use of the DSH audit and reporting data as the source of uncompensated care cost data for the DHRM.

Comment: Several commenters expressed concern regarding the use of DSH audit and reporting data for the DHRM. The commenters cited various concerns regarding the DSH audit data, including the use of out-of-date data which causes a lag between DSH policy and programmatic changes that is not reflected in audit and reporting data. One commenter indicated that use of the DSH audit data penalized states because it is not reflective of DSH payment policy changes that have been made in later time periods following the audit year. Many commenters requested that CMS provide states with at least 4 years advance notice of its intent to utilize DSH audit data for reductions based on payment targeting to give states proper time to consider adjustments to their programs. One commenter expressed concern that the timeliness of the DSH audit data undermines the incentive for states to target DSH payments because states have to wait 5 years, which the approximate lag time between a particular SPRY subject to audit and when related data for that year becomes available for use in the DHRM, to see the benefits of targeting hospitals with high Medicaid utilization and high uncompensated care costs. Some commenters recommended that CMS use uniform data in the DHRM wherever possible among all hospitals. Other commenters recommended that we consider initiating a separate survey to determine uncompensated care costs for a more recent year than the DSH audit data we propose to use in the DHRM. Several commenters recommended that CMS revise the DHRM if a source of timelier data become available.

Response: The Medicaid DSH audit and reporting data is the most comprehensive reported data available that is consistent with Medicaid program requirements. To date, we have received audit and reporting data from each state that makes Medicaid DSH payments. To facilitate the provision of high quality data, we provided explicit parameters in the 2008 DSH final rule and associated policy guidance for calculating and reporting data elements. The 2008 DSH final rule included a transition period in which states and auditors could develop and refine audit and reporting techniques. Moreover, states have had ample time to implement DSH payment methodologies that could mitigate DSH allotment reductions related to the DSH payment targeting factors, which have been codified in statute since March 23, 2010, and prior rulemaking as finalized in the 2013 DSH allotment reduction rule and as discussed in the July 2017 proposed rule. This final rule will not affect the considerable flexibility afforded to states with regard to establishing DSH state plan payment methodologies to the extent that these methodologies are consistent with section 1923(c) of the Act and all other applicable statutes and regulations.

We currently have no plans to develop a separate survey to serve as a

[3] CMS published a final rule in the April 3, 2017 **Federal Register** (82 FR 16114) revising the text of § 447.299(c)(1). Effective June 2, 2017, the rule amended paragraph (c)(1) to clarify that uncompensated care costs are calculated using total cost of care for Medicaid inpatient and outpatient services, net of third-party payments.

timelier source of uncompensated care costs. However, we do not believe a timelier source of high quality data could be developed given that cost reports used to calculate uncompensated care costs may not be settled for 2 or more years following the end of a fiscal year. Moreover, an additional time period would be needed to allow for review and/or audit of this data to ensure its quality and accuracy. This would impose administrative burden on states, hospitals and us by essentially doubling effort relating to DSH auditing and reporting. As such, we are finalizing reliance on existing DSH audit and reporting data in the DHRM because it represents the best available data that is consistent with existing program requirements without imposing duplicative and otherwise unnecessary burden. Notwithstanding, we will continue to monitor the reduction methodology after implementation and will consider whether the development of a timelier data source is warranted, which we would undertake through future rulemaking, as necessary.

Comment: Several commenters recommended that CMS modify DSH audit requirements to rely on estimated costs in calculating hospital-specific limits instead of relying on actual costs to allow for more recent data to be included in the DHRM. Two commenters suggested that this approach would also minimize the financial burden that conducting independent certified DSH audits places upon states.

Response: While we recognize that states must use estimates to determine DSH payments in a given Medicaid SPRY, the independent certified DSH audits are statutorily-required under section 1923(j) of the Act to verify the extent to which such estimates are reflective of the actual costs and that resultant payments do not exceed the limitations on DSH payments imposed by Congress.

Comment: One commenter expressed concern that the DSH audit and reporting data included negative values for uncompensated care.

Response: Negative values for uncompensated care costs occur where hospitals receive payments by or on the behalf of Medicaid patients and the uninsured for inpatient and outpatient hospital services that exceed the costs of providing inpatient hospital and outpatient hospital services to such individuals.

Comment: One commenter recommended that CMS modify the DSH reporting requirements to collect total hospital costs from the Medicare cost report for all hospitals that receive DSH payments.

Response: We confirm that as part of the DSH audit submission, states are currently required to report total hospital costs, meaning the total annual costs incurred by the hospital for furnishing inpatient hospital and outpatient hospital services, for each in-state hospital that receives a DSH payment, per § 447.299(c).

Comment: One commenter requested a detailed explanation of how CMS derived Massachusetts' HMF and HUF reduction or the HMF and HUF reduction for any state missing hospital-specific DSH payments.

Response: As of the publication of this final rule, we have not calculated FY 2020 DSH allotment reductions. We will calculate FY 2020 reductions for Massachusetts and all other states by utilizing the final DHRM. States that do not make DSH payments may still receive a DSH allotment reduction.

C. DHRM Overview

The statute requires aggregate annual reduction amounts to be implemented through a DHRM designed by the Secretary consistent with statutorily-established factors. Taking these factors into account for each state, we proposed that the DHRM would generate a state-specific DSH allotment reduction amount for each applicable fiscal year for all states and the District of Columbia, with the exception of Tennessee, whose DSH allotment is defined in section 1923(f)(6)(A)(vi) of the Act to be $53.1 million, notwithstanding DSH allotment reductions in section 1923(f)(7) of the Act, for each FY from 2015 through 2025. The total of all DSH allotment reduction amounts would equal the aggregate annual reduction amount identified in statute for each applicable fiscal year. To determine the effective annual DSH allotment for each state, we proposed that the state-specific annual DSH allotment reduction amount would be applied to the unreduced DSH allotment amount for its respective state.

We proposed to calculate an unreduced DSH allotment for each state prior to the beginning of each FY, as we do currently. This unreduced allotment is determined by calculating the allotment in section 1923(f) of the Act prior to the application of the DHRM under section 1923(f)(7) of the Act. We proposed that the unreduced allotment would serve as the base amount for each state to which the state-specific DSH allotment reduction amount would apply annually. In the July 2017 proposed rule, we utilized estimated unreduced DSH allotments for FY 2017 for illustrative purposes. Moreover, we indicated that the illustrative estimate may rely on different data than what we proposed to use when calculating annual DSH allotment reductions for FY 2018, which is when reductions were scheduled to begin when we published the July 2017 proposed rule, and anticipated that more recent data would be available when calculating the final allotment reductions.

We proposed to apply the DHRM to the unreduced DSH allotment amount on an annual basis for the fiscal years specified in statute as subject to DSH allotment reduction. In developing the proposed DHRM, we considered the factors identified in the statute to determine each state's annual state-specific DSH allotment reduction amount.

We proposed a DHRM that utilizes the best available data at the time of the annual DSH allotment reduction calculations, and proposed that we would not recalculate the reduction amounts based on revised or late DSH audit reports, MIUR data, or other relevant data. The DHRM would also rely on a series of interacting calculations that result in the identification of state-specific reduction amounts that, when summed, equal the aggregate DSH allotment reduction amount identified by the statute for each applicable year. The proposed DHRM accomplishes this through the following summarized steps:

1. Separate states into two overall groups, non-low DSH states and low DSH states, to give effect to the statutory low DSH criterion. (States falling into each category were listed in Table 1 of the July 2017 proposed rule).

2. Proportionately allocate aggregate DSH funding reductions to each of these two state groups based on each state group's proportion of the total national unreduced DSH allotment amount.

3. Apply a low DSH adjustment percentage to adjust the non-low DSH and low DSH state groups' DSH funding reduction amount. This step maintains the combined aggregate DSH funding reduction for the low DSH and non-low DSH state groups by distributing a portion of the unadjusted low DSH state DSH funding reduction amount across the non-low DSH state group, as described in greater detail below.

4. Divide each state group's DSH allotment reduction amount among three statutorily-identified factors, the uninsured percentage factor (UPF), the high level of uncompensated care factor (HUF), and the high volume of Medicaid inpatients factor (HMF). We proposed to assign a 50 percent weight to the UPF

and a 50 percent combined weight for the two DSH payment targeting factors (a 25 percent weight for the HUF, and a 25 percent weight for the HMF). This approach would assign equal weights based on the statutory structure under which the UPF is presented separately, in section 1923(f)(7)(B)(i)(I) of the Act, while the HMF and HUF are grouped together in section 1923(f)(7)(B)(i)(II) of the Act, at items (aa) and (bb). Additionally, compared to the approach taken in the 2013 DSH allotment reduction final rule, this weight assignment would place greater emphasis on the UPF to:

- Reduce the impact of the DSH allotment reduction for states with greater DSH need due to high uninsurance rates.
- Give greater weight to more recent data, since the UPF data relies on more recent data than the HUF and HMF.

We considered various alternative weight assignments prior to proposing equal weights for the UPF as specified in section 1923(f)(7)(B)(i)(I) of the Act and for the combined HMF and HUF as specified in section 1923(f)(7)(B)(i)(II) of the Act. We decided to propose the 50 percent weight for the UPF and a 50 percent combined weight for the two DSH payment targeting factors to reduce the impact of the DSH allotment reductions for states with high uninsurance rates, place a greater weight on more recent data, and reflect how these factors are specified in statute.

5. Limit the reduction to be applied to each state's total unreduced DSH allotment to 90 percent of its original unreduced allotment. Any excess reduction amounts called for under the DHRM which are limited by this reduction cap will be factored back into the reduction model and be redistributed among the remaining states that do not exceed the reduction cap based on the proportion of each remaining state's allotment reduction amount to the aggregate allotment reduction amount for its respective state group. This operation would be performed separately for each state group such that, for example, an excess reduction amount attributable to a low DSH state would be reapportioned only among other low DSH states and would not be reapportioned among any states in the non-low DSH state group. By limiting the overall amount by which each state's allotment may be decreased, we proposed to preserve at least 10 percent of each state's unreduced DSH allotment, thereby allowing all states to continue to make DSH payments. Placing limits on the reductions applied to each state's original unreduced allotments was a new proposal that was not considered in the 2013 DSH allotment reduction final rule. In view of the then-required aggregate DSH allotment reduction amounts and the DHRM under the 2013 DSH allotment reduction final rule, no state was in jeopardy of having its entire DSH allotment eliminated for FY 2014 or FY 2015 at the time that rule was promulgated. However, with the larger reduction amounts that were scheduled for FYs 2018 through 2025 under the statute as it was in effect at the time of the July 2017 proposed rule, and the reduction amounts currently scheduled for FYs 2020 through 2025, which are as high as $8 billion annually, states could experience the elimination of their entire DSH allotment without the inclusion of a reduction cap methodology in the DHRM. Although we did consider different reduction cap percentages, we believe the proposed 90 percent reduction cap strikes a balance between ensuring reduction amounts are determined based on the statutory DHRM factors and ensuring states maintain the ability to make an appreciable amount of DSH payments. Lower reduction caps would cause the reductions to approach even distribution among all states, instead of being based on the statutory DHRM factors. No cap might result in the complete elimination of some states' DSH allotments.

6. For each state group, determine state-specific DSH allotment reduction amounts relating to the UPF. To accomplish this, we will compare each state's uninsurance rate to the uninsurance rates of all states in relation to each state's unreduced allotment in proportion to its respective state group's total unreduced allotment to calculate each state's reduction. As required by statute, states with *lowest* uninsurance rates will receive *largest* percentage DSH reductions.

7. For each state group, determine state-specific DSH allotment reduction amounts relating to the HUF. By utilizing the most recently available Medicaid DSH audit and reporting data, we will determine the mean uncompensated care level for each state to determine the total payments each state makes to non-high uncompensated care level hospitals. We will then determine the HUF by dividing the total of each state's total payments made to non-high uncompensated care level hospitals by the total payments made non-high uncompensated care level hospitals for its respective state group.

8. For each state group, determine state-specific DSH allotment reduction amounts relating to the HMF. Again, by utilizing the most recently available Medicaid DSH audit and reporting data, we will determine the mean MIUR for each state to determine the amount of DSH payments each state makes to non-high Medicaid volume hospitals. We will then determine the HMF by dividing each state's total payments made to non-high volume Medicaid hospitals by the total payments made non-high volume Medicaid hospitals for its respective state group.

9. Apply a section 1115 budget neutrality factor (BNF) for each qualifying state. To apply this factor, we will not reduce any portion of a state's DSH allotment which was included in the budget neutrality calculation for a coverage expansion that was approved under section 1115 of the Act as of July 31, 2009. We will assign any qualifying states an average percentage reduction amount within its respective state group for diverted DSH allotment amounts that are not related to a coverage expansion in effect as of July 31, 2009 and for which the state does not have complete and/or relevant DSH payment data.

10. Identify the state-specific DSH allotment reduction amount.

11. Subtract each state's state-specific DSH allotment reduction amount from each state's unreduced DSH allotment to determine the state's available DSH allotment for the applicable year.

The manner in which we proposed that each of the five factors would be considered and calculated in the proposed DHRM is described in greater detail below.

The DHRM recognizes the variations in DSH allotments among states and the application of the methodology generates a lesser impact on low DSH states. The DHRM is designed to determine DSH allotment reductions in an equitable manner by grouping similar states together for purposes of applying the statutory reduction factors. Reductions assigned through the HMF and HUF would lessen the impact on states that have targeted DSH payments to hospitals that have high volumes of Medicaid inpatients and to hospitals that have high levels of uncompensated care, respectively, while incentivizing payment targeting for future DSH payments. As specified in statute, the DHRM would also take into account the extent to which the DSH allotment for a state was included in part or in whole in the budget neutrality calculation for a coverage expansion approved under section 1115 of the Act as of July 31, 2009 by excluding from DSH allotment reduction the amount of DSH that qualifying states continue to divert specifically for coverage expansion in

the budget neutrality calculation. Any amount of DSH diverted for other purposes under the demonstration would still be subject to reduction by automatically assigning qualifying states an average percentage reduction amount within its respective state group for factors for which the state does not have complete and/or relevant DSH payment data.

We received the following comments regarding the overall approach to the DHRM and have responded to the comments below.

Comment: One commenter expressed concern that the proposed DHRM would result in a significant reduction for its state and recommended revising the proposed methodology to reduce the impact of the DHRM on the commenter's state.

Response: We are finalizing a DHRM that will reduce DSH allotments annually by an aggregate amount set in statute, using a methodology that is consistent with statutory factors that direct the allocation of the annual reduction amount among the states.

Comment: One commenter requested information regarding which data will be used to calculate the preliminary DSH allotments. Other commenters recommended that CMS be transparent about the data sources, including by identifying which states will have the BNF applied to their allotment reduction calculation. Many commenters recommended that CMS post all the data sets used to implement the FY 2018 DHRM on its website and post a more comprehensive explanation of the calculation for each component of each state's total reduction.

Response: Currently, we calculate preliminary unreduced DSH allotments based on data available around the August preceding the start of each fiscal year and publish an annual notice in the **Federal Register** with detailed information regarding the data sources used for each fiscal year. These data sources include the previous year's preliminary unreduced DSH allotment, the change in the previous year's consumer price index, and state budget estimates from MBES. In addition to publishing an annual notice in the **Federal Register** and updating MBES at the beginning of each FY to reflect each state's preliminary DSH allotment amount, we also inform states prior to the beginning of each FY of their preliminary DSH allotment via direct electronic communication. In this communication, we provide states with all relevant data utilized to calculate both the annual preliminary DSH allotment and IMD limits, which is analogous to the information that is provided and published in the **Federal Register**.

In the July 2017 proposed rule, we included a detailed description of the proposed DHRM methodology. We thoroughly reviewed and carefully considered public comments, and issued this final rule in a timely manner incorporating input from public comments. This final rule also provides a detailed methodological description of the DHRM. To ensure the use of most recent available data, we do not intend to calculate the FY 2020 DSH allotment reductions until after the publication of this final rule. Also, we intend to publish a separate DHRM technical guide that provides information regarding the DHRM calculation and associated data sources.

Comment: Several commenters noted concern with CMS' use of the FY 2017 DSH allotments, FY 2013 DSH audit data, and state-reported MIUR data to generate FY 2018 DSH allotment reduction amounts. Commenters stated that the data were not consistent with Medicaid statute, transparent, and readily available to the public during the notice and comment period and that the lack of transparency significantly hampered state governments' and stakeholders' ability to assess how the DHRM would affect their state DSH allotment, particularly for FY 2018, the first year that annual state DSH allotment reductions were scheduled to be implemented at the time of the July 2017 proposed rule. Additionally, the commenters requested that we identify a more comprehensive and reliable source for calculating the uninsured rate for each state and not rely upon survey sampling results.

Response: We believe that the data used in the DHRM as described in the July 2017 proposed rule is consistent with the statute, transparent and readily available to CMS and the public. The statute requires that the percentage of uninsured individuals is determined on the basis of data from the Census Bureau, audited hospital cost reports, and other information likely to yield accurate data, during the most recent year for which such data are available. For hospitals that receive DSH payments and are included in the DSH audit and reporting data (which CMS makes readily available to the public on an annual basis), we proposed and are finalizing the use of the most recent complete DSH audit and reporting data for purposes of the DHRM. For purposes of this rule, we intend to use the most recent DSH audit and reporting data available at the time of allotment reduction calculation based on the existing DSH audit and reporting process. Additionally, we intend to publish a separate DHRM technical guide that provides information regarding the DHRM calculation and associated data sources.

Comment: A few commenters suggested that due to the lack of timely and transparent data it would be difficult to fully assess CMS' proposal and noted that it would be irresponsible for CMS to move forward with DSH allotment reductions without resolving commenters' data transparency concerns and technical questions. One commenter stated that a delay is warranted so that CMS can address important deficiencies with transparency and outstanding legal questions impacting the data that, if not addressed prior to implementation, would have a material impact on the distribution of the reductions across states.

Response: More recent data will be available at the time CMS calculates annual reductions for FY 2020 (and thereafter) than was available at the publication of the July 2017 proposed rule. Therefore, we used an illustrative example to assist in transparency and provided the detailed DHRM, which we are statutorily-required to develop, to specify the methodology for determining the annual DSH allotment reduction amounts. As finalized, we believe the DHRM will use the timeliest, most transparent, and comprehensive reported data available that is consistent with Medicaid program requirements. As stated above, while a number of issues related to Medicaid DSH payment calculations currently are the subject of litigation, the statutorily-required allotment reductions and the DHRM are not among them, and we are bound by statute to adopt a rule to implement the DSH reductions. With this final rule, we are doing so according to our view of the best interpretation of the DSH statute and will utilize the most recent data available to us that is consistent with applicable laws and regulations. In an effort to be transparent in the application of the DSH allotment reductions, we intend to publish a separate DHRM technical guide that provides information regarding the DHRM calculation and associated data sources.

Comment: One commenter requested that CMS provide an opportunity for qualified stakeholders and consultants to confer directly with the CMS contractor that has performed work relating to the DHRM.

Response: We will not provide stakeholders with a formal process to confer directly with CMS contractors involved with calculations or other

work relating to the DHRM. We are available to provide technical assistance to states regarding the DHRM following the publication of this final rule.

Comment: Several commenters suggested that the timeline of publication of preliminary DSH allotments does not support transparency, citing examples that the preliminary DSH allotments for FY 2016 were not public until late 2016 and the FY 2017 allotments were not expected to be made public until after 2018.

Response: We disagree and believe the rulemaking regarding proposed DSH allotment reductions has been timely. In addition, we notify states electronically and through MBES of their preliminary DSH allotments at the start of each federal fiscal year. We also finalize DSH allotment amounts as soon as all necessary information is available. The preliminary and final DSH allotment amounts are also published in the **Federal Register**. Moreover, we do not believe that knowledge of future preliminary unreduced DSH allotment amounts in necessary for evaluating the DHRM. In general, the DSH allotments for each state is increased by the consumer price index each year, so each state's unreduced DSH allotment remains constant in proportion to the total national DSH allotment.

Comment: One commenter stated that the methodology for calculating the state-specific cap on the annual DSH allotment reduction ignores what the commenter stated is an existing inequality across states in unreduced DSH allotments as established by the Balanced Budget Act of 1997 (Pub. L. 105–33, enacted August 5, 1997) which were based on each state's 1995 DSH spending levels. Several commenters supported a state-specific cap on annual reductions that will allow states to keep at least a portion of their DSH allotment. Commenters also recommended various modifications to the cap, and that CMS re-evaluate the cap based on experience. Some commenters recommended that states be permitted to retain more than 10 percent of their unreduced allotments, but did not recommend a percentage. One commenter suggested that CMS implement a reduction cap based on each state's cost coverage percentage determined by dividing each state's total uncompensated care by its respective unreduced DSH allotment. States with a cost coverage percentage below the national average would be subject to a cap on DSH allotment reductions with low-DSH states' reductions being capped at 5 percent reduction of their unreduced allotment, while non low-DSH states' reductions would be capped at 7 percent reduction of their unreduced allotment.

In addition, a few commenters did not support a state-specific cap on annual DSH allotment reductions that will allow states to keep at least a portion of their DSH allotment. One commenter indicated that a cap on DSH allotment reductions did not appear in the final 2013 DSH allotment reduction rule and should not be permitted to compete with the statutory obligations to implement the DSH allotment reductions. One commenter believes states can make their own determination regarding what level of funding is sufficient and that a cap on reductions shifts reductions away from states with lesser need to states with greater need for DSH funding.

Response: We believe that the DHRM, including the state-specific reduction cap methodology, calculates DSH allotment reductions in an equitable manner consistent with statutory requirements. We are finalizing our proposed state-specific cap that limits the reduction to be applied to each state's total unreduced DSH allotment to 90 percent of its original unreduced allotment because it strikes a balance between ensuring reduction amounts are determined based on the statutory DHRM factors and ensuring states maintain the ability to make an appreciable amount of DSH payments. Lower reduction caps might cause the reductions to approach even distribution among all states instead of being based on the statutory DHRM factors. No cap might result in the complete elimination of some states' DSH allotments and higher caps might result in states with an insignificant amount of DSH allotment with which to make DSH payments. We did not consider a state-specific reduction cap in the 2013 DSH allotment reduction rule since no state was in jeopardy of having its entire DSH allotment eliminated under the amounts designated under statute during that time. We will evaluate the reduction methodology after implementation and will consider whether modifications are warranted, which we would undertake through future rulemaking, as necessary.

Comment: Several commenters recommended that the DHRM reduce allotments by first applying it to unused state DSH allotments, then applying the factors set forth in the DHRM.

Response: Section 1923(f)(7) of the Act specifies the five factors for the DHRM, but does not distinguish between spent and unspent state DSH allotment amounts in directing that the allotments be reduced. Therefore, we did not propose and are not finalizing a policy to apply reductions first to unspent DSH allotment amounts before application of the DHRM. We believe that commenters' suggested method could serve to penalize unfairly states that do not currently expend their entire DSH allotment. Therefore, we are finalizing the structure of proposed DHRM that considers five factors identified by section 1923(f)(7)(B) of the Act when determining state-specific allotment reduction amounts.

Comment: One commenter noted concerned that CMS would use FY 2017 state DSH allotments to calculate allotment reduction amounts for FY 2018.

Response: As proposed, we will use the preliminary unreduced DSH allotment for each fiscal year to calculate DSH allotment reductions for the corresponding fiscal year. Specifically, we will utilize the preliminary unreduced FY 2020 DSH allotment amounts to calculate FY 2020 DSH allotment reductions.

Comment: One commenter expressed concern that the DHRM, by considering the five factors separately and summing the results, could create disproportionately large reductions for states with high levels of uninsured that are targeting hospitals with both a high volume of Medicaid inpatients and a high level of uncompensated care. The commenter stated this is in violation of the statutory intent.

Response: We disagree and believe the proposed methodology, which we are adopting in this final rule, supports the intent of the statute and the proposed rule, as it imposes smaller percentage reductions on low DSH states compared to non-low DSH states and, within each state group, imposes larger percentage reductions on states that have the lowest percentages of uninsured individuals and on states that do not target their DSH payments to hospitals with high volumes of Medicaid inpatients and high levels of uncompensated care. Further, the proposed DHRM takes into account the extent to which a state's DSH allotment was included in the budget neutrality calculation for a coverage expansion that was approved under section 1115 demonstration authority as of July 31, 2009.

We interpret the statute to require CMS to utilize both the UPF and the two targeting factors. We proposed to assign a 50 percent weight to the UPF and a 50 percent combined weight for the two DSH payment targeting factors (a 25 percent weight for the HUF, and a 25 percent weight for the HMF). We believe that this is an equitable approach for assigning factor weights, and

appropriately implements the statutorily-required factors. This weight distribution does preserve more DSH allotment (that is, it imposes smaller allotment reductions) for states that may have greater DSH need due to high uninsurance rates while still incentivizing states to continue to target DSH payments to hospitals with both a high volume of Medicaid inpatients and high level of uncompensated care. Additionally, we proposed, and are finalizing, a weight of 50 percent for the UPF to rely more heavily on more recent Census Bureau data and to align the factor weights with how these factors are set forth in statute. We believe the proposed DHRM is an equitable method for calculating reduction amounts based on each state's rate of uninsurance and how well each state is targeting its DSH payments to hospitals with high volumes of Medicaid inpatients and high levels of uncompensated care.

Comment: Two commenters requested that CMS require states to allocate the reduction amount between Institutions for Mental Diseases (IMD) and all other hospitals proportionately so IMDs do not have to absorb a higher proportion of the DSH reductions.

Response: We will calculate the IMD DSH limit under section 1923(h) of the Act based on the state's DSH allotment after the reduction is applied, to ensure that the IMD DSH limit is subject to a reduction consistent with the overall reduction of the state's annual DSH allotment.

Comment: Another commenter suggested that CMS apply the DSH allotment reductions to the unreduced allotment and treat any DSH payments states make over the reduced allotment as an overpayment.

Response: We are finalizing a DHRM that will calculate annual reductions that will apply to unreduced DSH allotments. Additionally, section 1923(f) of the Act limits FFP for total statewide DSH payments made to eligible hospitals in each federal fiscal year to the annual DSH allotment for each state, which will be reduced annually through the DHRM for FYs 2020 through 2025. Any state claims for FFP in excess of the state's reduced annual DSH allotment are subject to potential disallowance as specified in 42 CFR 430.42.

Comment: Several commenters recommended that CMS allow for a process to revise the calculation of DSH allotment reductions. Some commenters suggested that CMS publish the underlying data and calculations for each factor included in the DHRM for each year so that states can validate the accuracy of the data and the calculations and work with CMS to make any corrections that might be necessary based on more up to date or corrected data related to DSH audit reports, MIUR, or other data.

Response: We will conduct a thorough review to ensure the quality and accuracy of all data and calculations. To promote transparency, we intend to publish a separate DHRM technical guide that will include all data source information and the underlying DHRM calculations. During the development and publication of this final rule, we have continued to work with states to ensure that we are utilizing accurate, complete data that is the most recent available, prior to calculating the FY 2020 DSH allotment reductions. Due to the timeframes associated with the publication of this final rule and the statutorily-required DSH allotment reductions scheduled to be applied to state FY 2020 DSH allotments, we will calculate the FY 2020 DSH allotment reductions using the most currently available data at the time we apply the DHRM to determine the allotment reductions, prior to October 1, 2019. In subsequent years, beginning with FY 2021, we anticipate that we will assemble necessary data and perform calculations to determine the DSH allotment reductions for the FY during the months of July, August, and September before the start of the FY, to enable us to publish the DSH allotment reductions prior to the start of the FY to which they will apply. Accordingly, for the annual DSH allotment reductions beginning with FY 2021, states must have submitted all revised and corrected data to CMS by July 1st of the FY prior to the FY for which reductions will be calculated and applied to each state's unreduced preliminary DSH allotment, so that the most recent data available to us at the time we apply the DHRM reflects all revisions and corrections determined by the state. For example, to be used in applying the DHRM for FY 2021, all corrected and revised data would be required to be submitted to us by July 1, 2020 (and meet applicable federal requirements) to be reflected in the DHRM calculations for the DSH allotment reductions scheduled to be applied to the FY 2021 unreduced preliminary DSH allotments. We anticipate that this schedule would be in effect for any years following FY 2020 for which DSH allotment reductions are to be applied under the statute.

Comment: Several commenters noted support for CMS' emphasis on targeting of DSH payments to hospitals with high volumes of Medicaid inpatients and hospitals with high levels of uncompensated care in the DHRM. One commenter urged CMS to incentivize states to target DSH payments to hospitals providing the highest share of care to low-income patients within each state.

Response: We believe that the proposed DHRM, incorporating the statutory factors identified in section 1923(f)(7)(B) of the Act, does incentivize states to target their DSH payments, both through the HMF and HUF, to hospitals providing care to low-income individuals, and have incorporated this method in the final rule.

Comment: Many commenters expressed concern with CMS' proposed increase of the UPF from a 33 percent weight, as finalized in the 2013 DSH reduction rule, to a 50 percent weight. Commenters stated that the 50 percent UPF weight would disadvantage states that have expanded Medicaid coverage under the ACA and create disincentives for states to continue to cover the Medicaid expansion population. One commenter noted support for the 50 percent UPF weight due to the opinion that this would minimize annual DSH allotment reductions for non-expansion states. Many commenters recommended that CMS revert back to the 33 percent weight for each of the core factors, the UPF, the HMF and the HUF. One commenter suggested that an equal weighting of the three core factors is appropriate in this period of market uncertainty. Commenters also variously recommended: That the UPF be weighted at 25 percent or less; that an 80 percent weight be placed on the UPF and a 10 percent weight on each of the targeting factors, the HMF and the HUF, to mitigate annual DSH allotment reductions for states that did not expand Medicaid; that a 60 percent weight be applied to the UPF and 20 percent to each of targeting factors, the HMF and the HUF; and that the weight assigned to the UPF be increased if other consideration were not given to mitigate the impact of the reductions on non-expansion states.

Response: We are finalizing our proposal to apply a weight of 50 percent to the UPF to rely more heavily on the more recent Census Bureau data (as it is more recent than DSH audit data and, therefore, likely more reflective of current circumstances than DSH audit data) and to align the factor weights with how these factors are set forth in statute. Section 1923(f)(7)(B)(i)(I) of the Act requires that the UPF be incorporated into the DHRM, while section 1923(f)(7)(B)(i)(II)(aa) of the Act requires that the HMF be incorporated into the DHRM and section 1923(f)(7)(B)(i)(II)(bb) of the Act requires that the HUF be incorporated into the DHRM. This structure of subclauses and

items is consistent with a 50 percent weight being applied to the factor identified in section 1923(f)(7)(B)(i)(I) of the Act and an equal 50 percent weight being applied to the factors identified in section 1923(f)(7)(B)(i)(II) of the Act. The 50 percent UPF weight and combined 50 percent targeting factor weight will yield different results for both expansion and non-expansion states depending on each state's rate of uninsured and how well each state targets its DSH payments to hospitals with high volumes of Medicaid inpatients and uncompensated care. We believe that the weighting in the July 2017 proposed rule is a reasonable approach and have incorporated this methodology into the final rule.

Comment: One commenter recommended that the weight of the HMF be increased to provide consideration for states with high Medicaid enrollment.

Response: We disagree with the recommendation because we believe that the proposed DHRM reduces DSH allotments in an equitable manner that is consistent with the statute. The DHRM gives consideration to states with high Medicaid enrollment that target DSH payments to hospitals with high volumes of Medicaid inpatients. We believe that the proposed weighting is a reasonable approach to implementing the statutory requirements for the DHRM and are finalizing this methodology in § 447.294(e)(5) in this final rule.

D. Factor 1—Low DSH Adjustment Factor (LDF)

The first factor considered in the proposed DHRM is the Low DSH Adjustment Factor identified at section 1923(f)(7)(B)(ii) of the Act, which requires the DHRM to impose a smaller percentage reduction on ''low DSH states'' that meet the criterion described in section 1923(f)(5)(B) of the Act. To qualify as a low DSH state, total expenditures under the state plan for DSH payments for FY 2000, as reported to us as of August 31, 2003, had to have been greater than zero but less than 3 percent of the state's total Medicaid state plan expenditures during the FY. Historically, low DSH states have received lower DSH allotments relative to their total Medicaid expenditures than non-low DSH states.

We proposed to apply the LDF by imposing a greater proportion of the annual DSH funding reduction on non-low DSH states. To meet the statutory requirement to impose a smaller percentage reduction on low DSH states, the DHRM would create two state groups (low DSH states and non-low DSH states), then would apply the LDF when allocating reduction amounts to each state group. The LDF is calculated and applied as follows:

1. Separate states into two groups, non-low DSH states and low DSH states.
2. Divide each state's unreduced preliminary DSH allotment for the year for which the reduction is calculated by estimated Medicaid service expenditures for that same year. Currently, we create a preliminary DSH allotment based on the estimates available in August of the prior year and we issue a final DSH allotment once the federal FY ends.
3. For each state group, calculate the non-weighted mean of the value calculated in step 2 for states in the group.
4. Divide the average calculated in step 3 for the low DSH state group by the average calculated in step 3 for the non-low DSH state group.
5. Convert this number to a percentage. This percentage is the LDF.
6. Multiply the proportionately allocated DSH funding reductions for the low DSH state group by the LDF percentage to determine the aggregate DSH reduction amount that would be distributed across the low DSH state group.
7. Subtract the aggregate DSH reduction amount determined in step 6 from the proportionately allocated DSH funding reduction for the low DSH state group, and add the remainder to the aggregate DSH reduction amount that would be distributed across the non-low DSH state group.

We considered using various alternative proportional relationships to establish the LDF, including the proportion of each state group's annual Medicaid DSH expenditures to total Medicaid expenditures. However, we believe that this may benefit non-low DSH states that are unable to or otherwise do not spend their existing DSH allotment amount, which we believe is not the intent of the statute. Therefore, we proposed to calculate the LDF based on the proportion of each state group's DSH allotments to total Medicaid expenditures.

We received a number of public comments on the proposed Factor 1—LDF. A discussion of these comments, with our responses, appears below.

Comment: Several commenters suggested modifying the statutory definition of low DSH states in section 1923(f)(5)(B) of the Act.

Response: The statute directs the Secretary to impose a smaller percentage DSH allotment reduction on ''low DSH states'' that meet the criterion described in section 1923(f)(5)(B) of the Act, and we do not have the authority to modify this provision. We are implementing this statutory directive through the LDF.

Comment: In calculating the LDF, one commenter recommended that CMS use the median instead of mean to normalize non-low DSH state outlier values.

Response: We believe use of the mean, instead of the median, ensures arithmetically that the value representing each state's DSH allotment as a percentage of Medicaid service expenditures has an equal impact in determining the average used in step 2 of the LDF, regardless of whether the value is an outlier value (either very high or very low). We believe this is important as the values have a large variance and each value, including outliers, represents the situation of a state. Using the median, instead of the mean, would not adequately capture the variance among all the states.

Comment: One commenter stated that the proposed DHRM conflicts with section 1923(f)(7)(B)(iii) of the Act in that it could result in percentage reductions for certain low DSH states that are greater than the percentage reductions for certain non-low DSH states.

Response: We disagree that the reduction methodology conflicts with the statutory direction to impose ''a smaller percentage reduction on low DSH States.'' While the final DHRM includes the LDF to impose smaller percentage reductions on low DSH states, it is possible that the annual DSH allotment reduction percentage could be higher for one or more low DSH states than for one or more non-low DSH states based on the application of other factors identified by the statute. In this case, the annual DSH allotment reduction percentage for the low DSH state would be smaller than if the state were instead a non-low DSH state, due to the application of the LDF, consistent with section 1923(f)(7)(B)(iii) of the Act.

Comment: One commenter suggested that low DSH states be exempt from the reduction.

Response: The statute directs the DHRM to impose ''a smaller percentage reduction on low DSH States,'' but does not permit that low DSH states be categorically exempted from reduction. Consistent with the statute, the final DHRM imposes smaller percentage reductions on low DSH states, but does not exempt low DSH states from reduction. We believe that this methodology is consistent with the statute and is an equitable approach to allocating annual DSH allotment reductions.

Comment: One commenter expressed concerns that the LDF calculation is overly beneficial to low DSH states. The commenter stated that the formula exceeds the statutory requirements and recommended an alternative approach that would rely on calculating each group's proportion of annual Medicaid expenditures to total Medicaid expenditures.

Response: The proposed DHRM imposes smaller percentage reductions on low DSH states, which historically have received lower DSH allotments relative to their total Medicaid expenditures than non-low DSH states. This historical difference, between low DSH and non-low DSH state groups, serves as the basis for calculating the LDF value and addresses the statutory requirement to impose ''a smaller percentage reduction on low DSH States.'' Although we considered alternate methods for calculating the LDF, we believe that the proposed methodology for determining the LDF best addresses this historical difference while adhering to statutory direction. Furthermore, our proposed methodology is consistent with the statutory designation of low DSH or non-low DSH states. Therefore, we are finalizing the LDF as proposed.

Comment: One commenter stated that step 6 in the calculation should read ''multiply the proportion of total unreduced allocations for the low DSH states group to total unreduced allocations for all states by the LDF percentage.''

Response: We believe that we have described the process accurately in calculating the total reduction amount for low DSH states once the LDF is applied. While the commenter's suggested language is accurate in describing the steps to calculate the revised percent of total weighting for the low DSH state group, our proposed language provides the steps to calculate the total reduction amount for the low DSH state group. We proposed to separate states into two overall groups, non-low DSH states and low DSH states, to give effect to the statutory low DSH criterion. Then, we proposed to proportionately allocate aggregate DSH funding reductions to each of these two state groups based on each state group's proportion of the total national unreduced DSH allotment amount. Next, we proposed to apply a low DSH adjustment percentage to adjust the non-low DSH and low DSH state groups' DSH funding reduction amounts. This step maintains the combined aggregate DSH funding reduction for the low DSH and non-low DSH state groups together, as specified by statute for the applicable FY, by distributing a portion of the unadjusted low DSH state DSH funding reduction amount to the non-low DSH state group.

Comment: Several commenters urged CMS to minimize annual DSH allotment reductions for states that have relatively low ratios of the unreduced annual DSH allotment to the number of uninsured individuals in the state. One commenter recommended that states that receive less than $125 in unreduced annual DSH allotments per uninsured individual should receive no more than a 5 percent annual DSH allotment reduction.

Response: The statute directs the DHRM to impose ''a smaller percentage reduction on low DSH States,'' which is described in paragraph 1923(f)(5)(B) of the Act where it defines low DSH states as states with total Medicaid DSH payments for FY 2000 between 0 and 3 percent of total (state and federal) Medicaid medical assistance expenditures. We do not have the authority to modify the statutory definition of a low DSH state in order to impose smaller percentage reductions on states that have low annual DSH allotments relative to the number of uninsured individuals in the state. Consistent with the statute, the final DHRM imposes smaller percentage reductions on low DSH states described in section 1923(f)(5)(B) of the Act. While we are statutorily-required to impose ''a smaller percentage reduction on low DSH States,'' the final DHRM does allocate reductions taking into account the size of the existing state DSH allotments prior to reduction in the UPF, which does give consideration to states that historically have smaller unreduced DSH allotments relative to similarly situated states with higher allotments.

Comment: One commenter stated that CMS did not provide total computable medical assistance expenditures used to calculate the LDF in the illustrative DHRM example in the July 2017 proposed rule. Further, the commenter stated that the proposed rule did not specify whether the denominator of the LDF includes or excludes DSH and whether it is total computable or Federal share.

Response: The July 2017 proposed rule included an illustrative example, not an actual DHRM calculation. For purposes of the final DHRM, we will exclude DSH expenditures from total computable Medical assistance expenditures described in § 447.294(e)(3)(i). The denominator for the value calculated in § 447.294(e)(3)(i) is the estimated Medicaid service expenditures. The denominator for the value calculated in § 447.294(e)(3)(iii) is the mean value of the ratio of each non-low DSH state's proportion of preliminary DSH allotment to estimated Medicaid service expenditures, calculated in § 447.294(e)(3)(ii). Additionally, we intend to publish a separate DHRM technical guide that provides information regarding the final DHRM calculation, including the additional information regarding data sources.

Comment: One commenter requested that CMS consider an alternative methodology for calculating the low DSH adjustment and stated CMS should consider a flat percentage rather than basing it on a factor ratio.

Response: We considered using various alternative proportional relationships to establish the LDF. However, we are finalizing the LDF as proposed without change to our proposal to use the LDF as currently codified in § 447.594(e)(3). The low DSH adjustment percentage is consistent with the statutory method used for classifying low DSH states at section 1923(f)(5)(B) of the Act by utilizing the proportion of each state group's DSH allotments to total Medicaid expenditures. Further, the proposed LDF percentage can evolve over time, respond to changes in state situations, and use better data as it becomes available while a flat percentage would remain static and not be responsive to state or data changes. Given that low-DSH states collectively receive lower DSH allotments relative to their total Medicaid expenditures than non-low DSH states, the LDF results in the application of a smaller percentage reduction to low DSH states.

E. Factor 2—Uninsured Percentage Factor (UPF)

The second factor considered in the DHRM is the UPF identified in section 1923(f)(7)(B)(i)(I) of the Act, which requires that the DHRM impose the largest percentage DSH allotment reductions on states that have the lowest percentages of uninsured individuals. The statute also requires that the percentage of uninsured individuals be determined on the basis of data from the Census Bureau, audited hospital cost reports, and other information likely to yield accurate data, during the most recent year for which such data are available.

To determine the percentage of uninsured individuals in each state, the DHRM relies on the total population and uninsured population as identified in the most recent ''1-year estimates'' data available from the ACS conducted by the Census Bureau. The Census

Bureau generates ACS ''1-year estimates'' data annually based on a point-in-time survey of approximately 3 million individuals. For purposes of the DHRM, we would utilize the most recent ACS data available at the time of the calculation of the annual DSH allotment reduction amounts.

The UPF, as applied through the DHRM, has the effect of imposing the lowest relative DSH allotment reductions on states that have the highest percentage of uninsured individuals, and thereby mitigates the annual DSH allotment reductions for states with the highest percentage of uninsured individuals.

The UPF is determined separately for each state group as follows:

1. *Uninsured Value*—Using United States Census Bureau data, calculate each state's uninsured value by dividing the total state population by the number of uninsured in the state. (This is different than the percentage rate of uninsurance; the rate of uninsurance can be obtained by dividing 100 by this number.)

2. *Uninsured Allocation Component*—Determine the relative Uninsured Value for each state compared to other states in the state group by dividing the value in step one by the state group (low DSH state and non-low DSH state) total of step one values. The result will be a percentage, and the total of the percentages for all states in the state group will total 100 percent.

3. *Allocation Weighting Factor*—To ensure that larger and smaller states are given fair weight in the final UPF, divide each state's preliminary unreduced DSH allotment by the sum of all unreduced preliminary DSH allotments in the respective state group to obtain the allocation weighting factor, expressed as a percentage. The sum of all weighting factors will equal 100 percent. Then, take this percentage for each state and multiply it by the state's uninsured allocation component determined in step 2. The result is the allocation weighting factor.

4. *UPF*—For each state group, divide each state's allocation weighting factor by the sum of all allocation weighting factors. The resulting percentage is the UPF.

We would determine the UPF portion of the aggregate DSH allotment reduction allocation for each state by multiplying the state's UPF by the aggregate DSH allotment reduction allocated to the UPF factor for the respective state group. As with the prior factor, we proposed to utilize preliminary DSH allotment estimates to develop the DSH reduction factors, including the UPF. We received the following comments concerning this topic.

We received a number of public comments on the proposed Factor 2—UPF. A discussion of these comments, with our responses, appears below.

Comment: Many commenters supported the DHRM's identification of uninsured individuals based on 1-year estimates of the number of uninsured from the Census Bureau's ACS.

Response: We appreciate the support and are finalizing the use of 1-year estimates of the number of uninsured from the ACS in the DHRM, as discussed in the proposed rule and as described in the definition of ''Uninsured population'' in § 447.294(b).

Comment: Many commenters expressed concerns that the uninsured individual data used for the UPF may undercount the number of undocumented individuals as reported and estimated through the ACS. One commenter noted that this is particularly concerning, given the 50 percent UPF weight. Additionally, many commenters recommended that CMS work with Pew Research Institute, Census Bureau, and other researchers to develop a methodology that accounts for all uninsured individuals regardless of citizenship status.

Response: Section 1923(f)(7)(B)(i)(I) of the Act specifically requires that the percentage of uninsured individuals be determined on the basis of data from the Census Bureau, audited hospital cost reports, and other information likely to yield accurate data. According to the Census Bureau, the foreign-born population includes anyone who is not a U.S. citizen at birth. This includes two groups: (1) Naturalized U.S. citizens; and (2) noncitizens. Noncitizens include lawful permanent residents (immigrants), temporary migrants (such as foreign students), humanitarian migrants (such as refugees and asylees), and persons not lawfully present in the United States.

The Census Bureau collects data from all foreign-born individuals who participate in its censuses and surveys, regardless of legal status. Thus, unauthorized migrants are included in ACS estimates of the total foreign-born population. However, the Census Bureau only asks foreign-born respondents if they are naturalized U.S. citizens or noncitizens, so it is not possible to tabulate separate estimates of unauthorized migrants using the ACS. Accordingly, we believe the ACS data does account for uninsured individuals regardless of citizenship status and are finalizing our proposed use of ACS data without an adjustment in the uninsured data.

Comment: Several commenters noted support for CMS' goal of relying on the most recently available data for calculating the UPF, but expressed concern that CMS would use 2014 ACS data to calculate the FY 2018 DSH allotment reductions. Commenters recommended that CMS utilize more recent data when calculating final DSH allotments. One commenter recommended that CMS utilize ACS 5-year estimates for the uninsured to better align the years of the Census Bureau ACS data with the DSH audit and MIUR data.

Response: We are finalizing, as proposed, the application of a DHRM that utilizes the most recent year available for all data sources and aligns data sources whenever possible. That is, section 1923(f)(7)(B)(i)(I) of the Act requires the use of Census Bureau data, audited hospital cost reports, and other information likely to yield accurate data, for the most recent year for which such data are available. Therefore, with respect to annual DSH allotment reductions for FY 2020, we intend to use 2018 ACS data, which we anticipate will be the most recent year available at the time the DHRM is applied for FY 2020.

We will use the ACS 1-year estimates because it depicts the most current data on the uninsured population. The ACS 5-year estimates use 60 months of data. For example, 2013–2017 estimate is data collected from January 1, 2013 through December 31, 2017. This is the least current of the ACS estimates. The Census Bureau recommends using ACS 1-year when currency is more important.

Comment: One commenter expressed concern that the ACS data considers an individual's uninsured status based only on whether respondent has coverage at time of interview, and that ACS data may undercount the population of individuals experiencing homelessness. Another commenter recommended that CMS work with the Census Bureau to attain the point in time estimate as well as a determination of whether an individual was uninsured at any point in time during the past year.

Response: Section 1923(f)(7)(B)(i)(I) of the Act requires that CMS utilize data from the Census Bureau, from the most recent year for which data are available to calculate the UPF. Moreover, while the ACS data determine whether the respondent has coverage at the time of the interview, these interviews are conducted at various times throughout the year. The Census Bureau randomly

selects addresses, through scientific sampling, to represent the total population. As such, we believe that the ACS 1-year estimates represent the best available data for use in determining the number of uninsured individuals in the states. Further, we understand that the Census Bureau works with organizations such as the National Coalition for the Homeless to help ensure a more accurate and comprehensive census, including with respect to individuals experiencing homelessness.

Comment: One commenter expressed concern that the DHRM assigns too much weight to the UPF and suggested that the UPF calculation methodology rely on state levels of insured individuals instead of percentages of uninsured individuals. Additionally, the commenter indicated the UPF and factor weighting would result in the DHRM penalizing Medicaid expansion states.

Response: The UPF, as applied through the DHRM, has the effect of imposing lower relative DSH allotment reductions on states that have higher percentage of uninsured individuals. Section 1923(f)(7)(B)(i)(I) of the Act specifies the ''percentage of uninsured individuals,'' not the level of insured individuals. To determine the percentage of uninsured individuals in each state, the DHRM relies on the total population and uninsured population as identified in the most recent ''1-year estimates'' data available from the ACS conducted by the Census Bureau. This approach is consistent with statutory requirements and mitigates the DSH allotment reductions for states with the highest percentage of uninsured individuals. Further, we believe that the final DHRM, including the factor weighting discussed above, distributes DSH allotment reduction amounts among the states in an equitable manner, consistent with statutory requirements and does not penalize Medicaid expansion states.

Comment: One commenter recommended that we rely on the Medicaid DSH definition of uninsured used for calculating hospital-specific DSH limits, adjusted also to include certain insured individuals who might be more likely to be associated with unpaid copayments and deductibles (such as individuals with high deductible plans), for purposes of defining uninsured individuals for the UPF.

Response: Section 1923(f)(7)(B)(i)(I) of the Act requires the use of Census Bureau data to determine the percentages of uninsured individuals. We are finalizing the use of 1-year estimates of the number of uninsured from the ACS conducted by the Census Bureau in the DHRM, as discussed in the proposed rule and as described in the definition of ''Uninsured population'' in § 447.294(b).

Comment: One commenter recommended that CMS distribute the entire available DSH allotment for all states based on its uninsured rate. Several commenters stated that statute does not require CMS to use both the UPF and the two targeting factors in the DHRM and suggested that CMS apply only the UPF in the determination of DSH allotment reductions. These commenters recommended this approach to mitigate reductions for both states that have not expanded Medicaid under the ACA and for states that have strict criteria for eligibility to receive DSH payments. One commenter suggested that, given the statutory language, CMS could and should use only the targeting factors (both the HUF and the HMF) in the DRHM, or that the UPF weight be lowered if both the UPF and the targeting factors are to be considered.

Response: Section 1923(f) of the Act specifies the manner in which each state's DSH allotment is determined. Moreover, section 1923(f)(7)(B) of the Act establishes the five factors that must be considered in the establishment of a DHRM to calculate the annual DSH allotment reductions. We interpret the statute to require CMS to utilize both the UPF and the two targeting factors. We proposed to assign a 50 percent weight to the UPF and a 50 percent combined weight for the two DSH payment targeting factors (a 25 percent weight for the HUF, and a 25 percent weight for the HMF). As described in detail in section III.C. of this final rule, we believe that this is an equitable approach for assigning factor weights, and appropriately implements the statutorily-required factors. This weight distribution does preserve more DSH allotment (that is, it imposes smaller allotment reductions) for states that may have greater DSH need due to high uninsurance rates while still incentivizing states to continue to target DSH payments to hospitals with both a high volume of Medicaid inpatients and high level of uncompensated care. Additionally, we proposed, and are finalizing, a weight of 50 percent for the UPF to rely more heavily on more recent Census Bureau data and to align the factor weights with how these factors are set forth in statute.

F. Factor 3—High Volume of Medicaid Inpatients Factor (HMF)

The third factor considered in the DHRM is the HMF identified in section 1923(f)(7)(B)(i)(II)(aa) of the Act, which requires that the DHRM impose the largest percentage DSH allotment reductions on states that do not target DSH payments to hospitals with high volumes of Medicaid inpatients. For purposes of the DHRM, the statute defines hospitals with high volumes of Medicaid inpatients as those defined in section 1923(b)(1)(A) of the Act. These hospitals must meet minimum qualifying requirements at section 1923(d) of the Act and have an MIUR that is at least one standard deviation above the mean MIUR for hospitals receiving Medicaid payments in the state. Every hospital that meets that definition is deemed a disproportionate share hospital and is statutorily-required to receive a DSH payment.

States that have been, and continue to, target a large percentage of their DSH payments to hospitals that are federally deemed as a DSH based on their MIUR would receive the lowest reduction amounts relative to their total DSH spending. States that target the largest amounts of DSH payments to hospitals that are not federally deemed based on MIUR would receive the largest reduction amounts under this factor. The current DSH allotment amounts are unrelated to the number of MIUR-deemed hospitals within each state and their DSH-eligible uncompensated care costs. By basing the HMF reduction on the amounts that states do not target to hospitals with high volumes of Medicaid inpatients as described below, this methodology incentivizes states to target DSH payments to such hospitals.

To ensure that all deemed disproportionate share hospitals receive a required DSH payment, states are already required to determine the mean MIUR for hospitals receiving Medicaid payments in the state and the value of one standard deviation above the mean. We proposed to rely on MIUR information for use in the DHRM that CMS collects from states on an annual basis under § 447.294(d). When a state or states do not submit this required MIUR information timely, for purposes of this factor, we would assume that the state(s) have the highest value of one standard deviation above the mean reported among all other states that did submit this information timely.

The calculation of the HMF will rely on extant data that should be readily available to states. The following data elements are used in the HMF calculation: The preliminary unreduced

DSH allotment for each state; the DSH hospital payment amount reported for each DSH in accordance with § 447.299(c)(17); the MIUR for each DSH reported in accordance with § 447.299(c)(3); and the value of one standard deviation above the mean MIUR for hospitals receiving Medicaid payments in the state, reported separately.

The HMF is a state-specific percentage that is calculated separately for each state group (low DSH and non-low DSH) as follows:

1. For each state, classify each DSH that has an MIUR at least one standard deviation above the mean MIUR for hospitals receiving Medicaid payments in the state as a High Medicaid Volume hospital.

2. For each state, determine the amount of DSH payments to non-High Medicaid Volume DSH hospitals using data from the most recently submitted and accepted DSH audit template.

3. For each state, determine a percentage by dividing the state's total DSH payments made to non-High Medicaid Volume hospitals by the aggregate amount of DSH payments made to non-High Medicaid Volume hospitals for the entire state group. The result of step 3 is the HMF.

4. Determine each state's HMF reduction amount by applying the HMF percentage to the aggregate reduction amount allocated to this factor for each state group.

As a result of this methodology, there are a number of interactions that may occur for states among DSH payment methodologies, DSH allotments, and DSH allotment reductions. Most of these scenarios work in concert with this factor's established reduction relationship. For example, if a state paid out its entire DSH allotment to hospitals with high volumes of Medicaid inpatients, it would receive no reduction associated with this factor because all DSH payments were made only to hospitals that qualify as high volume. The results of this scenario would be consistent with the methodology because the state is incentivized to target DSH payments to high Medicaid volume hospitals.

Another example is a state that makes DSH payments up to the hospital-specific DSH limit to all hospitals with high Medicaid volume but also uses its remaining allotment to make DSH payments to hospitals that do not qualify as high Medicaid volume. In this example, the state would receive a reduction under this factor based on the amount of DSH payments it made to non-high Medicaid volume hospitals. Although the state targeted DSH payments to hospitals with high Medicaid volume, the existing size of its DSH allotment permitted it to make DSH payments to hospitals that did not meet the statutory definition of a hospital with a high volume of Medicaid inpatients. In that situation, we stated in the proposed rule that this allotment reduction would effectively reduce a state's existing DSH allotment if the allotment exceeded the maximum amount that the state could pay to hospitals that are high Medicaid volume. The resulting HMF reduction would be greater for states with DSH allotments large enough to pay significant amounts to non-high Medicaid volume hospitals. This helps ensure that states target DSH payments to high Medicaid volume hospitals and distributes the reductions in such a way as to promote the ability of all states to provide DSH funds to high Medicaid volume hospitals.

We described the HMF in greater detail in the July 2017 proposed rule (82 FR 35155). We received a number of public comments on the proposed Factor 3—HMF. A discussion of these comments, with our responses, appears below.

Comment: One commenter expressed concern that CMS will use DSH audit data and MIUR data from different years to calculate reductions based on the HMF. In addition, the commenter recommended that the DHRM rely on MIUR data from the audited Medicaid DSH audits and reports to improve accuracy of the DHRM.

Response: In the July 2017 proposed rule, we proposed, as a general principle, to utilize the most recent year available for all data sources and to align the Medicaid SPRY of data sources. The proposed DHRM relies on the most recent data for all data sources with one exception. For this exception, we believe the benefits of aligning the SPRYs of two data sources outweighs the benefits of using the most recent data. Specifically, the MIUR data required by § 447.294(d) used for the HMF may not be the most recent year available. We proposed to align and utilize MIUR data from the year that corresponds to the DSH audit SPRY used in the calculation of each state's DSH allotment reduction. Although more recent MIUR data might be available, we are aligning the MIUR data SPRY with the DSH audit SPRY for the HMF to ensure the universe of hospitals is the same and to ensure the DSH payment for a particular SPRY corresponds with the receiving hospital's MIUR for that same SPRY.

The Medicaid DSH audits and reports do not include the MIUR for all hospitals that receive a Medicaid payment. Therefore, we believe the DHRM is more accurate relying on MIUR information that we will collect from states on an annual basis as required under § 447.294(d).

Comment: Two commenters expressed concern that expansion states could receive relatively greater reduction through the HMF when many of their hospitals meeting MIUR-related deeming requirements defined in section 1923(b)(1)(A) of the Act have little or no uncompensated care costs, particularly due to the state targeting Medicaid supplemental payments to such deemed hospitals. One commenter suggested that CMS develop an alternative methodology for judging how well states target DSH payments to MIUR-deemed hospitals that recognizes that states may not pay in excess of the hospital-specific DSH limit.

Response: The proposed HMF would apply to states without regard to their Medicaid expansion status. Additionally, we understand that the proposed HMF reduction would be greater for states with DSH allotments large enough to pay significant amounts to non-high Medicaid volume hospitals, including in cases where states cannot target DSH payment to high volume Medicaid hospitals because they do not have significant uncompensated care costs. This helps ensure that states target DSH payments to high Medicaid volume hospitals and distributes the reductions in such a way as to promote the ability of all states to provide DSH funds to high Medicaid volume hospitals.

Comment: One commenter expressed concern that the DHRM could penalize some states that target deemed hospitals based on the LIUR. The commenter noted that about half of all deemed-DSH hospitals nationally qualify on the basis of their LIUR. The commenter suggested that the DHRM should either consider all payments made to deemed hospitals as being paid to high Medicaid volume hospitals, or DSH payments to LIUR-deemed hospitals should be excluded from the calculation of the HMF.

Response: We believe the DHRM as proposed will promote state targeting of payments to hospitals that qualify for DSH payments based on MIUR deeming requirements defined in section 1923(b)(1)(A) of the Act, consistent with section 1923(f)(7)(B)(i)(II)(aa) of the Act. The HMF targeting factor in the DHRM is consistent with the statutory direction to impose larger percentage reductions on states that do not target their DSH payments on hospitals with high volumes of Medicaid inpatients and do not target their DSH payments on

hospitals with high levels of uncompensated care.[4] The HMF provides mitigation of the state-specific DSH reduction amount for states that have targeted and do target DSH payments to these hospitals federally-deemed on the basis of their MIUR. We recognize the importance of hospitals with high LIURs and such hospitals may also experience high levels of uncompensated care costs. If those LIUR-deemed hospitals have high levels of uncompensated care, the HUF will provide mitigation of the state-specific DSH reduction amount for states that have targeted and do target DSH payments to those hospitals.

Comment: One commenter recommended that the demographics of the Medicaid population be taken into account when determining DSH allotment reductions. The commenter recommended that if a large percentage of the Medicaid expansion population represents individuals who shifted from other insurance coverage, that state should not have as large of a DSH allotment reduction as a state in which a larger share of the Medicaid expansion population was previously uninsured.

Response: The statute requires that larger percentage reductions be imposed on states that do not target their DSH payments on hospitals with high volumes of Medicaid inpatients and on hospitals with high levels of uncompensated care (excluding bad debt). The statutory requirements do not address the prior coverage status of Medicaid enrollees.

Comment: Several commenters expressed concern that many states had not submitted MIUR data to CMS, and therefore, CMS utilized proxy MIUR data for calculation of illustrative DSH allotment reductions. These commenters expressed concern that the use of proxy data may affect the distribution of DSH allotment reductions. One commenter recommended that CMS accept late MIUR submissions for FY 2018 and should consider accepting late MIUR submissions for subsequent years.

Response: Section 447.294(d) specifies the timeline according to which states are required to submit MIUR data to CMS. The example included in the July 2017 proposed rule was for illustrative purposes only. As specified in the final 2013 DSH allotment reduction rule (78 FR 57305), when a state does not timely submit this separately required MIUR information, for purposes of this factor, we will assume that the state has the highest value of one standard deviation above the mean reported among all other states.

Comment: One commenter suggested that CMS propose a standard definition of which hospitals should be included in each state's annual MIUR data submission. Another commenter suggested that the requested MIUR data is duplicative of data collected as part of the DSH audits.

Response: We believe the laws and regulations already provide a standard definition of hospitals with high volumes of Medicaid inpatients and which hospitals must be included in the annual MIUR submission required in § 447.294(d). Section 1923(f)(7)(B)(i)(II)(aa) of the Act defines hospitals with high volumes of Medicaid inpatients as those defined in section 1923(b)(1)(A) of the Act. Section 447.294(d) specifies that states must submit the MIUR for all hospitals receiving Medicaid payments in the State.

Although the DSH audits do contain MIUR data for each hospital that receives a DSH payment, the MIUR submission required under § 447.294(d) contains the Medicaid utilization for all hospitals that receive a Medicaid payment (including those that do not receive a DSH payment), which information is necessary to the calculation of the HMF.

G. Factor 4—High Level of Uncompensated Care Factor (HUF)

The fourth factor considered in the DHRM is the HUF identified at section 1923(f)(7)(B)(i)(II)(bb) of the Act, which requires that the DHRM impose the largest percentage DSH allotment reductions on states that do not target DSH payments to hospitals with high levels of uncompensated care (excluding bad debt). We proposed to rely on the existing statutory definition of uncompensated care cost used in determining the hospital-specific limit on FFP for Medicaid DSH payments.

As defined in section 1923(g)(1) of the Act, the state must calculate for each hospital, for each FY, the difference between the costs incurred by that hospital for furnishing inpatient hospital and outpatient hospital services during the applicable state FY to Medicaid individuals and individuals who have no health insurance or other source of third party coverage for the inpatient hospital and outpatient hospital services they receive, less all applicable revenues received for these hospital services. This difference, if any, between incurred inpatient hospital and outpatient hospital costs and associated revenues is considered a hospital's uncompensated care costs, or hospital-specific DSH limit.

We proposed to rely on this definition of uncompensated care costs for the calculation of the HUF, as reported by states on the most recent available Medicaid DSH audit and reporting data. For the proposed DHRM, hospitals with high levels of uncompensated care costs are defined based on a comparison with other Medicaid DSH hospitals in the state. Any hospital that exceeds the mean ratio of uncompensated care costs to total Medicaid and uninsured inpatient hospital and outpatient hospital service costs within the state is considered a hospital with a high level of uncompensated care. This data is consistent with the existing Medicaid DSH program definition of uncompensated care and is readily available to states and CMS.

The following data elements would be used in the HUF calculation:

- The preliminary unreduced DSH allotment for each state;
- DSH hospital payment amounts reported for each DSH in accordance with § 447.299(c)(17);
- Uncompensated care cost amounts reported for each DSH in accordance with § 447.299(c)(16);
- Total Medicaid cost amounts reported for each DSH in accordance with § 447.299(c)(10);
- Total uninsured cost amounts reported for each DSH in accordance with § 447.299(c)(14); and
- Total hospital cost amounts reported for each DSH in accordance with § 447.299(c)(20).

The statute also requires that uncompensated care costs used in this factor of the DHRM exclude bad debt. The DHRM relies on the uncompensated care cost data derived from Medicaid DSH audit and reporting required by section 1923(f) of the Act and implementing regulations. This uncompensated care data excludes bad debt, including unpaid copayments and deductibles, associated with individuals with a source of third party coverage for the service.

The HUF is a state-specific percentage that is calculated separately for each state group (low DSH and non-low DSH) as follows:

1. Determine each disproportionate share hospital's uncompensated care level by dividing its uncompensated care cost by total hospital cost. This data element would come from the most recently submitted and accepted Medicaid DSH audit and associated reporting.

2. For each state, calculate the mean uncompensated care level.

[4] See section 1923(f)(7)(B)(i)(II)(bb) of the Act.

3. Identify all hospitals that meet or exceed the mean uncompensated care level as high uncompensated care level hospitals, and all hospitals with uncompensated care costs below this mean as non-high uncompensated care level hospitals.

4. For each state, determine the total amount of DSH payments to non-high uncompensated care level hospitals.

5. For each state, determine a percentage by dividing the state's total DSH payments made to non-high uncompensated care level hospitals by the aggregate amount of DSH payments made to non-high uncompensated care level hospitals for the entire state group. The result would be the HUF.

6. Determine each state's HUF reduction amount by applying the HUF percentage to the aggregate reduction amount allocated to this factor for each state group.

In previous rulemaking, we identified some potential scenarios, due to data limitations, where the DHRM finalized in 2013 could have produced some paradoxical outcomes when comparing hospital levels of uncompensated care for purposes of evaluating DSH payment targeting through the HUF. Specifically, in § 447.294(e), the 2013 DSH allotment reduction final rule, it was possible for a hospital not to have been considered to have a higher level of uncompensated care even though it provided a higher percentage of services to Medicaid and uninsured individuals and had greater total qualifying uncompensated care costs than another hospital that did qualify as having a high level of uncompensated care. This was due to the previous formula determining the level of uncompensated care by dividing uncompensated care costs by the sum of total Medicaid costs and total uninsured costs. We propose to resolve this problem at § 447.294(e) by determining the level of uncompensated care by dividing uncompensated care costs by the total hospital costs.

We sought comments on the proposed DHRM with respect to whether the proposed implementation of this factor is expected to be effective in tying the level of DSH reductions to the targeting of DSH payments to hospitals with high levels of uncompensated care. We believe that the proposed DHRM methodology, in using the mean uncompensated care cost level as the measure to identify hospitals with high levels of uncompensated care, captures a better balance in tying the level of DSH reductions to the targeting of DSH payments to such high level uncompensated care hospitals, imposing smaller annual state DSH allotment reductions on states that more effectively target DSH payments to hospitals with high levels of uncompensated care.

We described the HUF in greater detail in the July 2017 proposed rule (82 FR 35155). We received a number of public comments on the proposed Factor 4—HUF. A discussion of these comments, with our responses, is below.

Comment: One commenter suggested that the formula in the July 2017 proposed rule would disadvantage hospitals for their size and services provided to the insured by using the total hospital cost in the HUF denominator. The commenter requested that CMS not adopt the formula or adopt both the 2013 HUF calculation and the new formula and letting hospitals use the option that results in the higher UCC amount.

Response: We disagree that the policy reflected in the July 2017 proposed rule disproportionately harms hospitals with high uncompensated care costs related to the insured population and believe that the proposed formula, which we are adopting in this final rule, accurately and equitably calculates levels of uncompensated care costs. This rule specifies the methodology to be used to calculate the statutorily-required Medicaid DSH reductions. In the 2013 DSH allotment reduction final rule, we finalized a DHRM, which gave the HUF a 33⅓ percent weight and that would be in place only for FY 2014 and FY 2015 to allow time for reevaluation of the methodology with improved and more recent data and information about the impact of the ACA on levels of coverage and uncompensated care. As a result of our reevaluation, in the July 2017 proposed rule, we proposed to modify the DHRM factor weights and to use improved data sources where possible, as discussed in this final rule. We believe this rule ensures the appropriate allocation of the DSH allotment reductions to those states that target their DSH payments to hospitals with high volumes of Medicaid inpatients and high levels of uncompensated care (excluding bad debt), as required under the statute. Therefore, we will only be using the policy reflected in the July 2017 proposed rule and this final rule, and we will not adopt the 2013 HUF calculation as an alternative option.

Comment: One commenter recommended that CMS include costs other than inpatient and outpatient hospital services, including physician services, transportation costs, and non-hospital services, in the calculation of the hospital-specific DSH limit. One other commenter recommended that CMS update the definition of uncompensated care to align with the definition under the Internal Revenue Code to determine community benefit, and that CMS require hospitals receiving DSH payments to report Medicaid shortfall, charity care, and bad debt to better understand the impact of DSH payments on hospitals.

Response: Consistent with statutory direction, the DHRM will use uncompensated care data that excludes bad debt, including unpaid copayments and deductibles associated with individuals with a source of third party coverage for the service. Changes to calculating the hospital-specific DSH limit are outside the scope of the July 2017 proposed rule. We are not addressing the calculation of hospital-specific DSH payment limits under section 1923(g) of the Act, or the DSH audit reporting requirements under section 1923(j) of the Act, through this rulemaking.

Comment: One commenter noted that the MIUR data do not appropriately account for state-created programs for low-income individuals that are funded by DSH payments, or were so funded prior to Medicaid expansion.

Response: We disagree. The DHRM relies on MIUR data as the data source specified in statute. Modifying the MIUR used in the DHRM to account for state-created programs would be inconsistent with statutory requirements.

Comment: Several commenters expressed concerns that the HUF does not properly address the statutory direction to impose larger percentage reductions on states that do not target their DSH payments to hospitals with high levels of uncompensated care because Medicaid DSH audit and reporting data does not include all hospitals in a state. These commenters noted that using only the hospitals identified on the DSH audit report creates a higher mean uncompensated care value than that of states with less strict criteria for eligibility for receiving DSH payments. One commenter suggested that the DHRM should account for states that have strict criteria for qualifying to receive DSH payments and recommended that CMS collect and utilize high LIUR values to consider hospitals targeted under the HUF. Another commenter suggested that for purposes of calculation reductions under the HUF, CMS cap each state's average uncompensated care level at the national mean plus one standard deviation. Yet another commenter suggested that CMS obtain average uncompensated care levels from all hospitals with Medicaid days, not just from those hospitals identified through DSH audit and reporting data.

Response: We recognize that the DSH audit and reporting data does not include uncompensated care information for all hospitals; however, the Medicaid DSH audit and reporting data represent the only existing uncompensated care cost data consistent with the existing statutory definition of uncompensated care cost used in determining the hospital-specific limit on FFP for DSH payments. We disagree that the HUF does not address the statutory direction to impose larger percentage reductions on states that do not target their DSH payments to hospitals with high levels of uncompensated care. The proposed and final HUF is designed to promote state targeting of DSH payments to hospitals with high levels of uncompensated care by imposing reductions based on the payments to non-high uncompensated care-level hospitals. We believe that the proposed calculation of the HUF represents an equitable method for comparing how states target payments to high uncompensated care hospitals, and therefore, we are not adopting the commenters' recommendations.

Comment: Many commenters noted support for total hospital cost in the denominator of the HUF. One commenter stated that using total hospital cost in the denominator of the HUF mitigates reductions for states that target deemed DSH hospitals.

Response: We believe this is an accurate and equitable method for calculating reductions under the HUF, and as such, we are finalizing the rule with the use of the total hospital cost as the denominator for purposes of calculating reductions under the HUF.

Comment: One commenter requested that CMS clarify the description of total hospital cost in the July 2017 proposed rule.

Response: The description of total hospital costs as it relates to the July 2017 proposed rule and this final rule is codified in § 447.299(c)(20). Total hospital cost is the total annual costs incurred by each hospital for furnishing inpatient hospital and outpatient hospital services.

Comment: One commenter suggested CMS use a standardized calculation for uncompensated care costs to promote more consistent results across all states, so that the states currently including third party payments for Medicaid eligible individuals in calculating uncompensated care cost for purposes of the hospital-specific DSH limit would not be disadvantaged.

Response: While a number of issues related to Medicaid DSH payment calculations currently are the subject of litigation, the statutorily-required allotment reductions and the DHRM are not among them, and we are bound by statute to adopt a rule to implement the DSH reductions. With this final rule, we are doing so according to our view of the best interpretation of the DSH statute and will utilize the most recent data available to us that is consistent with applicable laws and regulations. We believe the proposed DHRM relies on a standard definition of uncompensated costs for the HUF, which relies on data derived from Medicaid DSH audit and reporting data. Further, the DHRM, in using this data, imposes larger percentage reductions on states that do not target their DSH payments to hospitals with high levels of uncompensated care.

Comment: Several commenters noted support of CMS utilizing total hospital cost in the denominator of the HUF. Commenters expressed concern that the HUF should include an adjustment to account for the relative size of hospitals, and that utilizing total hospital costs in the denominator of the HUF disadvantages academic medical centers. The commenters noted that the need for academic medical centers to provide training, to maintain emergency standby capacity for rarely used hospital services, and to provide additional highly specialized services increases their total hospital cost compared to peer hospitals and, therefore, understates their HUF uncompensated care level compared to peer hospitals. One commenter expressed concern that CMS did not provide any data indicating which states would be impacted by this proposal.

Response: We disagree with this commenter that utilizing total hospital costs in the denominator of the HUF disadvantages academic medical centers and note that we received multiple comments in support of utilizing total hospital costs in the denominator of the HUF as opposed to our previous 2013 final rule approach of using only Medicaid and uninsured costs in the denominator. By using total hospital costs, we are accounting for the size of hospitals, therefore making an additional hospital size adjustment unnecessary. While we believe using total hospital costs in the denominator of the HUF represents a reasonable method for determining hospitals with high levels of uncompensated care costs, consistent with statutory requirements, we will monitor the application of this factor and the DHRM generally and may propose modifications if a better option avails itself in the future, nothing prevents CMS from readdressing the calculation of the HUF through future rulemaking, if appropriate.

H. Factor 5—Section 1115 Budget Neutrality Factor (BNF)

The statute requires that we take into account the extent to which a state's DSH allotment was included in the budget neutrality calculation for a coverage expansion that was approved under section 1115 demonstration authority as of July 31, 2009. These states possess full annual DSH allotments as calculated under section 1923(f) of the Act. Under an approved section 1115 demonstration, however, some states have limited authority to make DSH payments under section 1923 of the Act because all or a portion of their DSH allotment was included in the budget neutrality calculation for a coverage expansion under an approved section 1115 demonstration or to fund uncompensated care pools and/or safety net care pools. For applicable states, DSH payments under section 1923 of the Act are limited to the DSH allotment calculated under section 1923(f) of the Act less the allotment amount included in such a budget neutrality calculation. If a state's entire DSH allotment is included in such a budget neutrality calculation, it would have no available DSH funds with which to make DSH payments under section 1923 of the Act for the period of the demonstration.

Consistent with the statute, for states that include DSH allotment in budget neutrality calculations for coverage expansion under an approved section 1115 demonstration as of July 31, 2009, we proposed to exclude from the DSH allotment reduction, for the HMF and the HUF factors, the amount of DSH allotment that each state currently continues to divert specifically for coverage expansion in the budget neutrality calculation. DSH allotment amounts included in budget neutrality calculations for non-coverage expansion purposes under approved demonstrations would still be subject to reduction. Uncompensated care pools and safety net care pools are considered non-coverage expansion purposes for the BNF. For section 1115 demonstrations not approved as of July 31, 2009, any DSH allotment amounts included in budget neutrality calculations, whether for coverage expansion or otherwise, under a later approval would also be subject to reduction.

We proposed to determine for each reduction year if any portion of a state's DSH allotment qualifies for consideration under this factor. To qualify annually, CMS and the state would have to have included the state's

DSH allotment (or a portion thereof) in the budget neutrality calculation for a coverage expansion that was approved under section 1115 of the Act as of July 31, 2009, and the coverage expansion would have to still exist in the approved section 1115 demonstration at the time that reduction amounts are calculated for each FY. If a state had a DSH allotment amount for coverage expansion approved under a demonstration under a section 1115 of the Act as of July 31, 2009 but subsequently reduced this amount, the approved amount remaining under the section 1115 demonstration would not be subject to reduction.

The proposed DHRM took into account the extent to which the DSH allotment for a state was included in the budget neutrality calculation for a demonstration approved under section 1115 of the Act as of July 31, 2009 by excluding from reduction under the HMF and HUF amounts diverted specifically for a coverage expansion and automatically assigning qualifying states an average percentage reduction amount (that is, the average HUF and HMF of the state's respective state group) for any DSH allotment diverted for non-coverage expansion purposes and any amounts diverted for coverage expansion if the section 1115 demonstration was not approved as of July 31, 2009. DSH allotment reductions relating to two DHRM factors (the HUF and the HMF) are determined based on how states target DSH payments to certain hospitals. Since states that diverted all or a portion of their DSH allotments would have limited or no relevant data for these two factors, we would be unable to evaluate how they spent the diverted portion of their DSH allotment for these targeting criteria. Accordingly, for diversion amounts subject to reduction, we proposed to maintain the HUF and HMF formula for DSH payments for which qualifying states would have available data. Because we would not have DSH payment data for DSH allotment amounts diverted for non-coverage expansion (or for coverage expansions not approved as of July 31, 2009), we proposed to assign average HUF and HMF reduction percentages for the portion of the DSH allotment that a state diverted for non-coverage expansion (or for coverage expansions not approved as of July 31, 2009) that it was consequently unable to use to target payments to disproportionate share hospitals. Instead of assigning the average percentage reduction to non-qualifying amounts, we considered using alternative percentages higher or lower than the average. However, these alternative percentages might provide an unintended benefit or penalty to these states for DSH diversions approved under a demonstration under section 1115 of the Act. We sought comment on the use of different percentages for the reductions to diversion amounts that do not qualify under the BNF and regarding alternative BNF methodologies that may be preferable.

We described the BNF in greater detail in the July 2017 proposed rule (82 FR 35155). We received a number of public comments on the proposed Factor 5—BNF. A discussion of these comments, with our responses, are below.

Comment: One commenter noted support for the BNF excluding diverted DSH allotment amounts, but stated that limiting this to waivers approved before July 31, 2009, unfairly limits the ability of some states to expand coverage using a model that has proven successful in the commenter's state. The commenter noted that if the rule is finalized as proposed, it could jeopardize their state's section 1115 demonstration program, which has currently been extended, but due to the statutory requirement that coverage expansion DSH diversion funding have been approved by July 31, 2009, its demonstration coverage expansion DSH diversion funding would not be excluded. The commenter stated this is contrary to the purpose of excluding DSH funds for coverage expansions from the DHRM, which the commenter noted is to ensure that DSH funds diverted to expand health coverage are insulated from reductions.

Response: The statute requires that we take into account the extent to which a state's DSH allotment was included in the budget neutrality calculation for a coverage expansion that was approved under section 1115 of the Act as of July 31, 2009, specifically. The ACA made non-DSH funds available to support Medicaid expansion and the purchase of private insurance for eligible individuals through Health Insurance Exchanges, which may have reduced the need for states to divert DSH funds through demonstration projects. In recognition of the reduced need for DSH diversion, the July 31, 2009 date, which predates the enactment of the ACA, serves to ensure that states could not newly divert DSH under demonstration projects to avoid allotment reductions. If a state's initial section 1115 demonstration was approved as of July 31, 2009 and later extended, the amount approved under the associated the waiver would still be excluded for purposes of the HMF and HUF factors from DSH allotment reductions in the DHRM. However, for section 1115 demonstrations not approved as of July 31, 2009, any DSH allotment amounts included in budget neutrality calculations, whether for coverage expansion or otherwise, under a later approval would be subject to reduction. We note that, in some cases, modifications made by amendment (including in connection with a renewal or extension) to a coverage expansion DSH diversion initially approved as of July 31, 2009 may be so significant that the DSH diversion is no longer appropriately considered the same coverage expansion DSH diversion program as was approved as of July 31, 2009. In such a case, we would cease excluding the diverted DSH amounts from reduction under the DHRM. We are finalizing the rule as proposed.

Comment: Several commenters urged CMS to take into account that there is no policy reason to differentiate DSH funding for a coverage expansion demonstration in relation to the July 2009 date, and noted that the only policy reason given by CMS was that subsequent to July 31, 2009, the ACA provided states with other, non-DSH funds for such coverage expansion, thus limiting the need for diverted DSH under demos. The commenters suggested that CMS did this because it did not want to provide financial relief to states that chose not to effectuate coverage through a mechanism other than Medicaid expansion through the ACA and that CMS has the legal authority to exclude funding approved after July 31, 2009. The commenters stated their belief that their state has the only section 1115 waiver approved after July 31, 2009 that diverted DSH allotment for coverage expansion, and states that choose to expand coverage through a section waiver 1115, rather than expanding Medicaid to the adult expansion population as permitted under the ACA, will save the federal government money. The commenters urged CMS to exclude from the DHRM any DSH funding diverted to support any section 1115 demonstration coverage expansion approved at any time between July 31, 2009, and the effective date of the new regulation, or at a minimum, to include such projects approved on or before July 31, 2012.

Response: Consistent with the statute, for states that include DSH allotment amounts in budget neutrality calculations for coverage expansion under an approved section 1115 demonstration as of July 31, 2009, we are excluding from the DSH allotment reduction, for the HMF and the HUF

factors, the amount of DSH allotment that each state currently continues to divert specifically for coverage expansion in the budget neutrality calculation. To promote equitable DSH allotment reductions across states, other than this specified statutory exception implemented through this rule, the final DHRM does not provide additional relief to states that include all or a portion of their DSH allotment in their section 1115 demonstration budget neutrality calculation.

Comment: One commenter noted that CMS proposed to estimate the targeting of section 1115 payments not excluded from reductions under the BNF for states by using DSH data from other states as a proxy, but did not provide a timeline for replacing the proxy data with actual hospital-specific data. The commenter recommended that a better long term approach would be to collect hospital-specific data on these payments to calculate the DSH targeting factors for these states directly.

Response: DSH allotment reductions relating to two DHRM targeting factors (the HUF and the HMF) are determined based on how states target DSH payments to certain hospitals. States that diverted all or a portion of their DSH allotments either make limited or no DSH payments using this diverted DSH allotment amount; therefore, actual hospital-specific DSH payment data suggested by the commenter for use often does not exist. We are finalizing use of a proxy as proposed for calculating DSH allotment reductions for purposes of the HUF and HMF. We will assign any qualifying states an average percentage reduction amount within its respective state group for diverted DSH allotment amounts that are not related to a coverage expansion in effect as of July 31, 2009, and for which the state does not have complete and/or relevant DSH payment data. We believe this is a reasonable approach for determining reductions for the HUF and HMF factors given the absence of relevant hospital-specific DSH payment data for these payments.

Comment: Some commenters suggested that CMS should re-examine the definition of ''coverage for expansion purposes'' and as it applies to the BNF to include safety net care pools and Uncompensated Care pools to the extent that they are established or used as part of broader efforts to expand coverage. Additionally, the commenters stated that there is no rational basis and that it is in fact contrary to the statutory intent to automatically designate all safety net care pools and uncompensated care pools as not contributing to coverage expansion purposes, and the July 2017 proposed rule provided no discussion of or justification for CMS' decision. The commenters requested that the full amount of a state's diverted DSH allotment in effect on July 31, 2009, be excluded from reduction.

Response: Uncompensated care pools and safety net care pools are designed to pay providers directly for uncompensated care costs, do not provide or pay for health care coverage for individuals, and do not result in the expansion of Medicaid coverage. Accordingly, they are excluded from consideration as coverage expansion for purposes of this factor.

Comment: Multiple commenters noted that CMS' proposed methodology would exclude from the DSH allotment reduction, for the HMF and HUF, the amount of DSH allotment that each state uses for coverage expansion in the budget neutrality calculation and recommended that CMS change the way in which the BNF is applied to also exclude the amount of DSH allotment that each state uses for coverage expansion from the UPF to account for the level of uninsured in the state.

Response: The statute requires that we take into account the extent to which a state's DSH allotment was included in the budget neutrality calculation for a coverage expansion that was approved under a demonstration project under section 1115 of the Act as of July 31, 2009. The proposed DHRM takes into account the extent to which the DSH allotment for a state was included in the budget neutrality calculation approved under section 1115 demonstration as of July 31, 2009, by excluding amounts diverted specifically for a coverage expansion and automatically assigning qualifying states an average percentage reduction amount (based on the state group) for any DSH allotment diverted for non-coverage expansion purposes and any amounts diverted for coverage expansion if the section 1115 demonstration was or is approved after July 31, 2009. DSH allotment reductions relating to two DHRM factors (the HUF and the HMF) are determined based on how states target DSH payments to certain hospitals. Since states diverting their DSH allotments under section 1115 demonstration projects would have limited or no relevant data for these two factors, we would be unable to evaluate how they spent the portion of their DSH allotment that was diverted for non-coverage expansion, which is why we proposed and are adopting the proxy methodology of assigning an average percentage reduction amount. However, the data necessary to calculate the UPF is unaffected by whether a state has diverted its DSH allotment under a section 1115 demonstration. Therefore, we do not exclude the amount of DSH allotment that each state has diverted through a section 1115 demonstration for coverage expansion from the UPF. We believe that the proposed methodology is an accurate and equitable approach, and we are finalizing this method in this final rule.

Comment: Two commenters noted that CMS did not propose to change the regulatory language at paragraph (e)(12)(i), stating that the phrase ''(without regard to approved amendments since that date)'' within the regulatory language may be confusing and possibly lead to misinterpretation or uncertainty and requested that CMS clarify its proposal regarding the amount excluded under the BNF calculation.

Response: We agree that the regulatory language could be misinterpreted and we are clarifying our intent in this final rule. For section 1115 demonstrations not approved as of July 31, 2009, any DSH allotment amounts included in budget neutrality calculations, whether for coverage expansion or otherwise, would also be subject to reduction.

Comment: One commenter questioned whether certain hospitals involved with Medicaid demonstration programs are subject to DSH audit and reporting requirements. Additionally, the commenter requested information on the impact of the reductions on state demonstration programs in states that use both DSH payments and section 1115 demonstration payments to fund hospitals.

Response: The final rule relies on DSH audit and reporting data as submitted by states in accordance with section 1923(j) of the Act and implementing regulations. The implementing regulations and associated policy guidance specify all audit and reporting requirements, including which hospitals must be included in the audit and associated reporting. The DSH audit and reporting requirements apply to all hospitals receiving DSH payments under section 1923 of the Act. Moreover, the DSH audit and reporting requirements continue to apply to states with section 1115 demonstrations, unless requirements of that section are specifically identified as waived or inapplicable to expenditures under the demonstration. As the reductions are not in effect at the time of publication of this final rule, we cannot know the specific impact the reductions will have on state demonstration programs, which is also likely to be affected by states'

policy decisions regarding their Medicaid programs. Other than states that have a qualifying coverage expansion under the BNF of the DHRM, we generally anticipate a similar impact of the reductions on states that utilize DSH payments and section 1115 demonstration payments to fund hospitals, as on states that do not make section 1115 demonstration payments to hospitals.

Comment: One commenter noted that states would like to know the impact of the July 2017 proposed rule on Medicaid demonstration programs, including those related to Medicaid DSH.

Response: The statute requires that we take into account the extent to which a state's DSH allotment was included in the budget neutrality calculation for a coverage expansion that was approved under section 1115 of the Act as of July 31, 2009. This final rule implements this requirement by excluding from DSH allotment reduction the amount of DSH that qualifying states continue to divert specifically for coverage expansion in the budget neutrality calculation. Any amount of DSH diverted for other purposes under the demonstration (or diverted for a coverage expansion approved after July 1, 2009) would still be subject to reduction by automatically assigning qualifying states an average percentage reduction amount within its respective state group for factors for which the state does not have complete and/or relevant DSH payment data. DSH allotment amounts included in budget neutrality calculations for non-coverage expansion purposes under approved demonstrations (or for a coverage expansion approved after July 1, 2009) would still be subject to reduction.

IV. Provisions of the Final Rule

As discussed in section III. of this final rule, this final rule generally finalizes the provisions as proposed in the July 2017 proposed rule. However, we are adding paragraph § 447.294(e)(14)(iv) to finalize a proposed state-specific cap that limits the annual DSH allotment reduction for each fiscal year to be applied to each state's total unreduced DSH allotment to 90 percent of its original unreduced DSH allotment for that fiscal year. This addition is a technical change to correct an unintentional omission of proposed regulatory text to implement this proposed policy, which was discussed in the July 2017 proposed rule.

V. Collection of Information Requirements

Beginning with each state's Medicaid state plan for rate year 2005, each state must submit to CMS (at the same time as it submits the completed DSH audit as required under § 455.304) the data specified under § 447.299 for each DSH hospital to which the state made a DSH payment. The reporting requirements which allows CMS to verify the appropriateness of such payments are currently approved by OMB under control number 0938–0746 (CMS–R–266). This rule does not impose any new/revised information collection requirements or burden pertaining to § 447.299.

Although mentioned in sections III.B and III.B.2. of this preamble, this rule does not impose any new/revised SPA or auditing requirements or burden nor any new/revised information collection requirements or burden associated with CMS–64 (control number 0938–1265) or CMS–2552 (control number 0938–0050).

Since this rule does not impose any new or revised ''collection of information'' requirements or burden, it need not be reviewed by OMB under the authority of the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*). For the purpose of this section of the preamble, collection of information is defined under 5 CFR 1320.3(c) of the PRA's implementing regulations.

VI. Regulatory Impact Analysis

A. Statement of Need

The ACA amended the statute by requiring aggregate reductions to state Medicaid DSH allotments annually from FY 2014 through FY 2020. Subsequent legislation extended the reductions, modified the amount of the reductions, and delayed the start of the reductions until FY 2020. The most recent related amendments to the statute were through the BBA 18. This final rule delineates the DHRM to implement the annual reductions for FY 2020 through FY 2025.

B. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking. Under the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as a major rule, as defined by 5 U.S.C. 804(2).

C. Anticipated Effects

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $7.5 million to $38.5 million in any 1 year). Individuals and states are not included in the definition of a small entity. We are not

preparing an RFA analysis because we have determined, and the Secretary certifies, that this final rule would not have a significant economic impact on a substantial number of small entities (including hospitals and providers) because states still have considerable flexibility to determine DSH state plan payment methodologies.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this final rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2019, that threshold is approximately $154 million. This final rule would not mandate any requirements for state, local, or tribal governments, nor would it affect private sector costs.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this rule does not impose substantial direct costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

C. Anticipated Effects

1. Effects on State Medicaid Programs

We anticipate, effective for FY 2020, that the DSH allotment reductions would have a direct effect on the ability for some or all states to maintain state-wide Medicaid DSH payments at FY 2017 levels. Federal share DSH allotments, which are published by CMS in an annual **Federal Register** notice and otherwise communicated to states and made publicly available on the *Medicaid.gov* website, limit the amount of FFP in the aggregate that states can pay annually in DSH payments to hospitals. This final rule would reduce state DSH allotment amounts, and therefore, would limit the states' ability to make DSH payments and claim FFP for DSH payments at FY 2017 levels. By statute, the rule would reduce state DSH allotments by $44,000,000,000 for FY 2020 through FY 2025. We anticipate that the rule would reduce total FFP claimed by states by similar amounts, although it may not equal the exact amount of the allotment reductions. Due to the complexity of the interaction among the DHRM methodology, state DSH allotments, DHRM data, future state DSH payment levels and methodologies for these years, we cannot provide a specific estimate of the total federal financial impact for each year.

The final rule utilizes a DHRM that would mitigate the negative impact on states that continue to have high percentages of uninsured and are targeting DSH payments to hospitals that have a high volume of Medicaid patients and to hospitals with high levels of uncompensated care, consistent with statutorily-required factors.

2. Effects on Providers

We anticipate that the final rule would affect certain providers through the reduction of state DSH payments that states would need to implement in order to comply with their reduced annual state DSH allotments. However, we cannot estimate the impact on individual providers or groups of providers. This final rule would not affect the considerable flexibility afforded states in setting DSH state plan payment methodologies to the extent that these methodologies are consistent with section 1923(c) of the Act and all other applicable statutes and regulations. States would retain the ability to preserve existing DSH payment methodologies, to the extent consistent with the state's reduced annual DSH allotment, or to propose modified methodologies by submitting state plan amendments to us. Some states may determine that implementing a proportional reduction in DSH payments for all qualifying hospitals is the preferred method to account for the reduced allotment. Alternatively, states could determine that the best action is to propose a methodology that would direct DSH payments reductions to hospitals that do not have high Medicaid volume and do not have high levels of uncompensated care. Some states could opt to take a different approach. Regardless, the rule would incentivize states to target DSH payments to hospitals that are most in need of Medicaid DSH funding based on their serving a high volume of Medicaid inpatients and having a high level of uncompensated care.

This final rule also does not affect the calculation of the hospital-specific DSH limit established at section 1923(g) of the Act. This hospital-specific limit requires that Medicaid DSH payments to a qualifying hospital not exceed the costs incurred by that hospital for providing inpatient and outpatient hospital services furnished during the year to Medicaid patients and individuals who have no health insurance or other source of third party coverage for the services provided during the year, less applicable revenues for those services.

Although this rule would reduce state DSH allotments, the management of the reduced allotments still largely remains with the states. Given that states would retain the same flexibility to design DSH payment methodologies under the state plan and that individual hospital-specific DSH payment limits would not be affected, we cannot predict whether and how states would exercise their flexibility in setting DSH payments to account for their reduced DSH allotment and how this would affect individual providers or specific groups of providers.

D. Alternatives Considered

The statute specifies the annual DSH allotment reduction amounts. Therefore, we were unable to consider alternative reduction amounts. However, we did consider various methodological alternatives to the DHRM discussed in individual sections above. Some of the various alternatives included using alternative weight assignments, utilizing various alternative data sources for uncompensated cost and uninsured data, and considering alternate methods for capping individual state allotment reductions. However, we decided to move forward with the approach specified in the proposed rule in an effort to pursue an equitable and reasonable approach in calculating the DSH allotment reductions while ensuring that the DHRM complies with federal statutory requirements.

E. Accounting Statement and Table

As required by OMB Circular A–4 (available at *www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf*), we have prepared an accounting statement table showing the classification of the impacts associated with implementation of this final rule. Table 1 provides our best estimate of the

reductions to state Medicaid Disproportionate Share Hospital (DSH)	allotments annually beginning with fiscal year (FY) 2020 based on the data.

TABLE 1—ACCOUNTING STATEMENT

Category	Estimates ($ in millions)	Units		
		Year dollar	Discount rate (percent)	Period covered
Transfers: Annualized Reductions in Disproportionate Share Hospital Allotment (in millions)	−7,215.7	2017	7	2020–2025
	−7,283.1	2017	3	2020–2025
From Whom to Whom	Federal Government to the States due to assumed reduced number of uninsured and uncompensated care.			

F. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017, and requires that the costs associated with significant new regulations ''shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' It has been determined that this final rule is a transfer rule that does not impose more than *de minimis* costs and thus is not a regulatory action for the purposes of Executive Order 13771.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 447

Accounting, Administrative practice and procedure, Drugs, Grant programs-health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, Rural areas.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 447—PAYMENTS FOR SERVICES

■ 1. The authority citation for part 447 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1396r–8.

■ 2. Section 447.294 is amended—
■ a. By revising the section heading;
■ b. By revising paragraph (a);
■ c. In paragraph (b), by adding the definition of ''Total hospital cost'' in alphabetical order;
■ d. By revising paragraphs (d), (e) introductory text, (e)(3)(i), and (e)(5)(i) through (iii);
■ e. By adding paragraph (e)(14)(iv); and
■ f. By revising paragraph (f).

The revisions and additions reads as follows:

§ 447.294 Medicaid disproportionate share hospital (DSH) allotment reductions.

(a) *Basis and purpose.* This section sets forth the DSH health reform methodology (DHRM) for calculating State-specific annual DSH allotment reductions as required under section 1923(f) of the Act.

(b) * * *

Total hospital cost has the meaning given the term in § 447.299(c)(20).

* * * * *

(d) *State data submission requirements.* States are required to submit the mean MIUR, determined in accordance with section 1923(b)(1)(A) of the Act, for all hospitals receiving Medicaid payments in the State and the value of one standard deviation above such mean. The State must provide this data to CMS by June 30 of each year. To determine which state plan rate year's data the state must submit, subtract 3 years from the calendar year in which the data is due.

(e) *DHRM methodology.* Section 1923(f)(7) of the Act requires aggregate annual reduction amounts as specified in paragraph (f) of this section to be reduced through the DHRM. The DHRM is calculated on an annual basis based on the most recent data available to CMS at the time of the calculation. The DHRM is determined as follows:

* * * * *

(3) * * *

(i) Dividing each State's preliminary unreduced DSH allotment by their respective total estimated Medicaid service expenditures for the applicable fiscal year.

* * * * *

(5) * * *

(i) UPF—50 percent.

(ii) HMF—25 percent.

(iii) HUF—25 percent.

* * * * *

(14) * * *

(iv) No state will receive a reduction as calculated in paragraph (e)(14) of this section in excess of 90 percent of its preliminary unreduced DSH allotment for the respective fiscal year. For any state assigned a reduction amount determined under paragraph (e)(14) of this section in excess of 90 percent of its unreduced DSH allotment, the reduction amount that exceeds 90 percent of that state's unreduced DSH allotment will be distributed among the remaining states in the state group that do not exceed the 90 percent reduction cap, based on the proportion of each of these remaining states' allotment reduction amount before any distribution is performed pursuant to this paragraph (e)(14)(iv) to the aggregate allotment reduction amount for the state group. This operation will be performed until all reduction amounts in excess of the 90 percent reduction cap for all states are allocated within each respective state group.

(f) *Annual DSH allotment reduction application.* For each fiscal year identified in section 1923(f)(7)(A)(ii) of the Act, CMS will subtract the State-specific DSH allotment amount determined in paragraph (e)(14) of this section from that State's final unreduced DSH allotment. This amount is the State's final DSH allotment for the fiscal year.

Dated: September 12, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: September 17, 2019.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2019–20731 Filed 9–23–19; 11:15 am]

BILLING CODE 4120–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 402

[Docket No. FWS–HQ–ES–2018–0009; FXES11140900000–189–FF09E300000; Docket No. 180207140–8140–01; 4500090023]

RIN 1018–BC87; 0648–BH41

Endangered and Threatened Wildlife and Plants; Regulations for Interagency Cooperation

AGENCY: U.S. Fish and Wildlife Service, Interior; National Marine Fisheries Service, National Oceanic and Atmospheric Administration, Commerce.

ACTION: Final rule; delay of effective date.

SUMMARY: We, the U.S. Fish and Wildlife Service (FWS) and the National Marine Fisheries Service (NMFS) (collectively referred to as the ''Services'' or ''we''), are delaying the effective date of a rule we published on August 27, 2019.

DATES: The effective date of the rule that published at 84 FR 44976, August 27, 2019, is delayed until October 28, 2019.

FOR FURTHER INFORMATION CONTACT: Gary Frazer, U.S. Fish and Wildlife Service, Department of the Interior, Washington, DC 20240, telephone 202/208–4646; or Samuel D. Rauch, III, National Marine Fisheries Service, Department of Commerce, 1315 East-West Highway, Silver Spring, MD 20910, telephone 301/427–8000. If you use a telecommunications device for the deaf (TDD), call the Federal Relay Service at 800/877–8339.

SUPPLEMENTARY INFORMATION: On August 27, 2019, we published a final rule to revise portions of our regulations that implement section 7 of the Endangered Species Act of 1973, as amended (''Act''; 16 U.S.C. 1531 *et seq.*). The revisions to the regulations clarify, interpret, and implement portions of the Act concerning the interagency cooperation procedures. The rule was to be effective on September 26, 2019.

Since the announcement of the final rule, we have conducted numerous informational webinars, meetings, and briefings for internal staff and external audiences, including hundreds of State, Federal, industry, and other conservation partners. During the course of these presentations, we have received many questions regarding implementation of the final rule. Additional time is needed to adequately educate and train staff of the Services and all of the affected Federal agencies on these interagency implementing regulations, which set forth requirements for both the Services and Federal action agencies. We are, therefore, delaying the effective date of the rule published on August 27, 2019, at 84 FR 44976 (see **DATES**, above) to ensure a smooth transition and allow for additional coordination and training prior to the final rule becoming effective.

Administrative Procedure Act

To the extent that 5 U.S.C. 553 applies to this action, it is exempt from notice and comment because it constitutes a rule of procedure under 5 U.S.C. 553(b)(A). Alternatively, our implementation of this action without opportunity for public comment, effective immediately upon publication in the **Federal Register**, is based on the good cause exceptions in 5 U.S.C. 553(b)(B) and 553(d)(3). Pursuant to 5 U.S.C. 553(b)(B), we have determined that good cause exists to forgo the requirement to provide prior notice and an opportunity for public comment thereon for this rule as such procedures would be impracticable, unnecessary, and contrary to the public interest. We are temporarily postponing the effective date of the rule (see **DATES**, above) to allow for additional time to coordinate with our internal staff and external partners. As a result, seeking public comment on this delay is unnecessary and contrary to the public interest. For these same reasons, we find good cause to waive the 30-day delay in effective date provided for in 5 U.S.C. 553(d).

Authority: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245, unless otherwise noted.

Dated: September 20, 2019.

Rob Wallace,

Assistant Secretary for Fish and Wildlife and Parks, Department of the Interior.

Dated: September 20, 2019.

Neil Jacobs,

Assistant Secretary of Commerce for Environmental Observation and Prediction, performing the duties of Under Secretary of Commerce for Oceans and Atmosphere, Department of Commerce.

[FR Doc. 2019–20936 Filed 9–24–19; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 120815345–3525–02]

RIN 0648–XS013

Snapper-Grouper Fishery of the South Atlantic; 2019 Recreational Accountability Measure and Closure for the South Atlantic Other Jacks Complex

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS implements an accountability measure (AM) for the recreational sector for the other jacks complex (lesser amberjack, almaco jack, and banded rudderfish) in the South Atlantic for the 2019 fishing year through this temporary rule. NMFS has determined that recreational landings of the other jacks complex has exceeded its recreational annual catch limit (ACL). Therefore, NMFS closes the recreational sector for this complex on September 25, 2019, through the remainder of the 2019 fishing year in the exclusive economic zone (EEZ) of the South Atlantic. This closure is necessary to protect the lesser amberjack, almaco jack, and banded rudderfish resources.

DATES: This rule is effective 12:01 a.m., local time, September 25, 2019, until 12:01 a.m., local time, January 1, 2020.

FOR FURTHER INFORMATION CONTACT: Mary Vara, NMFS Southeast Regional Office, telephone: 727–824–5305, email: *mary.vara@noaa.gov.*

SUPPLEMENTARY INFORMATION: The snapper-grouper fishery of the South Atlantic includes lesser amberjack, almaco jack, and banded rudderfish, and is managed under the Fishery Management Plan for the Snapper-Grouper Fishery of the South Atlantic Region (FMP). The FMP was prepared by the South Atlantic Fishery Management Council and is implemented by NMFS under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622.

The recreational ACL for the other jacks complex is 267,799 lb (121,472 kg), round weight. Under 50 CFR 622.193(l)(2)(i), NMFS is required to close the recreational sector for the other jacks complex when the recreational ACL has been reached, or is

projected to be reached, by filing a notification to that effect with the Office of the Federal Register, unless NMFS determines that no closure is necessary based on the best scientific information available. The NMFS Southeast Fisheries Science Center has determined that the recreational sector for this complex has exceeded its ACL. Therefore, this temporary rule implements an AM to close the recreational sector for the other jacks complex in the South Atlantic EEZ, effective 12:01 a.m., local time, September 25, 2019, until January 1, 2020, the start of the next fishing year.

During the recreational closure, the bag and possession limits for the fish in the other jacks complex in or from the South Atlantic EEZ are zero. Additionally, NMFS closed the commercial sector for the other jacks complex effective on July 16, 2019, when that sector was projected to reach its sector ACL (84 FR 32648; July 9, 2019). Therefore, as of 12:01 a.m. on September 25, 2019, no commercial or recreational harvest of fish in the other jacks complex in or from the South Atlantic EEZ is allowed for the remainder of the 2019 fishing year.

Classification

The Regional Administrator, Southeast Region, NMFS, has determined this temporary rule is necessary for the conservation and management of the other jacks complex, a component of the South Atlantic snapper-grouper fishery, and is consistent with the FMP, the Magnuson-Stevens Act, and other applicable laws.

This action is taken under 50 CFR 622.193(l)(2)(i) and is exempt from review under Executive Order 12866.

These measures are exempt from the procedures of the Regulatory Flexibility Act because the temporary rule is issued without opportunity for prior notice and public comment.

This action responds to the best scientific information available. The Assistant Administrator for NOAA Fisheries (AA) finds that the need to immediately implement this action to close the recreational sector for the other jacks complex constitutes good cause to waive the requirements to provide prior notice and opportunity for public comment pursuant to the authority set forth in 5 U.S.C. 553(b)(B), as such procedures are unnecessary and contrary to the public interest. Such procedures are unnecessary because the rule implementing the AM itself has been subject to notice and comment, and all that remains is to notify the public of the closure. Such procedures are contrary to the public interest because of the need to immediately implement this action to protect the other jacks complex. Prior notice and opportunity for public comment would require time and would potentially allow the recreational sector to further exceed its ACL.

For the aforementioned reasons, the AA also finds good cause to waive the 30-day delay in the effectiveness of this action under 5 U.S.C. 553(d)(3).

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

Dated: September 19, 2019.

Jennifer M. Wallace,

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

[FR Doc. 2019–20764 Filed 9–20–19; 4:15 pm]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 100812345–2142–03]

RIN 0648–XS012

Snapper-Grouper Fishery of the South Atlantic; 2019 Recreational Accountability Measure and Closure for South Atlantic Red Grouper

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS implements accountability measures (AMs) for the red grouper recreational sector in the exclusive economic zone (EEZ) of the South Atlantic for the 2019 fishing year through this temporary rule. NMFS estimates recreational landings of red grouper in 2019 have exceeded the recreational annual catch limit (ACL). Therefore, NMFS closes the red grouper recreational sector in the South Atlantic EEZ at 12:01 a.m., local time, on September 25, 2019, for the remainder of the 2019 fishing year. This closure is necessary to protect the red grouper resource.

DATES: This rule is effective 12:01 a.m., local time, September 25, 2019, until 12:01 a.m., local time, January 1, 2020.

FOR FURTHER INFORMATION CONTACT: Mary Vara, NMFS Southeast Regional Office, telephone: 727–824–5305, email: *mary.vara@noaa.gov.*

SUPPLEMENTARY INFORMATION: The snapper-grouper fishery of the South Atlantic includes red grouper and is managed under the Fishery Management Plan for the Snapper-Grouper Fishery of the South Atlantic Region (FMP). The FMP was prepared by the South Atlantic Fishery Management Council and is implemented by NMFS under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622.

In August of 2018, as a result of the determination that red grouper was undergoing overfishing, the final rule for Abbreviated Framework Amendment 1 to the FMP (83 FR 35435; July 26, 2018) reduced the red grouper ACL to 84,000 lb (38,102 kg), round weight, for 2019 (§ 622.193(d)(2)(ii)). In accordance with regulations at 50 CFR 622.193(d)(2)(i), if recreational landings of red grouper are projected to reach the recreational ACL, the Assistant Administrator for NOAA Fisheries (AA) will file a notification with the Office of the Federal Register to close the recreational sector for the remainder of the fishing year regardless if the stock is overfished, unless NMFS determines that no closure is necessary based on the best scientific information available. The NMFS Southeast Fisheries Science Center has estimated that the red grouper recreational ACL for 2019 has been exceeded. Therefore, this temporary rule implements the AM to close the red grouper recreational sector for the remainder of the 2019 fishing year. The recreational sector for red grouper in the South Atlantic EEZ will be closed effective 12:01 a.m., local time September 25, 2019, through December 31, 2019. During the recreational closure, the bag and possession limits for red grouper in or from the South Atlantic EEZ are zero.

NMFS notes that while the 2020 fishing year begins on January 1, the commercial and recreational harvest of red grouper is prohibited annually from January through April of each year (§ 622.183(b)(1)). Therefore, the recreational sector for red grouper will reopen on May 1, 2020, the beginning of the recreational fishing season. The recreational ACL for 2020 and subsequent fishing years is 90,720 lb (41,150 kg), round weight (§ 622.193(d)(2)(ii)).

Classification

The Regional Administrator for the NMFS Southeast Region has determined this temporary rule is necessary for the conservation and management of South Atlantic red grouper and is consistent with the FMP, the Magnuson-Stevens Act, and other applicable laws.

This action is taken under 50 CFR 622.193(d)(2)(i) and is exempt from review under Executive Order 12866.

These measures are exempt from the procedures of the Regulatory Flexibility Act because the temporary rule is issued without opportunity for prior notice and comment.

This action responds to the best scientific information available. The AA finds that the need to immediately implement this action to close the recreational sector for red grouper constitutes good cause to waive the requirements to provide prior notice and opportunity for public comment on this temporary rule pursuant to 5 U.S.C. 553(b)(B), because such procedures are unnecessary and contrary to the public interest. Such procedures are unnecessary because the AM implementing the recreational closure has already been subject to notice and comment. All that remains is to notify the public of the recreational closure for red grouper for the remainder of the 2019 fishing year. Prior notice and opportunity for comment are contrary to the public interest because of the need to immediately implement this action to protect the red grouper resource. Time required for notice and public comment would allow for continued recreational harvest and further exceedance of the recreational ACL.

For the aforementioned reasons, the AA also finds good cause to waive the 30-day delay in the effectiveness of this action under 5 U.S.C. 553(d)(3).

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

Dated: September 20, 2019.

Jennifer M. Wallace,

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

[FR Doc. 2019–20779 Filed 9–20–19; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register

Vol. 84, No. 186

Wednesday, September 25, 2019

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–2019–0700; Product Identifier 2019–NM–105–AD]

RIN 2120–AA64

Airworthiness Directives; Dassault Aviation Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2018–19–25 and AD 2014–03–12, which apply to all Dassault Aviation Model FALCON 2000 airplanes. Those ADs require revising the maintenance or inspection program, as applicable, to incorporate new maintenance requirements and airworthiness limitations. Since the FAA issued AD 2018–19–25, the FAA has determined that new or more restrictive airworthiness limitations are necessary. This proposed AD would require revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations. 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 November 12, 2019.

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 *http://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 Dassault Falcon Jet Corporation, Teterboro Airport, P.O. Box 2000, South Hackensack, NJ 07606; telephone 201–440–6700; internet *http://www.dassaultfalcon.com.* You may view this referenced service information at the FAA, Transport Standards 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 *http://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0700; 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 regulatory evaluation, 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: Tom Rodriguez, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3226.

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 the **ADDRESSES** section. Include ''Docket No. FAA–2019–0700; Product Identifier 2019–NM–105–AD'' at the beginning of your comments. The FAA specifically invites comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. The FAA will consider all comments received by the closing date and may amend this proposed AD based on those comments.

The FAA will post all comments, without change, to *http://www.regulations.gov,* including any personal information you provide. The FAA will also post a report summarizing each substantive verbal contact the agency receives about this proposed AD.

Discussion

The FAA issued AD 2018–19–25, Amendment 39–19426 (83 FR 48924, September 28, 2018) (''AD 2018–19–25''), for all Dassault Aviation Model FALCON 2000 airplanes. AD 2018–19–25 requires revising the maintenance or inspection program, as applicable, to incorporate new maintenance requirements and airworthiness limitations. AD 2018–19–25 resulted from a determination that new or more restrictive airworthiness limitations are necessary. The FAA issued AD 2018–19–25 to address reduced controllability of the airplane. AD 2018–19–25 specified that accomplishing the actions required by that AD would terminate the requirements of AD 2014–03–12, Amendment 39–17749 (79 FR 11693, March 3, 2014) (''AD 2014–03–12''); however, AD 2014–03–12 was not superseded by that AD.

Actions Since AD 2018–19–25 Was Issued

Since the FAA issued AD 2018–19–25, the FAA has determined that new or more restrictive airworthiness limitations are necessary.

The European Union Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2019–0131, dated June 11, 2019 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for all Dassault Aviation Model FALCON 2000 airplanes. The MCAI states:

> The airworthiness limitations for Falcon 2000 aeroplanes, which are approved by EASA, are currently defined and published in Dassault Falcon 2000 AMM [Aircraft Maintenance Manual], Chapter 5–40. These instructions have been identified as mandatory for continued airworthiness.
>
> Failure to accomplish these instructions could result in an unsafe condition.
>
> EASA previously issued AD 2017–0236 [which corresponds to FAA AD 2018–19–25], requiring the actions described in Dassault Falcon 2000 AMM Chapter 5–40 (DGT 113876) at Revision 18.
>
> Since that [EASA] AD was issued, Dassault published Revisions 19 and 20 of Dassault Falcon 2000 AMM Chapter 5–40 (DGT 113876). Revision 20 contains new and/or more restrictive maintenance tasks.

For the reason described above, this [EASA] AD retains the requirements of EASA AD 2017–0236, which is superseded, and requires accomplishment of the actions specified in the [Airworthiness Limitations Section] ALS, as defined in this [EASA] AD.

You may examine the MCAI in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0700.

Related Service Information Under 1 CFR Part 51

Dassault Aviation has issued Chapter 5–40, Airworthiness Limitations, Revision 20, dated November 2018, of the Dassault Aviation Falcon 2000 Maintenance Manual. This service information describes airworthiness limitations for safe life limits.

This proposed AD would also require Chapter 5–40, Airworthiness Limitations, DGT 113876, Revision 19, dated November 2017, of the Dassault Falcon 2000 Maintenance Manual, which the Director of the Federal Register approved for incorporation by reference as of November 2, 2018 (83 FR 48924, September 28, 2018).

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 Requirements of This NPRM

This proposed AD would retain all requirements of AD 2018–19–25. This proposed AD would also require revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations.

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

Differences Between This Proposed AD and the MCAI or Service Information

The MCAI specifies that if there are findings from the airworthiness limitations section (ALS) inspection tasks, corrective actions must be accomplished in accordance with Dassault Aviation maintenance documentation. However, this proposed AD does not include that requirement. Operators of U.S.-registered airplanes are required by general airworthiness and operational regulations to perform maintenance using methods that are acceptable to the FAA. The FAA considers those methods to be adequate to address any corrective actions necessitated by the findings of ALS inspections required by this proposed AD.

Costs of Compliance

The FAA estimates that this proposed AD affects 200 airplanes of U.S. registry.

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

The FAA estimates the total cost per operator for the retained actions from AD 2018–19–25 to be $7,650 (90 work-hours × $85 per work-hour).

The FAA has determined that revising the maintenance or inspection program takes an average of 90 work-hours per operator, although the FAA recognizes that this number may vary from operator to operator. In the past, the FAA has estimated that this action takes 1 work-hour per airplane. Since operators incorporate maintenance or inspection program changes for their affected fleet(s), the FAA has determined that a per-operator estimate is more accurate than a per-airplane estimate.

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

Authority for This Rulemaking

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

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

This proposed AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes and associated appliances to the Director of the System Oversight Division.

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) Will not affect intrastate aviation in Alaska, and

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

List of Subjects in 14 CFR Part 39

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

The 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) 2014–03–12, Amendment 39–17749 (79 FR 11693, March 3, 2014); and AD 2018–19–25, Amendment 39–19426 (83 FR 48924, September 28, 2018); and

■ b. adding the following new AD:

Dassault Aviation: Docket No. FAA–2019–0700; Product Identifier 2019–NM–105–AD.

(a) Comments Due Date

The FAA must receive comments by November 12, 2019.

(b) Affected ADs

(1) This AD replaces AD 2014–03–12, Amendment 39–17749 (79 FR 11693, March 3, 2014) (''AD 2014–03–12''); and AD 2018–19–25, Amendment 39–19426 (83 FR 48924, September 28, 2018) (''AD 2018–19–25'').

(2) This AD affects AD 2010–26–05, Amendment 39–16544 (75 FR 79952, December 21, 2010) (''AD 2010–26–05'').

(c) Applicability

This AD applies to all Dassault Aviation Model FALCON 2000 airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 05, Time limits/maintenance checks.

(e) Reason

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

(f) Compliance

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

(g) Retained Revision, With No Changes

This paragraph restates the requirements of paragraph (g) of AD 2018–19–25, with no changes. Within 90 days after November 2, 2018 (the effective date of AD 2018–19–25), revise the maintenance or inspection program, as applicable, to incorporate the information specified in Chapter 5–40, Airworthiness Limitations, DGT 113876, Revision 19, dated November 2017, of the Dassault Falcon 2000 Maintenance Manual. The initial compliance times for doing the tasks are at the time specified in Chapter 5–40, Airworthiness Limitations, DGT 113876, Revision 19, dated November 2017, of the Dassault Falcon 2000 Maintenance Manual, or within 90 days after November 2, 2018 (the effective date of AD 2018–19–25), whichever occurs later; except as required by paragraphs (g)(1) through (g)(3) of this AD. The term ''LDG'' in the ''First Inspection'' column of any table in Chapter 5–40, Airworthiness Limitations, DGT 113876, Revision 19, dated November 2017, of the Dassault Falcon 2000 Maintenance Manual, means total airplane landings. The term ''FH'' in the ''First Inspection'' column of any table in Chapter 5–40, Airworthiness Limitations, DGT 113876, Revision 19, dated November 2017, of the Dassault Falcon 2000 Maintenance Manual, means total flight hours. The term ''FC'' in the ''First Inspection'' column of any table in Chapter 5–40, Airworthiness Limitations, DGT 113876, Revision 19, dated November 2017, of the Dassault Falcon 2000 Maintenance Manual, means total flight cycles.

(1) For Task 30–11–09–350–801 identified in the service information specified in the introductory text of paragraph (g) of this AD, the initial compliance time is the later of the times specified in paragraphs (g)(1)(i) and (g)(1)(ii) of this AD.

(i) At the earlier of the times specified in paragraphs (g)(1)(i)(A) and (g)(1)(i)(B) of this AD.

(A) Prior to the accumulation of 2,400 total flight hours or 2,000 total flight cycles, whichever occurs first.

(B) Within 2,400 flight hours or 2,000 flight cycles after April 7, 2014 (the effective date of AD 2014–03–12), whichever occurs first.

(ii) Within 30 days after April 7, 2014 (the effective date of AD 2014–03–12).

(2) For Task 52–20–00–610–801–01 identified in the service information specified in the introductory text of paragraph (g) of this AD, the initial compliance time is within 24 months after April 7, 2014 (the effective date of AD 2014–03–12).

(3) The limited service life of part number F2MA721512100 is 3,750 total flight cycles on the part or 6 years since the manufacturing date of the part, whichever occurs first.

(h) Retained No Alternative Actions or Intervals With a New Exception

This paragraph restates the requirements of paragraph (h) of AD 2018–19–25, with a new exception. Except as required by paragraph (i) of this AD: After the maintenance or inspection program has been revised as required by paragraph (g) of this AD, no alternative actions (*e.g.,* inspections), or intervals, may be used unless the actions, or intervals, are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in paragraph (l)(1) of this AD.

(i) New Requirement of This AD: Maintenance or Inspection Program Revision

Within 90 days after the effective date of this AD, revise the existing maintenance or inspection program, as applicable, to incorporate the information specified in Chapter 5–40, Airworthiness Limitations, Revision 20, dated November 2018, of the Dassault Aviation Falcon 2000 Maintenance Manual. The initial compliance time for doing the tasks is at the time specified in Chapter 5–40, Airworthiness Limitations, Revision 20, dated November 2018, of the Dassault Aviation Falcon 2000 Maintenance Manual, or within 90 days after the effective date of this AD, whichever occurs later, except as required by paragraphs (i)(1) through (3) of this AD. The term ''LDG'' in the ''First Inspection'' column of any table in the service information specified in this paragraph means total airplane landings. The term ''FH'' in the ''First Inspection'' column of any table in the service information specified in this paragraph means total flight hours. The term ''FC'' in the ''First Inspection'' column of any table in the service information specified in this paragraph means total flight cycles. The term ''M'' in the ''First Inspection'' column of any table in the service information specified in this paragraph means months since date of issuance of the original airworthiness certificate or original export certificate of airworthiness. Accomplishing the actions required by this paragraph terminates all requirements of paragraph (g) of this AD.

(1) For Task 30–11–09–350–801 identified in the service information specified in the introductory text of paragraph (i) of this AD, the initial compliance time is the later of the times specified in paragraphs (i)(1)(i) and (ii) of this AD.

(i) At the earlier of the times specified in paragraphs (i)(1)(i)(A) and (B) of this AD.

(A) Prior to the accumulation of 2,400 total flight hours or 2,000 total flight cycles, whichever occurs first.

(B) Within 2,400 flight hours or 2,000 flight cycles after April 7, 2014 (the effective date of AD 2014–03–12), whichever occurs first.

(ii) Within 30 days after April 7, 2014 (the effective date of AD 2014–03–12).

(2) For Task 52–20–00–610–801–01 identified in the service information specified in the introductory text of paragraph (i) of this AD, the initial compliance time is within 24 months after April 7, 2014 (the effective date of AD 2014–03–12).

(3) The limited service life of part number F2MA721512100 is 3,750 total flight cycles on the part or 6 years since the manufacturing date of the part, whichever occurs first.

(j) New No Alternative Actions or Intervals

After the maintenance or inspection program has been revised as required by paragraph (i) of this AD, no alternative actions (*e.g.,* inspections) or intervals may be used unless the actions or intervals are approved as an AMOC in accordance with the procedures specified in paragraph (l)(1) of this AD.

(k) Terminating Action for Certain Actions in AD 2010–26–05

Accomplishing the actions required by paragraph (g) of this AD or paragraph (i) of this AD terminates the requirements of paragraph (g) of AD 2010–26–05 for all Dassault Aviation Model FALCON 2000 airplanes.

(l) Other FAA AD Provisions

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Section, Transport Standards 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 International Section, send it to the attention of the person identified in paragraph (m)(2) of this AD. Information may be emailed to *9-ANM-116-AMOC-REQUESTS@faa.gov.*

(i) 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.

(ii) AMOCs approved previously for AD 2018–19–25, Amendment 39–19426 (83 FR 48924, September 28, 2018), are approved as AMOCs for the corresponding provisions of this AD.

(2) *Contacting the Manufacturer:* As of the effective date of this AD, for any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or the European Union Aviation Safety Agency (EASA); or Dassault Aviation's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(m) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA AD 2019–0131, dated June 11 2019, for related information. This MCAI may be found in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0700.

(2) For more information about this AD, contact Tom Rodriguez, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3226.

(3) For service information identified in this AD, contact Dassault Falcon Jet Corporation, Teterboro Airport, P.O. Box 2000, South Hackensack, NJ 07606; telephone 201–440–6700; internet *http://www.dassaultfalcon.com.* You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Issued in Des Moines, Washington, on September 19, 2019.

Suzanne Masterson,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–20761 Filed 9–24–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2019–0704; Product Identifier 2019–NM–132–AD]

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 adopt a new airworthiness directive (AD) for certain Airbus SAS Model A350–941 airplanes. This proposed AD was prompted by an investigation that identified the cargo lining gutter assembly would be unable to drain a certain quantity of water in case of leakage or rupture of certain water pipes. This proposed AD would require modification of the cargo lining gutter assemblies, as specified in a European Union Aviation Safety Agency (EASA) AD, which will be incorporated 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 November 12, 2019.

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 *http://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 the material identified in this proposed AD that will be incorporated by reference (IBR), contact the EASA, at Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 89990 1000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this IBR material on the EASA website at *https://ad.easa.europa.eu.* You may view this IBR material at the FAA, Transport Standards 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 on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0704.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0704; 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 regulatory evaluation, 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: Kathleen Arrigotti, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3218.

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 the **ADDRESSES** section. Include ''Docket No. FAA–2019–0704; Product Identifier 2019–NM–132–AD'' at the beginning of your comments. The FAA specifically invites comments on the overall regulatory, economic, environmental, and energy aspects of this NPRM. The FAA will consider all comments received by the closing date and may amend this NPRM based on those comments.

The FAA will post all comments, without change, to *http://www.regulations.gov,* including any personal information you provide. The FAA will also post a report summarizing each substantive verbal contact the agency receives about this NPRM.

Discussion

The EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2019–0183, dated July 26, 2019 (''EASA AD 2019–0183'') (also referred to as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Airbus SAS Model A350–941 airplanes.

This proposed AD was prompted by an investigation that identified the cargo lining gutter assembly would be unable to drain a certain quantity of water in case of leakage or rupture of certain water pipes. The FAA is proposing this AD to address this condition, which, if not corrected, could lead to fluid contamination of certain electrical equipment and connectors, possibly resulting in the loss of several flight control functions, with consequent reduced control of the airplane. See the MCAI for additional background information.

Related IBR Material Under 1 CFR Part 51

EASA AD 2019–0183 describes procedures for modifying the cargo lining gutter assemblies. 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 and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to the agency's bilateral agreement with the State of Design Authority, the FAA has been notified of the unsafe condition described in the MCAI 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 in other products of the same type design.

Proposed AD Requirements

This proposed AD would require accomplishing the actions specified in EASA AD 2019–0183 described previously, as incorporated by reference, except for any differences identified as exceptions in the regulatory text of this AD.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA initially worked with Airbus and EASA to develop a process to use certain EASA ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has since coordinated with other manufacturers and civil aviation authorities (CAAs) to use this process. As a result, EASA AD 2019–0183 will be incorporated by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2019–0183 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 the EASA AD 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 the EASA AD. Service information specified in EASA AD 2019–0183 that is required for compliance with EASA AD 2019–0183 will be available on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0704 after the FAA final rule is published.

Costs of Compliance

The FAA estimates that this proposed AD affects 5 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
17 work-hours × $85 per hour = $1,445	$12,000	$13,445	$67,225

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

Authority for This Rulemaking

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

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

This proposed AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes and associated appliances to the Director of the System Oversight Division.

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) Will not affect intrastate aviation in Alaska, and

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

List of Subjects in 14 CFR Part 39

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

The 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 (AD):

Airbus SAS: Docket No. FAA–2019–0704; Product Identifier 2019–NM–132–AD.

(a) Comments Due Date

The FAA must receive comments by November 12, 2019.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus SAS Model A350–941 airplanes, certificated in any category, as identified in European Union Aviation Safety Agency (EASA) AD 2019–0183, dated July 26, 2019 (''EASA AD 2019–0183'').

(d) Subject

Air Transport Association (ATA) of America Code 92, Electric and electronic common installation.

(e) Reason

This AD was prompted by an investigation that identified the cargo lining gutter assembly would be unable to drain a certain quantity of water in case of leakage or rupture of certain water pipes. The FAA is issuing this AD to address this condition, which, if not corrected, could lead to fluid contamination of certain electrical equipment and connectors, possibly resulting in the loss of several flight control functions, with consequent reduced control 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 2019–0183.

(h) Exception to EASA AD 2019–0183

The ''Remarks'' section of EASA AD 2019–0183 does not apply to this AD.

(i) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Section, Transport Standards 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 International Section, send it to the attention of the person identified in paragraph (j)(2) of this AD. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, International Section, Transport Standards 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 2019–0183 that contains RC procedures and tests: Except as required by paragraph (i)(2) of this AD, RC procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are 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 procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(j) Related Information

(1) For information about EASA AD 2019–0183, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 89990 6017; 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 EASA AD at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. EASA AD 2019–0183 may be found in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0704.

(2) For more information about this AD, contact Kathleen Arrigotti, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3218.

Issued in Des Moines, Washington, on September 19, 2019.

Suzanne Masterson,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–20760 Filed 9–24–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2019–0661; Airspace Docket No. 19–AEA–9]

RIN 2120–AA66

Proposed Amendment of Area Navigation Routes Q–75 and Q–475, Northeast Corridor Atlantic Coast Routes; Northeastern United States

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to modify high altitude area navigation (RNAV) routes Q–75, and Q–475 in the northeastern United States. This action would support the Northeast Corridor Atlantic Coast Route (NEC ACR) Project. The modified routes were developed to improve the efficiency of the National Airspace System (NAS), expand the availability of area navigation (RNAV) routing, and reduce dependency of the NAS on ground-based navigational systems.

DATES: Comments must be received on or before November 12, 2019.

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–2019–0661; Airspace Docket No. 19–AEA–9 at the beginning of your comments. You may also submit comments through the internet at *http://www.regulations.gov.*

FAA Order 7400.11D, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *http://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. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11D at NARA, email: *fedreg.legal@nara.gov* or go to *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: Paul Gallant, Airspace Policy Group, Office of Airspace Services, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

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

airspace capacity, and reduce complexity in high air traffic volume areas.

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 (FAA Docket No. FAA–2019–0661; Airspace Docket No. 19–AEA–9) and be submitted in triplicate to the Docket Management Facility (see **ADDRESSES** section for address and phone number). You may also submit comments through the internet at *http://www.regulations.gov.*

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2019–0661; Airspace Docket No. 19–AEA–9.'' The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified comment closing date will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the comment closing date. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM's

An electronic copy of this document may be downloaded through the internet at *http://www.regulations.gov.* Recently published rulemaking documents can also accessed through the FAA's web page at *http://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 **ADDRESSES** section for 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 office of the Eastern Service Center, Federal Aviation Administration, Room 210, 1701 Columbia Ave., College Park, GA 30337.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11D, Airspace Designations and Reporting Points, dated August 8, 2019, and effective September 15, 2019. FAA Order 7400.11D is publicly available as listed in the **ADDRESSES** section of this proposed rule. FAA Order 7400.11D lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

Background

The Northeast Corridor Atlantic Coast Route (NEC ACR) project developed Performance Based Navigation (PBN) routes involving the Washington, Boston, New York, and Jacksonville Air Route Traffic Control Centers (ARTCC). The proposed routes would enable aircraft to travel from most locations along the east coast of the United States mainland from Maine to Charleston, SC. The proposed NEC ACR routes would tie-in to the Florida Metroplex high altitude route structure that became effective on November 8, 2018 (83 FR 43750; August 28, 2018) Docket No. FAA–2018–0437. This tie-in would enable more efficient direct routings between the U.S. east coast and Caribbean area locations. Additionally, the proposed routes would extend the availability of RNAV routing from the Boston, MA, area northeastward to the Newfoundland, Canada area.

The proposed Q-routes would support the strategy to transition the NAS from a ground-based navigation aid and radar-based system to a satellite-based PBN system.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 to amend Q-routes Q–75 and Q–475, in the northeastern United States in support of the Northeast Corridor Atlantic Coast Route project.

The proposed Q-route amendments are as follows:

Q–75: Q–75 currently extends between the ENEME, GA, WP, and the Greensboro, NC, (GSO) VORTAC. As proposed, the route would be extended from the Greensboro, NC, VORTAC northeast to the COPLY, MA, WP (approximately 20 NM east of the Boston, MA, (BOS) VOR/DME). Between the Greensboro, NC, VORTAC and the COPLY WP, the following points would be added to the route: BROSK, NC, WP; DRAIK, VA, Fix; Gordonsville, VA, (GVE) VORTAC; HAMMZ, VA, WP; TOOBN, MD, WP; MURPH, MD, Fix; SACRI, MD, Fix ; STOEN, PA, Fix; Modena, PA, (MXE) VORTAC; COPES, PA, Fix; BIGGY, NJ, Fix; Solberg, NJ, (SBJ) VOR/DME; JERSY, NJ, Fix; DUEYS, NY, Fix; BIZEX, NY, WP; GREKI, CT, Fix; NELIE, CT, Fix; SWALO, MA, Fix; and the Boston, MA, (BOS) VOR/DME. This would provide RNAV routing between Greensboro, NC and the Boston, MA, area.

Q–475: Q–475 currently extends between the TUSKY, OA, Fix and the PERLU, Canada, WP. This proposal would extend Q–475 from the TUSKY fix westward to the COPLY, MA, WP (located approximately 20 NM northeast of the Boston, MA, VOR/DME). The CANAL, MA, WP, and the SCUPP, OA, fix would be added between the TUSKY Fix and the COPLY WP.

Note: The Q–475 route description includes the SCUPP and TUSKY fixes located over international waters. In the route description, in place of a two-letter state abbreviation for the SCUPP and TUSKY fixes, ''OA,'' meaning ''Offshore Atlantic,'' is used.

Full route descriptions of the proposed amended routes are listed in ''The Proposed Amendment'' section of this notice.

The proposed amended routes in this notice would significantly expand the availability of high altitude RNAV routing along the eastern seaboard of the U.S. The project is designed to increase airspace capacity and reduce complexity in high volume areas through the use of optimized routes through congested airspace.

RNAV routes are published in paragraph 2006 of FAA Order 7400.11D dated August 8, 2019, and effective September 15, 2019, which is incorporated by reference in 14 CFR 71.1. The RNAV routes listed in this document would be subsequently published in the Order.

FAA Order 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 proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a ''significant regulatory action'' under Executive

Order 12866; (2) is not a ''significant rule'' under Department of Transportation (DOT)

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

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

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

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

■ 1. The authority citation for 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 7400.11D, Airspace Designations and Reporting Points, dated August 8, 2019, and effective September 15, 2019, is amended as follows:

Paragraph 2006—United States Area Navigation Routes

* * * * *

Q75 ENEME, GA to COPLY, MA [Amended]

ENEME, GA	WP	(Lat. 30°42′12.09″ N, long. 082°26′09.31″ W)
TEUFL, GA	WP	(Lat. 31°52′00.46″ N, long. 082°01′04.56″ W)
TEEEM, GA	WP	(Lat. 32°08′41.20″ N, long. 081°54′50.57″ W)
SHRIL, GA	WP	(Lat. 32°54′42.21″ N, long. 081°34′09.78″ W)
FISHO, SC	WP	(Lat. 33°16′46.25″ N, long. 081°24′43.52″ W)
ILBEE, SC	WP	(Lat. 34°18′41.66″ N, long. 081°01′07.88″ W)
SLOJO, SC	WP	(Lat. 34°38′46.31″ N, long. 080°39′25.63″ W)
GREENSBORO, NC (GSO)	VORTAC	(Lat. 36°02′44.49″ N, long. 079°58′34.95″ W)
BROSK, NC	WP	(Lat. 36°14′52.55″ N, long. 079°47′39.93″ W)
DRAIK, VA	FIX	(Lat. 37°08′02.15″ N, long. 078°58′58.56″ W)
Gordonsville, VA (GVE)	VORTAC	(Lat. 38°00′48.96″ N, long. 078°09′10.90″ W)
HAMMZ, VA	WP	(Lat. 38°43′51.56″ N, long. 077°19′59.85″ W)
TOOBN, MD	WP	(Lat. 38°59′54.31″ N, long. 076°59′25.83″ W)
MURPH, MD	FIX	(Lat. 39°27′51.22″ N, long. 076°23′07.24″ W)
SACRI, MD	FIX	(Lat. 39°36′07.34″ N, long. 076°10′24.70″ W)
STOEN, PA	FIX	(Lat. 39°50′17.54″ N, long. 075°47′54.92″ W)
Modena, PA (MXE)	VORTAC	(Lat. 39°55′05.00″ N, long. 075°40′14.96″ W)
COPES, PA	FIX	(Lat. 40°07′50.57″ N, long. 075°22′36.37″ W)
BIGGY, NJ	FIX	(Lat. 40°25′10.62″ N, long. 074°58′21.73″ W)
Solberg, NJ (SBJ)	VOR/DME	(Lat. 40°34′58.95″ N, long. 074°44′30.45″ W)
JERSY, NJ	FIX	(Lat. 40°47′28.99″ N, long. 074°23′58.00″ W)
DUEYS, NY	FIX	(Lat. 41°09′09.46″ N, long. 073°47′48.52″ W)
BIZEX, NY	WP	(Lat. 41°17′02.86″ N, long. 073°34′50.20″ W)
GREKI, CT	FIX	(Lat. 41°28′48.03″ N, long. 073°18′50.98″ W)
NELIE, CT	FIX	(Lat. 41°56′27.64″ N, long. 072°41′18.88″ W)
SWALO, MA	FIX	(Lat. 42°03′55.75″ N, long. 072°11′37.10″ W)
Boston, MA (BOS)	VOR/DME	(Lat. 42°21′26.82″ N, long. 070°59′22.37″ W)
COPLY, MA	WP	(Lat. 42°29′52.21″ N, long. 070°33′28.57″ W)

Q475 COPLY, MA to PERLU, Canada [Amended]

COPLY, MA	WP	(Lat. 42°29′52.21″ N, long. 070°33′28.57″ W)
SCUPP, OA	FIX	(Lat. 42°36′11.01″ N, long. 070°13′49.35″ W)
CANAL, MA	FIX	(Lat. 42°40′08.51″ N, long. 070°01′21.76″ W)
TUSKY, OA	FIX	(Lat. 43°33′54.00″ N, long. 067°00′00.00″ W)
SCOTS, Canada	WP	(Lat. 44°30′00.00″ N, long. 064°00′00.00″ W)
BITRA, Canada	WP	(Lat. 45°06′26.00″ N, long. 061°52′44.00″ W)
PERLU, Canada	WP	(Lat. 47°17′25.00″ N, long. 054°02′46.00″ W)

Excluding the portion within Canada.

* * * * *

Issued in Washington, DC, on September 18, 2019.

Scott M. Rosenbloom,

Acting Manager, Airspace Policy Group.

[FR Doc. 2019–20692 Filed 9–24–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2019–0729; Airspace Docket No. 19–AGL–12]

RIN 2120–AA66

Proposed Amendment of Air Traffic Service (ATS) Routes V–82, V–217, and T–383 in the Vicinity of Baudette, MN

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend two VHF Omnidirectional Range (VOR) Federal airways, V–82 and V–217, and one area navigation (RNAV) route, T–383. The FAA is proposing this action due to the planned decommissioning of the VOR portion of the Baudette VOR/Distance Measuring Equipment (VOR/DME) navigation aid (NAVAID). The Baudette VOR is being decommissioned in support of the FAA's VOR Minimum Operational Network (MON) program.

DATES: Comments must be received on or before November 12, 2019.

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–2019–0729; Airspace Docket No. 19–AGL–12 at the beginning of your comments. You may also submit comments through the internet at *http://www.regulations.gov.* FAA Order 7400.11D, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *http://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. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11D at NARA, email: *fedreg.legal@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: Colby Abbott, Airspace Policy Group, Office of Airspace Services, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

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

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 (FAA Docket No. FAA–2019–0729; Airspace Docket No. 19–AGL–12) and be submitted in triplicate to the Docket Management Facility (see **ADDRESSES** section for address and phone number). You may also submit comments through the internet at *http://www.regulations.gov.*

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2019–0729; Airspace Docket No. 19–AGL–12.'' The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified comment closing date will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the comment closing date. 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 *http://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *http://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 **ADDRESSES** section for 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 office of the Operations Support Group, Central Service Center, Federal Aviation Administration, 10101 Hillwood Blvd., Fort Worth, TX 76177.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11D, Airspace Designations and Reporting Points, dated August 8, 2019, and effective September 15, 2019. FAA Order 7400.11D is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11D lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

Background

The FAA is planning to decommission the VOR portion of the Baudette, MN (BDE), VOR/DME in May 2020. The Baudette VOR was one of the candidate VORs identified for discontinuance by the FAA's VOR MON program and listed in the Final policy statement notice, ''Provision of Navigation Services for the Next Generation Air Transportation System (NextGen) Transition to Performance-Based Navigation (PBN) (Plan for Establishing a VOR Minimum Operational Network),'' published in the

Federal Register of July 26, 2016 (81 FR 48694), Docket No. FAA–2011–1082. Although the VOR portion of the Baudette, MN, VOR/DME NAVAID is planned for decommissioning, the DME portion is being retained with the ''BDE'' identifier. The ATS routes effected by the Baudette VOR decommissioning are VOR Federal airways V–82 and V–217.

With the planned decommissioning of the Baudette VOR, the remaining ground-based NAVAID coverage in the area is insufficient to enable the continuity of V–82 and V217 within the affected area. As such, proposed modifications to V–82 and V–217 would result in the V–82 airway segment between the Baudette VOR/DME and the intersection of the Baudette VOR/DME 194° radial and the Park Rapids, MN, VOR/DME 003° radial (BLUOX fix) and the V–217 airway segment between the Hibbing, MN, VOR/DME and the Winnipeg, MB, Canada, VOR/Tactical Air Navigation (VORTAC) being removed.

To overcome the removal of the V–82 and V–217 airway segments, the FAA plans to retain the current fixes located along those airway segments to assist pilots and air traffic controllers already familiar with them, for navigation purposes. Additionally, the Baudette, MN, DME facility is planned to be retained and charted in its current location as a DME facility with the ''BDE'' identifier. Further, the FAA proposes to extend RNAV route T–383 between the BLUOX fix and the Baudette, MN, DME facility to overlay the V–82 routing being removed. Instrument flight rules (IFR) traffic could use the extended T–383 route segment, file point-to-point using the fixes that will remain in place, or receive air traffic control (ATC) radar vectors to continue operating through the affected area. Visual flight rules (VFR) pilots who elect to navigate via the airways through the affected area could also take advantage of the air traffic services previously listed.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 to remove VOR Federal airways V–82 and V–217 airway segments and extend RNAV route T–383 to overlay the V–82 routing being removed. The planned decommissioning of the VOR portion of the Baudette, MN, VOR/DME has made this action necessary. The proposed air traffic service (ATS) route actions are described below.

V–82: V–82 currently extends between the Baudette, MN, VOR/DME and the intersection of the Baudette VOR/DME 194° and Park Rapids, MN, VOR/DME 003° radials (BLUOX fix), and between the Gopher, MN, VORTAC and the Dells, WI, VORTAC. The FAA proposes to remove the airway segment between the Baudette VOR/DME and the intersection of the Baudette VOR/DME 194° and Park Rapids, MN, VOR/DME 003° radials. The unaffected portions of the existing airway would remain as charted.

V–217: V–217 currently extends between the intersection of the Madison, WI, VOR/DME 138° and Badger, WI, VOR/DME 193° radials and the Winnipeg, MB, Canada, VORTAC. The airspace within Canada is excluded and the portion of the airway that lies within the Beaver Military Operations Area (MOA) is excluded when the Beaver MOA is active. The FAA proposes to remove the airway segment between the Hibbing, MN, VOR/DME and the Winnipeg, MB, Canada, VORTAC, as well as the exclusion language addressing the airspace within Canada and the Beaver MOA. The unaffected portions of the existing airway would remain as charted.

T–383: T–383 currently extends between the Gopher, MN, VORTAC and the BLUOX, MN, fix. The FAA proposes to extend the route between the BLUOX fix and the Baudette, MN, DME. The unaffected portions of the existing airway would remain as charted.

The NAVAID radials listed in the V–217 airway description below are unchanged and stated in True degrees.

VOR Federal airways are published in paragraph 6010(a) and low altitude RNAV T-routes are published in paragraph 6011 of FAA Order 7400.11D dated August 8, 2019, and effective September 15, 2019, which is incorporated by reference in 14 CFR 71.1. The ATS routes listed in this document would be subsequently published in the Order.

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

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

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

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

■ 1. The authority citation for 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 7400.11D, Airspace Designations and Reporting Points, dated August 8, 2019, and effective September 15, 2019, is amended as follows:

Paragraph 6010(a) Domestic VOR Federal Airways.

* * * * *

V–82 [Amended]

From Gopher, MN; Farmington, MN; Rochester, MN; Nodine, MN; to Dells, WI.

* * * * *

V–217 [Amended]

From INT Madison, WI, 138° and Badger, WI, 193° radials; Badger; Green Bay, WI; Rhinelander, WI; Duluth, MN; to Hibbing, MN.

* * * * *

Paragraph 6011 United States Area Navigation Routes.

* * * * *

T–383 Gopher, MN (GEP) to Baudette, MN (BDE) [Amended]

Gopher, MN (GEP)	VORTAC	(Lat.45°08′44.47″ N, long. 093°22′23.45″ W)
BRNRD, MN	WP	(Lat. 46°20′53.81″ N, long. 094°01′33.54″ W)
BLUOX, MN	FIX	(Lat. 47°34′33.13″ N, long. 095°01′29.11″ W)
Baudette, MN (BDE)	DME	(Lat. 48°43′22.07″ N, long. 094°36′26.24″ W)

Issued in Washington, DC, on September 18, 2019.

Scott M. Rosenbloom,

Acting Manager, Airspace Policy Group.

[FR Doc. 2019–20715 Filed 9–24–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2019–0662; Airspace Docket No. 19–AWA–2]

RIN 2120–AA66

Proposed Amendment of Class C Airspace; Lansing, MI

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to modify the Lansing, MI, Class C airspace area by amending the effective hours to coincide with the associated radar approach control facility hours of operation. The designated boundaries and altitudes of the Lansing, MI, Class C airspace area would not change. Class C airspace areas are predicated on an operational air traffic control tower serviced by a radar approach control facility. Additionally, this proposed action would establish Class D airspace at Capital Region International Airport, MI, when the associated radar approach control facility is not in operation.

DATES: Comments must be received on or before November 25, 2019.

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–2019–0662; Airspace Docket No. 19–AWA–2 at the beginning of your comments. You may also submit comments through the internet at *http://www.regulations.gov.* FAA Order 7400.11D, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *http://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. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11D at NARA, email: *fedreg.legal@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: Colby Abbott, Airspace Policy Group, Office of Airspace Services, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

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

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 (FAA Docket No. FAA–2019–0662; Airspace Docket No. 19–AWA–2) and be submitted in triplicate to the Docket Management Facility (see **ADDRESSES** section for address and phone number). You may also submit comments through the internet at *http://www.regulations.gov.*

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2019–0662; Airspace Docket No. 19–AWA–2.'' The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified comment closing date will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the comment closing date. 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 *http://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *http://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 **ADDRESSES** section for 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 office of the Operations Support Group, Central Service Center, Federal Aviation Administration, 10101 Hillwood Blvd., Fort Worth, TX 76177.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11D, Airspace Designations and Reporting Points,

dated August 8, 2019, and effective September 15, 2019. FAA Order 7400.11D is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11D lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

Background

The Federal Aviation Administration (FAA) Modernization and Reform Act of 2012, Section 804, (Pub. L. 112–95) required the FAA to developed a plan for realigning and consolidating facilities and services to support the transition to a Next Generation Air Transportation System (NextGen) and to reduce capital, operating, maintenance, and administrative costs where such reductions could be implemented without adversely affecting safety. As a result, the FAA transferred radar approach control service for the Capital Region International Airport from the Lansing Airport Traffic Control Tower (ATCT) to the Kalamazoo ATCT as part of the consolidation of terminal radar approach control facilities in the State of Michigan. The Kalamazoo ATCT now operates as ''Great Lakes Approach,'' but is not a 24-hour radar approach control facility.

Although radar approach control service for the Capital Region International Airport was transferred to Kalamazoo ATCT, which is not a 24-hour radar approach control facility, the Lansing control tower remains a 24-hour facility supporting airport operations. With the Lansing control tower operating 24-hours daily, the Capital Region International Airport meets the criteria for Class D airspace when the Kalamazoo ATCT is not providing radar approach control service.

The Proposal

The FAA is proposing an amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 to modify the Lansing, MI, Class C airspace area. The proposal would modify the Lansing, MI, Class C airspace by amending the effective hours to coincide with the associated radar approach control facility's hours of operation. The designated boundaries and altitudes of the Class C airspace area would not change. In addition, this action proposes to establish the Lansing, MI, Class D airspace area at the Capital Region International Airport to provide controlled airspace for airport operations and instrument approach and departure procedures when the associated radar approach control facility is not in operation.

Class C airspace areas are published in paragraph 4000 and Class D airspace areas are published in paragraph 5000 of FAA Order 7400.11D, dated August 8, 2019, and effective September 15, 2019, which is incorporated by reference in 14 CFR 71.1. The Class C airspace area modification and Class D airspace establishment proposed in this document would be published subsequently in the Order.

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

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

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

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

■ 1. The authority citation for 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 7400.11D, Airspace Designations and Reporting Points, dated August 8, 2019, and effective September 15, 2019, is amended as follows:

Paragraph 4000 Subpart C—Class C Airspace

* * * * *

AGL MI C Lansing, MI [Amended]

Capital Region International Airport, MI
(Lat. 42°46′43″ N, long. 84°35′10″ W)

That airspace extending upward from the surface to and including 4,900 feet MSL within a 5-mile radius of Capital Region International Airport; and that airspace extending upward from 2,100 feet MSL to and including 4,900 feet MSL within a 10-mile radius of Capital Region International Airport. This Class C airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

* * * * *

Paragraph 5000 Subpart D—Class D Airspace

* * * * *

AGL MI D Lansing, MI [New]

Capital Region International Airport, MI
(Lat. 42°46′43″ N, long. 84°35′10″ W)

That airspace extending upward from the surface to and including 3,400 feet MSL within a 5-mile radius of Capital Region International Airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

* * * * *

Issued in Washington, DC, on September 18, 2019.

Scott M. Rosenbloom,

Acting Manager, Airspace Policy Group.

[FR Doc. 2019–20714 Filed 9–24–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2019–0686; Airspace Docket No. 18–AGL–21]

RIN 2120–AA66

Proposed Amendment of VOR Federal Airway V–7 in the Vicinity of Sheboygan, WI

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend VHF Omnidirectional Range (VOR) Federal airway V–7 in the vicinity of Sheboygan, WI. The modifications are necessary due to the planned decommissioning of the VOR portion of the Falls, WI, VOR/Distance Measuring Equipment (VOR/DME) navigation aid (NAVAID), which provides navigation guidance for portions of the affected air traffic service (ATS) route. The Falls VOR is being decommissioned as part of the FAA's VOR Minimum Operational Network (MON) program.

DATES: Comments must be received on or before November 12, 2019

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: (800) 647–5527, or (202) 366–9826. You must identify FAA Docket No. FAA–2019–0686; Airspace Docket No. 18–AGL–21 at the beginning of your comments. You may also submit comments through the internet at *http://www.regulations.gov.*

FAA Order 7400.11D, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *http://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. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11D at NARA, email: *fedreg.legal@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: Colby Abbott, Airspace Policy Group, Office of Airspace Services, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would modify the route structure as necessary to preserve the safe and efficient flow of air traffic within the National Airspace System.

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 (FAA Docket No. FAA–2019–0686; Airspace Docket No. 18–AGL–21) and be submitted in triplicate to the Docket Management Facility (see **ADDRESSES** section for address and phone number). You may also submit comments through the internet at *http://www.regulations.gov.*

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2019–0686; Airspace Docket No. 18–AGL–21.'' The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified comment closing date will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the comment closing date. 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 *http://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *http://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 **ADDRESSES** section for 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 office of the Operations Support Group, Central Service Center, Federal Aviation Administration, 10101 Hillwood Blvd., Fort Worth, TX, 76177.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11D, Airspace Designations and Reporting Points, dated August 8, 2019, and effective September 15, 2019. FAA Order 7400.11D is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11D lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

Background

The FAA is planning decommissioning activities for the VOR portion of the Falls, WI, VOR/DME in May 2020, as one of the candidate VORs identified for discontinuance by the FAA's VOR MON program and listed in the final policy statement notice, ''Provision of Navigation Services for the Next Generation Air Transportation System (NextGen) Transition to Performance-Based Navigation (PBN) (Plan for Establishing a VOR Minimum Operational Network),'' published in the **Federal Register** of July 26, 2016 (81 FR 48694), Docket No. FAA–2011–1082. Although the VOR portion of the Falls, WI, VOR/DME NAVAID is planned for decommissioning, the DME portion is being retained. The only ATS route dependency to the Falls VOR is VOR Federal airway V–7.

With the planned decommissioning of the Falls VOR, the remaining ground-based NAVAID coverage in the area is insufficient to enable the continuity of the airway. As such, the proposed modification to V–7 would result in a gap in the airway and the PETTY fix, on V–7, being redefined using new intersecting NAVAID radials. To overcome the gap, instrument flight rules (IFR) traffic could use adjacent VOR Federal airways, including V–9, V–26, V–55, V–63, V–170, V–191, V–217, V–341, and V–450, to circumnavigate the affected area. Additionally, IFR

traffic could file point to point through the affected area using the fixes that will remain in place, or receive air traffic control (ATC) radar vectors through the area. Visual flight rules pilots who elect to navigate via the airways through the affected area could also take advantage of the adjacent VOR Federal airways or ATC services listed previously.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 by modifying VOR Federal airway V–7. The planned decommissioning of the VOR portion of the Falls, WI, VOR/DME has made this action necessary. The proposed VOR Federal airway change is outlined below.

V–7: V–7 currently extends between the Dolphin, FL, VOR/Tactical Air Navigation (VORTAC) and the Muscle Shoals, AL, VORTAC; and between the Central City, KY, VORTAC and the Sawyer, MI, VOR/DME. The airspace below 2,000 feet mean sea level (MSL) outside the United States is excluded. The portion outside the United States has no upper limit. The FAA proposes to amend the PETTY fix in the airway description to describe it as the intersection of the existing Chicago Heights, IL, VORTAC 358° radial and the Badger, WI, VOR/DME 117°(T)/119°(M) radial. Additionally, the FAA proposes to remove the airway segment between the intersection of the Chicago Heights, IL, VORTAC 358° and Badger, WI, VOR/DME 117°(T)/119°(M) radials (PETTY fix) and the Green Bay, WI, VORTAC. The unaffected portions of the existing airway would remain as charted.

All radials in the route description below that are unchanged are stated in True degrees. Radials that are stated in True (T) and Magnetic (M) degrees are new computations based on available NAVAIDS.

VOR Federal airways are published in paragraph 6010(a) of FAA Order 7400.11D dated August 8, 2019, and effective September 15, 2019, which is incorporated by reference in 14 CFR 71.1. The VOR Federal airway listed in this document would be subsequently published in the Order.

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

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

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

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

■ 1. The authority citation for 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 7400.11D, Airspace Designations and Reporting Points, dated August 8, 2019, and effective September 15, 2019, is amended as follows:

Paragraph 6010(a) Domestic VOR Federal Airways.

* * * * *

V–7

From Dolphin, FL; INT Dolphin 299° and Lee County, FL, 120° radials; Lee County; Lakeland, FL; Cross City, FL; Seminole, FL; Wiregrass, AL; INT Wiregrass 333° and Montgomery, AL, 129° radials; Montgomery; Vulcan, AL; to Muscle Shoals, AL. From Central City, KY; Pocket City, IN; INT Pocket City 016° and Terre Haute, IN, 191° radials; Terre Haute; Boiler, IN; Chicago Heights, IL; to INT Chicago Heights 358° and Badger, WI, 117°(T)/119°(M) radials. From Green Bay, WI; Menominee, MI; to Sawyer, MI. The airspace below 2,000 feet MSL outside the United States is excluded. The portion outside the United States has no upper limit.

* * * * *

Issued in Washington, DC, on September 18, 2019.

Scott M. Rosenbloom,

Acting Manager, Airspace Policy Group.

[FR Doc. 2019–20690 Filed 9–24–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 121

[Docket No.: FAA–2019–0770; Notice No. 19–10]

RIN 2120–AL41

Flight Attendant Duty Period Limitations and Rest Requirements

AGENCY: Federal Aviation Administration (FAA).

ACTION: Advance notice of proposed rulemaking (ANPRM).

SUMMARY: This action arises out of a statutory mandate in the FAA Reauthorization Act of 2018 that requires the FAA to increase the minimum rest period for flight attendants in domestic, flag, and supplemental operations who are scheduled for a duty period of 14 hours or less. Consistent with the statutory mandate, the FAA plans to amend its regulations to ensure that flight attendants scheduled to a duty period of 14 hours or less are given a scheduled rest period of at least 10 consecutive hours and that the rest period is not reduced under any circumstances. This document seeks input from the public to obtain more information about current domestic, flag, and supplemental operations with flight attendants and the potential benefits and costs to inform the rulemaking.

DATES: Send comments on or before November 12, 2019.

ADDRESSES: Send comments identified by docket number *[Insert docket number from heading]* using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.

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

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

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

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

FOR FURTHER INFORMATION CONTACT: For technical questions concerning this ANPRM, contact Daniel T. Ronneberg, Part 121 Air Carrier Operations, Air Transportation Division, AFS–220, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone (202) 267–1216; email *Dan.Ronneberg@faa.gov.*

SUPPLEMENTARY INFORMATION: The FAA seeks public comment on the areas outlined within this ANPRM. In particular, the FAA seeks comments on how the FAA could implement a rulemaking to address the requirement of section 335(a) of the Federal Aviation Administration Reauthorization Act of 2018 (FAARA 2018) in a manner that maximizes benefits and minimizes costs. In some areas of this ANPRM, the FAA requests specific information. Whenever possible, please provide citations and copies of any relevant studies or reports on which you rely, including benefit and cost data as well as any additional data that supports your comment. Please include the identifying number of the specific question(s) to which you are responding. The FAA will use comments to inform the rulemaking.

I. Authority for This Rulemaking

The FAA's authority to issue rules on 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 detail the scope of the Agency's authority. Section 44701(a)(4) requires the Administrator to promulgate regulations in the interest of safety for the ''maximum hours or periods of service of airmen and other employees of air carriers.'' Section 44701(a)(5) requires the Administrator to promulgate ''regulations and minimum standards for other practices, methods, and procedure that the Administrator finds necessary for safety in air commerce and national security.'' In addition, 49 U.S.C. 44701(d)(1)(A) states that the Administrator, when prescribing safety regulations, must consider ''the duty of an air carrier to provide service with the highest possible degree of safety in the public interest.''

II. Executive Summary

The purpose of this advance notice of proposed rulemaking (ANPRM) is to seek comments on the impact of increasing the rest period required for flight attendants who serve in operations conducted under 14 CFR part 121 when those flight attendants are scheduled for a duty period of 14 hours or less. These comments will inform the FAA's development of the rule implementing these changes.

Consistent with section 335(a) of the FAARA 2018, the FAA plans to amend part 121 regulations that apply to flight attendants who are scheduled for a duty period of 14 hours or less. Section 335(a) requires the regulations reflect that such flight attendants have a scheduled rest period of at least 10 consecutive hours that cannot be reduced under any circumstances. The FAA intends this ANPRM to result in information to further the FAA's rulemaking effort, including estimates of the benefits and costs.

III. Background

A *flight attendant* under 14 CFR part 121 is defined as an individual, other than a flightcrew member,[1] who is assigned by a certificate holder conducting domestic, flag, or supplemental operations to duty in an aircraft during flight time and whose duties include but are not necessarily limited to cabin-safety-related responsibilities.[2] Section 121.391 specifies the minimum number of flight attendants required on board a flight, based on maximum payload capacity and seating capacity, for certificate holders conducting passenger-carrying operations under part 121.[3]

Any person serving as a flight attendant in part 121 operations must complete the training and qualification requirements of part 121 subparts N and O.[4] All newly hired flight attendants must complete basic indoctrination training, crewmember emergency training, and initial and/or transition training on each type aircraft on which the flight attendant will be qualified to serve as a crewmember. Additionally, flight attendants must complete operating experience on each group of aircraft for which they will be qualified. Flight attendants must also continue to successfully complete annual recurrent training. These categories of training and qualification events include specific programmed hours, as well as airplane type specific knowledge and skill requirements.

Currently, certificate holders conducting passenger-carrying domestic, flag, and supplemental operations must fulfill the flight attendant duty period limitations and rest requirements in 14 CFR 121.467. Section 121.467(b) provides generally that a flight attendant scheduled to a duty period of 14 hours or less must be given a scheduled rest period of at least nine consecutive hours. This rest period must occur between the completion of the scheduled duty period and the commencement of the subsequent duty period. The certificate holder may schedule or reduce the rest period to eight consecutive hours if the certificate holder provides a subsequent rest period of at least 10 consecutive hours that is scheduled to begin no later than 24 hours after the beginning of the reduced rest period.

Section 335(a) of the FAARA 2018 requires the FAA to ''modify the final rule'' [5] relating to flight attendant duty period limitations and rest requirements to ''ensure that—(A) a flight attendant scheduled to a duty period of 14 hours or less is given a scheduled rest period of at least 10 consecutive hours; and (B) the rest period is not reduced under any circumstances.'' This mandate requires the FAA to increase the amount of rest that certificate holders operating under part 121 must provide to flight attendants scheduled to a duty period of

[1] A ''flightcrew member'' is a pilot, flight engineer, or flight navigator assigned to duty in an aircraft during flight time. 14 CFR 1.1.

[2] 14 CFR 121.467(a).

[3] 14 CFR 121.391 provides that a certificate holder may, however, use more than the required number of flight attendants.

[4] 14 CFR 121.392.

[5] The final rule implementing flight attendant duty period limitations and rest requirements is *Flight Attendant Duty Period Limitations and Rest Requirements.* The FAA notes that the correct **Federal Register** citation for this final rule is 59 FR 94–20372 (Aug. 19, 1994).

14 hours or less, and also requires the FAA to remove the flexibility to reduce the rest period. Amending § 121.467 to fulfill the requirements of section 335(a) requires the FAA to complete economic analyses.

The FAA believes that the economic impact associated with the changes Section 335(a) of the FAARA 2018 requires may cause a subsequently published notice of proposed rulemaking or final rule to be considered economically significant for the purposes of Executive Order 12866. To be sensitive to economic impact and to provide additional procedural protections and avenues for public participation, Section 12.b. of DOT Order 2100.6, *Policies and Procedures for Rulemakings,* directs DOT agencies to publish an ANPRM in the **Federal Register** prior to proposing an economically significant rule. In accordance with that order, and to better inform the FAA's analysis and rulemaking development, this ANPRM solicits public input on the regulatory impact of the statutorily-mandated changes to flight attendant duty and rest requirements codified in Section 335(a) of the FAARA 2018.

IV. Questions Concerning the Rulemaking

Changes to Federal regulations must undergo economic analyses. The FAA completes such analyses in accordance with Executive Order 12866 ''Regulatory Planning and Review,'' 58 FR 51735 (Oct. 4, 1993), Office of Management and Budget (OMB) Circular A–4, Regulatory Analysis (Sept. 17, 2003) and the Regulatory Flexibility Act of 1980, 5 U.S.C. 601, *et seq.* To ensure the FAA has adequate information to complete thorough analyses based on relevant, current information, the FAA requests information and data to develop the necessary regulatory impact analyses to quantify the economic impacts of section 335(a) of FAARA 2018. The FAA seeks responses to the questions below from the public to help inform the development of the rulemaking and its economic impact.

The FAA requests that responses to the following questions include *quantitative* information and data where possible. The FAA seeks all information pertinent to assessing the full impacts of implementing section 335(a). The FAA will use this information and data to develop analyses and further rulemaking that the FAA will make available to the public for comment.

Confidential Business Information

Confidential Business Information (CBI) is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this ANPRM 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 ANPRM, 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 ANPRM. Submissions containing CBI should be sent to Daniel T. Ronneberg, Part 121 Air Carrier Operations, Air Transportation Division, AFS–220, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone (202) 267–1216; email *Dan.Ronneberg@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.

Questions for the Public: The FAA is required to ensure that flight attendants under part 121 who are scheduled to a duty period of 14 hours or less be given a scheduled rest period of at least 10 consecutive hours that cannot be reduced under any circumstances. The FAA invites input from the public as follows—

A.1 The FAA requests information on the safety benefits of implementing section 335(a). Specifically, the FAA requests data and studies on the safety effects, including potential risks and consequences, of flight attendant fatigue on civil aviation and the incremental safety benefits of the rest requirements in section 335(a). Please provide information to quantify annual benefits to the public and industry, including flight attendants and flightcrew members. This information will help the FAA estimate safety benefits in the regulatory impact analysis of this rulemaking.

A2. The FAA requests estimates for initial and recurring annual costs that certificate holders conducting operations under part 121 will incur in implementing the requirements of section 335(a). Please provide estimates in the following table format, assuming the compliance date begins in year 1.

A2. TABLE OF IMPACTS—ADDITIONAL FLIGHT ATTENDANT COSTS, HOURS AND NEW HIRES

Impact category	Year									
	1	2	3	4	5	6	7	8	9	10
Initial implementation costs ($) [6]:										
• Software/reprogramming cost										
• New hire cost										
• Training cost										
• Travel, lodging & per diem										
Recurring costs ($) *:										
• Programming cost [7]										
• New hire turnover cost [8]										
• Training cost										
• Travel, lodging & per diem										
Number of additional flight attendant hours:										
• Flight time [9]										
• Duty time [10]										
○ Deadhead transportation as passenger [11]										
○										
• Reserve availability period [12]										
Number of additional flight attendant hires (new and turnover) [13]										
Other impacts (including additional operational costs or effects to operations) [14]										

In addition to the previous questions and table, the following questions request additional information and data.

A3. What is the average flight attendant hourly wage for reserve time, flight time, and duty time operations?

A4. What is the minimum number of flight attendant guaranteed reserve hours or guaranteed reserve pay?

A5. What is the average initial and recurring flight attendant training cost? Please describe what is included in training costs (*e.g.,* instructor and flight attendant time, supplies, etc.).

A6. What is the average cost to hire and onboard a new flight attendant, not including wages or training?

A7. Do you anticipate needing to hire additional flight attendants to implement section 335(a)? If so, how long will it take to initially hire additional flight attendants that may be needed to implement section 335(a) to maintain your current level of flight operations? Please quantify in months.

A8. What are the costs of modifying scheduling software and reprogramming any related scheduling management systems? What is included in this estimate?

A9. Based on your current preparation to comply with the provisions of section 335(a), what type and percentage of your operations have already incurred costs? What is the basis for these costs?

A10. How many affected flight attendants do you currently employ? Please provide data for the previous three years.

A11. Prior to the required change in the rest requirement, how many flight attendants did you expect to hire? Please provide data for the next three years.

A12. How many affected flight attendants have recently retired? Please provide data for the previous three years. If available, provide projected attrition rates for the next three years.

A13. Please provide recommendations and options to minimize the costs of compliance and implementation of section 335(a).

A14. Please provide any additional information and data that you believe would be useful to the FAA regarding the impacts of implementing section 335(a).

A15. Are there any specific issues related to small air carriers with domestic, flag, and supplemental operations with flight attendants that FAA should consider? Would this rule have a disproportionate economic impact on small entities?

V. Regulatory Requirements and Executive Order Determinations

The FAA will address the following requirements in future flight attendant duty period limitations and rest requirements rulemakings. Please provide comments that would assist the FAA in its consideration and analyses of these requirements.

A. Executive Order 12866, Executive Order 13563, and DOT Regulatory Policies and Procedures

The FAA would consider a rulemaking that would address section 335(a) of FAARA 2018 as a significant regulatory action under section 3(f) of Executive Order 12866 that would be reviewed by the Office of Management and Budget (OMB). The rulemaking would also be a significant regulatory action under DOT Order 2100.6 ''Policies and Procedures for Rulemakings,'' issued by the Department of Transportation on December 20, 2018.

Executive Orders 12866, ''Regulatory Planning and Review,'' 58 FR 51735 (Oct. 4, 1993), and 13563, ''Improving Regulation and Regulatory Review,'' 76 FR 3821 (Jan. 21, 2011), require agencies to regulate in the ''most cost-effective manner,'' to make a ''reasoned determination that the benefits of the intended regulation justify its costs,'' and to develop regulations that ''impose the least burden on society.'' Executive Order 13610, ''Identifying and Reducing Regulatory Burdens,'' 77 FR 28469 (May 14, 2012), urges agencies to conduct retrospective analyses of existing rules to examine whether they remain justified and whether they should be modified or streamlined in light of changed circumstances, including the rise of new technologies.

Additionally, Executive Orders 12866, 13563, and 13610 require agencies to provide a meaningful opportunity for public participation. Accordingly, FAA invites comments on these considerations, including any cost or benefit figures or factors, alternative approaches, and relevant scientific, technical and economic data.

B. Executive Order 13771

This action is not subject to the requirements of Executive Order 13771 because it is an advance notice of proposed rulemaking.

C. Executive Order 13132

Executive Order 13132, ''Federalism,'' 64 FR 43255 (Aug. 10, 1999), requires agencies to assure meaningful and timely input by State and local officials in the development of regulatory policies that may have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' FAA invites State and local governments with an interest in this ANPRM to comment on any effect that may result from implementation of section 335(a) of FAARA 2018.

D. Executive Order 13175

Consistent with Executive Order 13175, ''Consultation and Coordination with Indian Tribal Governments,'' and FAA Order 1210.20, ''American Indian and Alaska Native Tribal Consultation Policy and Procedures,'' the FAA ensures that Federally Recognized Tribes (Tribes) are given the opportunity to provide meaningful and timely input regarding proposed Federal actions that have the potential to uniquely or significantly affect their respective Tribes. At this point, the FAA has not identified any unique or significant effects, environmental or otherwise, on tribes resulting from this ANPRM.

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[6] Initial implementation costs may include: Additional flight attendant hires and turnover hires; background checks and onboarding; initial and recurring training; travel, lodging, and per diem; other additional operational costs to comply with section 335(a). Please itemize. Please consider existing regulatory compliance and company practices when estimating additional costs associated with hiring additional flight attendants and implementing section 335(a), such as security threat assessments and drug and alcohol screening.

[7] Programming costs such as software modifications to include the proposed flight attendant rest requirement.

[8] ''New hire turnover costs'' means the costs associated to new hire attrition.

[9] The FAA assumes that a flight attendant's hourly wage is calculated differently for flight time as a subset of the duty period. In this context, this ANPRM uses the definition for ''flight time'' that applies to pilots: time that commences when an aircraft moves under its own power for the purpose of flight and ends when the aircraft comes to rest after landing. 14 CFR 1.1.

[10] ''Duty time'' is the period of elapsed time between reporting for an assignment involving flight time and release from that assignment by the certificate holder conducting domestic, flag, or supplemental operations. 14 CFR 121.467(a).

[11] In this context, this ANPRM uses the definition for ''deadhead transportation'' that applies to pilots: Transportation of a flightcrew member as a passenger or non-operating flightcrew member, by any mode of transportation, as required by a certificate holder, excluding transportation to or from a suitable accommodation. 14 CFR 117.3.

[12] This ANPRM uses the term ''reserve availability period'' in this context to refer to a period of time in which the certificate holder requires a flight attendant to be available to receive an assignment for a duty period. 14 CFR 1.1.

[13] Include what is necessary to maintain the current level of flight operations and what is necessary for the level of future flight operations expected over a 10-year period.

[14] Examples of other impacts include additional transportation costs or impact to flight times etc.

E. Regulatory Flexibility Act, Executive Order 13272, and DOT Policies and Procedures

Under the Regulatory Flexibility Act of 1980, 5 U.S.C. 601, *et seq.,* FAA must consider whether a rulemaking would have a ''significant economic impact on a substantial number of small entities.'' ''Small entities'' include small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations under 50,000.

The FAA would develop any future rulemaking in accordance with Executive Order 13272, ''Proper Consideration of Small Entities in Agency Rulemaking,'' 68 FR 7990 (Feb. 19, 2003), and DOT's procedures and policies to promote compliance with the Regulatory Flexibility Act to ensure that potential impacts on small entities of a regulatory action are properly considered.

F. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.,* 5 CFR 1320.8(d) requires that FAA provide interested members of the public and affected agencies an opportunity to comment on information collection and recordkeeping requests. While the purpose of this ANPRM is to solicit comments, this action does not impose new information collection requirements as defined in 14 CFR part 1320. The FAA will consider how a future rulemaking that would address section 335(a) of FAARA 2018 would affect current information collection and recordkeeping requests.

G. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) governs the issuance of Federal regulations that require unfunded mandates. An unfunded mandate is a regulation that requires a state, local, or tribal government or the private sector to incur direct costs without the Federal government having first provided the funds to pay those costs. The FAA will need to determine if a rulemaking to address section 335(a) of the FAARA 2018 would result in costs of $155 million or more, adjusted for inflation, to either state, local, or tribal governments, in the aggregate, or to the private sector in any one year.

H. National Environmental Policy Act

The National Environmental Policy Act of 1969, 42 U.S.C. 4321–4375, requires that Federal agencies analyze proposed actions to determine whether the action will have a significant impact on the human environment. The Council on Environmental Quality (CEQ) regulations require Federal agencies to conduct an environmental review considering (1) the need for the proposed action, (2) alternatives to the proposed action, (3) probable environmental impacts of the proposed action and alternatives, and (4) the agencies and persons consulted during the consideration process. See 40 CFR 1508.9(b). FAA welcomes any data or information related to environmental impacts that may result from any future rulemaking to address section 335(a) of FAARA 2018.

I. Privacy Act

Anyone is able to search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the document (or signing the document, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000, see 65 FR 19477, or you may visit *http://www.regulations.gov.*

J. Executive Order 13069 and International Trade Analysis

Under Executive Order 13609, ''Promoting International Regulatory Cooperation,'' 77 FR 26413 (May 4, 2012), agencies must consider whether the impacts associated with significant variations between domestic and international regulatory approaches are unnecessary or may impair the ability of American businesses to export and compete internationally. In meeting shared challenges involving health, safety, labor, security, environmental, and other issues, regulatory approaches developed through international cooperation can provide equivalent protection to standards developed independently while also minimizing unnecessary differences.

Similarly, the Trade Agreements Act of 1979, Public Law 96–39, as amended by the Uruguay Round Agreements Act, Public Law 103–465, prohibits Federal agencies from establishing any standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. For purposes of these requirements, Federal agencies may participate in the establishment of international standards, so long as the standards have a legitimate domestic objective, such as providing for safety, and do not operate to exclude imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards. FAA welcomes any data or information related to international impacts that may result from future rulemaking to address section 335(a) of the FAARA 2018.

K. Executive Order 13211

Executive Order 13211, 66 FR 28355 (May 22, 2001), requires Federal agencies to prepare a Statement of Energy Effects for any ''significant energy action.'' Under the executive order, a ''significant energy action'' is defined as any action by an agency (normally published in the **Federal Register**) that promulgates, or is expected to lead to the promulgation of, a final rule or regulation (including a notice of inquiry, ANPRM, and NPRM) that (1)(i) is a significant regulatory action under Executive Order 12866 or any successor order and (ii) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (2) is designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. The FAA would consider this executive order for a future rulemaking to address section 335(a) of FAARA 2018.

Issued in Washington, DC, under authority provided by 49 U.S.C. 106(f) and 44701(a) on September 18, 2019.

Robert C. Carty,

Deputy Executive Director, Flight Standards Service, Federal Aviation Administration.

[FR Doc. 2019–20682 Filed 9–24–19; 8:45 am]

BILLING CODE 4910–13–P

POSTAL REGULATORY COMMISSION

39 CFR part 3050

[Docket No. RM2019–14; Order No. 5238]

Periodic Reporting

AGENCY: Postal Regulatory Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Commission is acknowledging a recent filing requesting the Commission initiate a rulemaking proceeding to consider changes to analytical principles relating to periodic reports (Proposal Eight). This document informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* October 16, 2019.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit

comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. Proposal Eight
III. Notice and Comment
IV. Ordering Paragraphs

I. Introduction

On September 18, 2019, the Postal Service filed a petition pursuant to 39 CFR 3050.11 requesting that the Commission initiate a rulemaking proceeding to consider changes to analytical principles relating to periodic reports.[1] The Petition identifies the proposed analytical changes filed in this docket as Proposal Eight.

II. Proposal Eight

Background. Proposal Eight relates to modifications to the Parcel Select/Parcel Return Service (PRS) mail processing and transportation cost models. Petition, Proposal Eight at 1. The cost models were last presented in Docket No. ACR2018, USPS–FY–18–NP15 and USPS–FY18–NP16, respectively. *Id.* The proposed modifications to the mail processing cost model are based on two observations made during the preparation of Docket No. ACR2017 materials: (1) A Parcel Select mail flow was missing from the cost model; and (2) the Postal Service had implemented new PRS processing methods for return delivery unit (RDU) and return sectional center facility (RSCF) mailpieces. *Id.*

With respect to the transportation cost model, the Postal Service explains that prior to being classified as a competitive product, Parcel Select Lightweight (PSLW) volume was part of Marketing Mail parcels and transportation costs estimates for that mail were included in the cost model presented mostly recently in Docket No. ACR2018. *Id.* The Postal Service states that there have been no PSLW transportation cost estimates presented in Annual Compliance Report dockets since PSLW was reclassified as a competitive product. *Id.*

Proposal. The Postal Service proposes two modifications to the Parcel Select/PRS mail processing cost model: (1) A machinable destination sectional center facility (DSCF) 3-Digit presort mail flow worksheet be added to the model to accommodate negotiated service agreements (NSAs); and (2) the results from a 2018 PRS field study be incorporated into the model. *Id.* at 2. The Postal Service also proposes that the Parcel Select/PRS transportation cost model be modified to incorporate PSLW into the analysis. *Id.* at 11.

Rationale and impact. The Postal Service states that the price list does not contain published prices for machinable 3-Digit DSCF presort parcels but there are some NSAs that include machinable DSCF 3-Digit presort parcels. *Id.* at 2. The Postal Service explains that the addition of a machinable DSCF 3-Digit presort model cost estimate to the mail processing cost model would increase that portion of the DSCF costs, which results in a lower Cost and Revenue Analysis (CRA) proportional adjustment factors. *Id.* at 13. Due to the lower proportional adjustment factor, the mail processing unit cost estimates for all other Parcel Select price categories would decrease roughly one percent. *Id.*

In 2018, the Postal Service conducted a field study to collect PRS-specific input data in order to improve the PRS portion of the cost model. *Id.* at 4. The Postal Service states that PRS mail processing unit cost estimates have historically been developed using proxy input data. *Id.* The Postal Service explains that the proposed treatment of the data collected from the field study is consistent with past rulemaking dockets where the proposals included productivity estimates that were collected manually in the field. *Id.* at 7. In describing the impact of the proposed modification, the Postal Service states that, in total, the PRS mail processing cost model changes would result in a lower proportional CRA adjustment factor which results in decreases to the Full Network machinable, nonmachinable, and oversize mail processing unit cost estimates. *Id.* at 14.

Finally, the Postal Service states that the addition of PSLW to the transportation cost model would have no impact on the Parcel Select/PRS transportation cost-per-cubic-foot estimates. *Id.*

III. Notice and Comment

The Commission establishes Docket No. RM2019–14 for consideration of matters raised by the Petition. More information on the Petition may be accessed via the Commission's website at *http://www.prc.gov.* Interested persons may submit comments on the Petition and Proposal Eight no later than October 16, 2019. Pursuant to 39 U.S.C. 505, Katalin K. Clendenin is designated as an officer of the Commission (Public Representative) to represent the interests of the general public in this proceeding.

IV. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. RM2019–14 for consideration of the matters raised by the Petition of the United States Postal Service for the Initiation of a Proceeding to Consider Proposed Changes in Analytical Principles (Proposal Eight), filed September 18, 2019.

2. Comments by interested persons in this proceeding are due no later than October 16, 2019.

3. Pursuant to 39 U.S.C. 505, the Commission appoints Katalin K. Clendenin to serve as an officer of the Commission (Public Representative) to represent the interests of the general public in this docket.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Darcie S. Tokioka,

Acting Secretary.

[FR Doc. 2019–20738 Filed 9–24–19; 8:45 am]

BILLING CODE 7710–FW–P

[1] Petition of the United States Postal Service for the Initiation of a Proceeding to Consider Proposed Changes in Analytical Principles (Proposal Eight), September 18, 2019 (Petition). The Postal Service filed a notice of filing of non-public materials relating to Proposal Eight. Notice of Filing of USPS–RM2019–14/NP1 and Application for Nonpublic Treatment, September 18, 2019.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2019–0377; FRL–10000–40–Region 5]

Air Plan Approval; Indiana; Second Maintenance Plan for 1997 Ozone NAAQS

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Pursuant to the Clean Air Act (CAA), the Environmental Protection Agency (EPA) is proposing to approve a state implementation plan (SIP) revision. On June 20, 2019, the Indiana Department of Environmental Management (IDEM) submitted the State's plan for maintaining the 1997 ozone National Ambient Air Quality Standards (NAAQS or standard) in the following areas: Indianapolis, La Porte County, and South Bend-Elkhart areas in Indiana; and the Indiana portions of the Chicago-Gary-Lake County, IL-IN (Chicago), Cincinnati-Hamilton, OH-KY-

IN (Cincinnati), and Louisville, KY-IN (Louisville) multi-state areas. EPA is proposing to approve these maintenance plans because they provide for the maintenance of the 1997 ozone NAAQS through the end of the second 10-year maintenance period. This action, when finalized would make certain commitments related to maintenance of the 1997 ozone NAAQS in these areas federally enforceable as part of the Indiana SIP.

DATES: Comments must be received on or before October 25, 2019.

ADDRESSES: Submit your comments, identified by Docket No. EPA–EPA–R05–OAR–2019–0377 at *https://www.regulations.gov* or via email to *blakley.pamela@epa.gov*. For comments submitted at *Regulations.gov,* follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. For either manner of submission, 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, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets*.

FOR FURTHER INFORMATION CONTACT: Charles Hatten, Environmental Engineer, Control Strategies Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–6031, *hatten.charles@epa.gov*.

SUPPLEMENTARY INFORMATION: Throughout this document, the terms ''we'', ''us'', and ''our'' refer to the EPA.

Table of contents

I. Summary of EPA's Proposed Action
II. Background
III. EPA's Evaluation of Indiana's SIP Submittal
A. Second Maintenance Plan
B. Transportation Conformity
IV. Proposed Action
V. Statutory and Executive Order Reviews

I. Summary of EPA's Proposed Action

EPA is proposing to approve the 1997 ozone NAAQS maintenance plans for the following areas: Indianapolis, La Porte County, South Bend-Elkhart, and the Indiana portions of the Chicago, Cincinnati, and Louisville multi-state areas. The maintenance plans are designed to keep these areas in attainment of the 1997 ozone NAAQS through the end of the second 10-year maintenance period.

II. Background

Ground-level ozone is formed when oxides of nitrogen (NO_X) and volatile organic compounds (VOC) react in the presence of sunlight. These two pollutants are referred to as ozone precursors. Scientific evidence indicates that adverse public health effects occur following exposure to ozone.

In 1979, under section 109 of the CAA, EPA established primary and secondary NAAQS for ozone at 0.12 parts per million (ppm), averaged over a 1-hour period. 44 FR 8202 (February 8, 1979). On July 18, 1997, EPA revised the primary and secondary NAAQS for ozone to set the acceptable level of ozone in the ambient air at 0.08 ppm, averaged over an 8-hour period. 62 FR 38856 (July 18, 1997).[1] EPA set the 8-hour ozone NAAQS based on scientific evidence demonstrating that ozone causes adverse health effects at lower concentrations and over longer periods of time than was understood when the pre-existing 1-hour ozone NAAQS was set.

Following promulgation of a new or revised NAAQS, EPA is required by the CAA to designate areas throughout the nation as attaining or not attaining the NAAQS. On April 15, 2004 (69 FR 23857), EPA designated areas for the 1997 ozone NAAQS, including the following areas in Indiana which were designated as nonattainment: Indianapolis (Boone, Hamilton, Hancock, Hendricks, Johnson, Madison, Marion, Morgan and Shelby Counties), La Porte County, South Bend-Elkhart (Elkhart and St. Joseph Counties), Chicago (Lake and Porter Counties in Indiana),[2] Cincinnati (Lawrenceburg Township in Dearborn County, Indiana),[3] and Louisville (Clark and Floyd Counties in Indiana).[4] These designations became effective on June 15, 2004. Under the CAA, states are also required to adopt and submit SIPs to implement, maintain, and enforce the NAAQS in designated nonattainment areas and throughout the state.

When a nonattainment area has three years of complete, certified air quality data that has been determined to attain the 1997 ozone NAAQS, and the area has met other required criteria described in section 107(d)(3)(E) of the CAA, the state can submit to EPA a request to be redesignated to attainment, referred to as a ''maintenance area''.[5]

One of the criteria for redesignation is to have an approved maintenance plan under CAA section 175A. The maintenance plan must demonstrate that the area will continue to maintain the standard for the period extending 10 years after redesignation, and it must contain such additional measures as necessary to ensure maintenance and such contingency provisions as necessary to assure that violations of the standard will be promptly corrected. At the end of the eighth year after the effective date of the redesignation, the state must also submit a second maintenance plan to ensure ongoing maintenance of the standard for an additional 10 years. CAA section 175A.

EPA has published long-standing guidance for states on developing maintenance plans. This includes ''Procedures for Processing Requests to Redesignate Areas to Attainment,'' Memorandum from John Calcagni, Director, Air Quality Management Division, September 4, 1992 (the ''Calcagni Memorandum'').

The Calcagni Memorandum provides that states may generally demonstrate maintenance by either performing air quality modeling to show that the future

[1] In March 2008, EPA completed another review of the primary and secondary ozone standards and tightened them further by lowering the level for both to 0.075 ppm. 73 FR 16436 (March 27, 2008). Additionally, in October 2015, EPA completed a review of the primary and secondary ozone standards and tightened them by lowering the level for both to 0.70 ppm. 80 FR 65292 (October 26, 2015)

[2] The entire Chicago (IL-IN) area includes Cook, DuPage, Kane, Lake, McHenry and Will Counties, Aux Sable and Goose Lake Townships in Grundy County, and Oswego Township in Kendall County in Illinois.

[3] The entire Cincinnati (OH-KY-IN) area includes Butler, Clermont, Clinton, Hamilton, and Warren Counties in Ohio; and Boone, Campbell, and Kenton Counties in Kentucky.

[4] The entire Louisville (KY-IN) area includes Bullitt, Jefferson and Oldham Counties in Kentucky.

[5] Section 107(d)(3)(E) of the CAA sets out the requirements for redesignation. They include attainment of the NAAQS, full approval under section 110(k) of the applicable SIP, determination that improvement in air quality is a result of permanent and enforceable reductions in emissions, demonstration that the state has met all applicable section 110 and part D requirements, and a fully approved maintenance plan under CAA section 175A.

mix of sources and emission rates will not cause a violation of the NAAQS or by showing that future emissions of a pollutant and its precursors will not exceed the level of emissions during a year when the area was attaining the NAAQS (*i.e.,* attainment year inventory). *See* Calcagni Memorandum at 9.

EPA approved maintenance plans for the following areas and redesignated them to attainment of the 1997 ozone NAAQS: The Indiana portion of Louisville, La Porte County, and South Bend-Elkhart effective July 19, 2007 (72 FR 39571, 39574, 39577); Indianapolis, effective October 19, 2007 (72 FR 59210); and the Indiana portions of Chicago and Cincinnati effective May 11, 2010 (75 FR 26113, 26118).

Under CAA section 175A(b), states must submit a revision to the first maintenance plan eight years after redesignation to provide for maintenance of the NAAQS for ten additional years following the end of the first 10-year period. EPA's final implementation rule for the 2008 ozone NAAQS revoked the 1997 ozone NAAQS and provided that one consequence of revocation was that areas that had been redesignated to attainment (*i.e.,* maintenance areas) for the 1997 standard no longer needed to submit second 10-year maintenance plans under CAA section 175A(b).[6] However, in *South Coast Air Quality Management District* v. *EPA*[7] (South Coast II), the D.C. Circuit vacated EPA's interpretation that, because of the revocation of the 1997 ozone standard, second maintenance plans were not required for ''orphan maintenance areas,'' *i.e.,* areas that had been redesignated to attainment for the 1997 NAAQS and were designated attainment for the 2008 ozone NAAQS. Thus, states with these ''orphan maintenance areas'' under the 1997 ozone NAAQS must submit maintenance plans for the second maintenance period. Accordingly, on June 20, 2019, IDEM submitted second maintenance plans for the Indianapolis, La Porte County, and South Bend-Elkhart areas and the Indiana portions of the Chicago, Cincinnati, and Louisville areas. The maintenance plans show that each area is expected to remain in attainment of the 1997 ozone NAAQS through the end of the full 20-year maintenance period.

III. EPA's Evaluation of Indiana's SIP Submittal

A. Second Maintenance Plan

Section 175A of the CAA sets forth the elements of a maintenance plan for areas seeking redesignation from nonattainment to attainment. Under section 175A, the maintenance plan must demonstrate continued attainment of the NAAQS for at least 10 years after the Administrator approves a redesignation to attainment. Eight years after the redesignation, the state must submit a revised maintenance plan which demonstrates that attainment of the NAAQS will continue for an additional 10 years beyond the initial 10-year maintenance period. To address the possibility of future NAAQS violations, the maintenance plan must contain contingency measures, as EPA deems necessary, to assure prompt correction of the future NAAQS violation.

The Calcagni Memorandum provides further guidance on the content of a maintenance plan, explaining that a maintenance plan should address five elements: (1) An attainment emission inventory; (2) a maintenance demonstration; (3) a commitment for continued air quality monitoring; (4) a process for verification of continued attainment; and (5) a contingency plan.

On June 20, 2019, IDEM submitted, as a SIP revision, a plan to provide for maintenance of the 1997 ozone standard in Indianapolis, La Porte County, South Bend-Elkhart, and Louisville areas through 2028, more than 20 years after the effective date of redesignation to attainment. Likewise, the revision to Indiana's SIP provides for maintenance of the standard for Chicago and Cincinnati areas through 2030, more than 20 years after the effective date of redesignation to attainment. As discussed below, EPA finds that Indiana's second maintenance plan includes the necessary components and proposes approve the maintenance plan as a revision to the Indiana SIP.

1. Attainment Inventory

For maintenance plans, a state should develop a comprehensive, accurate inventory of actual emissions for an attainment year to identify the level of emissions which is sufficient to maintain the NAAQS. A state should develop this inventory consistent with EPA's most recent guidance on emissions inventory development. For ozone, the inventory should be based on typical summer day VOC and NO_X emissions, as these pollutants are precursors to ozone formation.

The CAA section 175A maintenance plans approved by EPA for the first 10-year periods included attainment inventories that reflect typical summer day VOC and NO_X emissions for the following attainment years: Indianapolis, 2005; La Porte County, 2004; South Bend-Elkhart, 2004; the Indiana portion of Chicago, 2006; the Indiana portion of Cincinnati, 2008; and the Indiana portion of Louisville, 2003. In addition, because all of the maintenance areas in Indiana continued to monitor attainment of the 1997 ozone NAAQS in 2014, this is also an appropriate year to use for an attainment year inventory. As such, IDEM is using 2014 summer day emissions from EPA 2014 version 7.0 modeling platform as the basis for the attainment inventory[8] presented in Tables 1–6 below. Tables 1 through 6 show VOC and NO_X emission totals for all sectors for each maintenance area. These data are based on the most recently available National Emissions Inventory (2014 NEI version 2).

TABLE 1—INDIANAPOLIS AREA TYPICAL SUMMER DAY VOC AND NO_X EMISSIONS FOR ATTAINMENT YEAR 2014 IN TONS PER DAY (tpd)

Source category	VOC	NO_X
Nonroad	20.21	27.64
Onroad	53.04	110.53
Point	5.31	29.68
Area	66.47	9.26
Total	145.03	177.11

[6] *See* 80 FR 12315 (March 6, 2015).

[7] 882 F.3d 1138 (D.C. Cir. 2018).

[8] The inventory documentation for this platform can be found here: *https://www.epa.gov/air-emissions-modeling/2014-version-70-platform.*

TABLE 2—LA PORTE COUNTY AREA TYPICAL SUMMER DAY VOC AND NO_X EMISSIONS FOR ATTAINMENT YEAR 2014 (tpd)

Source category	VOC	NO_X
Nonroad	2.83	2.42
Onroad	3.96	10.55
Point	1.33	3.83
Area	5.73	4.46
Total	13.85	21.96

TABLE 3—SOUTH BEND-ELKHART AREA TYPICAL SUMMER DAY VOC AND NO_X EMISSIONS FOR ATTAINMENT YEAR 2014 (tpd)

Source category	VOC	NO_X
Nonroad	5.74	6.64
Onroad	12.66	23.35
Point	6.23	2.71
Area	22.86	6.14
Total	47.49	38.84

TABLE 4—LOUISVILLE AREA TYPICAL SUMMER DAY VOC AND NO_X EMISSIONS FOR ATTAINMENT YEAR 2014 (tpd)

Source category	VOC	NO_X
Indiana portion of area (Clark and Floyd counties):		
Nonroad	1.99	2.19
Onroad	4.83	12.31
Point	2.02	4.60
Area	9.70	0.95
Total	18.54	20.05
Entire area:		
Nonroad	9.61	10.98
Onroad	25.03	52.13
Point	32.49	59.71
Area	50.94	10.27
Total	118.07	133.09

TABLE 5—CINCINNATI AREA TYPICAL SUMMER DAY VOC AND NO_X EMISSIONS FOR ATTAINMENT YEAR 2014 (tpd)

Source category	VOC	NO_X
Indiana portion of area (Dearborn county):		
Nonroad	0.47	0.53
Onroad	1.76	3.94
Point	5.54	9.62
Area	1.39	0.20
Total	9.16	14.29
Entire area:		
Nonroad	20.39	22.30
Onroad	39.23	82.20
Point	15.73	91.69
Area	79.97	20.60
Total	155.32	216.79

TABLE 6—CHICAGO AREA TYPICAL SUMMER DAY VOC AND NO_X EMISSIONS FOR ATTAINMENT YEAR 2014 (tpd)

Source category	VOC	NO_X
Indiana portion of area (Lake and Porter counties):		
Nonroad	18.08	15.66
Onroad	11.59	28.05
Point	12.99	71.24
Area	20.00	12.52

TABLE 6—CHICAGO AREA TYPICAL SUMMER DAY VOC AND NO_X EMISSIONS FOR ATTAINMENT YEAR 2014 (tpd)—Continued

Source category	VOC	NO_X
Total	62.66	127.47
Entire area:		
Nonroad	94.43	96.73
Onroad	129.41	258.94
Point	51.33	146.39
Area	225.47	97.50
Total	500.64	599.57

2. Maintenance Demonstration

IDEM is demonstrating maintenance through 2028 by showing that future emissions of VOC and NO_X for the Indianapolis, La Porte County, South Bend-Elkhart, and Louisville areas remain at or below attainment year emission levels. 2028 is an appropriate maintenance year for these areas because it is more than 10 years beyond the first 10-year maintenance period. The 2028 emissions inventory is projected from the EPA's 2011 version 6.3 modeling platform.[9] The 2028 scenario was used to support past air quality modeling to support the regional haze program. The 2028 summer day emissions inventory for the Indianapolis, La Porte County, South Bend-Elkhart, and Louisville areas are summarized in Tables 7 through 10 below.

TABLE 7—INDIANAPOLIS AREA TYPICAL SUMMER DAY VOC AND NO_X EMISSIONS FOR MAINTENANCE YEAR 2028 (tpd)

Source category	VOC	NO_X
Nonroad	17.71	13.93
Onroad	15.95	28.53
Point	6.59	24.30
Area	51.46	13.34
Total	91.71	80.10

TABLE 8—LA PORTE COUNTY AREA TYPICAL SUMMER DAY VOC AND NO_X EMISSIONS FOR MAINTENANCE YEAR 2028 (tpd)

Source category	VOC	NO_X
Nonroad	1.69	1.41
Onroad	1.12	2.94
Point	1.28	0.53
Area	4.10	2.71
Total	8.19	7.65

TABLE 9—SOUTH BEND-ELKHART AREA TYPICAL SUMMER DAY VOC AND NO_X EMISSIONS FOR MAINTENANCE YEAR 2028 (tpd)

Source category	VOC	NO_X
Nonroad	4.44	3.56
Onroad	3.34	5.09
Point	7.46	4.12
Area	14.26	4.90
Total	29.50	17.67

TABLE 10—LOUISVILLE AREA TYPICAL SUMMER DAY VOC AND NO_X EMISSIONS FOR MAINTENANCE YEAR 2028

Source category	VOC	NO_X
Indiana portion of area (Clark and Floyd counties):		
Nonroad	1.59	1.14
Onroad	1.25	2.77
Point	1.70	6.72

[9] The inventory documentation for this platform can be found here: *https://www.epa.gov/air-emissions-modeling/2011-version-63-platform.*

TABLE 10—LOUISVILLE AREA TYPICAL SUMMER DAY VOC AND NO_X EMISSIONS FOR MAINTENANCE YEAR 2028—Continued

Source category	VOC	NO_X
Area	5.57	1.11
Total	10.11	11.74
Entire area:		
Nonroad	7.94	5.76
Onroad	6.45	12.78
Point	30.58	27.42
Area	30.29	10.33
Total	75.26	56.29

In addition, IDEM is demonstrating maintenance through 2030 by showing that future emissions of VOC and NO_X for the Cincinnati and Chicago areas remain at or below attainment year emission levels. 2030 is an appropriate maintenance year for these areas because it is more than 10 years beyond the first 10-year maintenance period. Indiana projected emissions to the year 2030 from EPA's 2028 emissions projected using the EPA's 2011 version 6.3 model platform. The 2030 summer day emissions inventory for Cincinnati and Chicago areas are summarized in Tables 11 through 12 below.

TABLE 11—CINCINNATI AREA TYPICAL SUMMER DAY VOC AND NO_X EMISSIONS FOR MAINTENANCE YEAR 2030 (tpd)

Source category	VOC	NO_X
Indiana portion of area (Dearborn county):		
Nonroad	0.34	0.25
Onroad	0.34	0.65
Point	3.94	1.79
Area	1.35	0.34
Total	5.97	3.03
Entire area:		
Nonroad	17.30	8.72
Onroad	9.71	16.11
Point	15.25	41.24
Area	47.73	14.71
Total	89.99	80.78

TABLE 12—CHICAGO AREA TYPICAL SUMMER DAY VOC AND NO_X EMISSIONS FOR MAINTENANCE YEAR 2030 (tpd)

Source category	VOC	NO_X
Indiana portion of area (Lake and Porter counties):		
Nonroad	8.81	9.73
Onroad	3.12	6.73
Point	17.61	67.99
Area	15.88	5.38
Total	45.42	89.83
Entire area:		
Nonroad	91.81	70.01
Onroad	22.80	71.23
Point	57.95	141.46
Area	201.20	71.37
Total	373.76	354.07

Tables 13 through 18 below show the changes in VOC and NO_X emissions between the attainment year (2014) and maintenance year (2028 or 2030) for each maintenance area.

TABLE 13—CHANGE IN TYPICAL SUMMER DAY VOC AND NO_X EMISSIONS IN THE INDIANAPOLIS AREA BETWEEN 2014 AND 2028 (tpd)

Source category	VOC			NO_X		
	2014	2028	Net change (2014–2028)	2014	2028	Net change (2014–2028)
Nonroad	20.21	17.71	−2.50	27.64	13.93	−13.71
Onroad	53.04	15.95	−37.09	110.53	28.53	−82.00
Point	5.31	6.59	1.28	29.68	24.30	−5.38
Area	66.47	51.46	−15.01	9.26	13.34	4.08
Total	145.03	91.71	−53.32	177.11	80.10	−97.01

TABLE 14—CHANGE IN TYPICAL SUMMER DAY VOC AND NO_X EMISSIONS IN THE LA PORTE AREA BETWEEN 2014 AND 2028 (tpd)

Source category	VOC			NO_X		
	2014	2028	Net change (2014–2028)	2014	2028	Net change (2014–2028)
Nonroad	2.83	1.69	−1.14	2.42	1.41	−1.01
Onroad	3.96	1.12	−2.84	10.55	2.94	−7.61
Point	1.33	1.28	−0.05	3.83	0.53	−3.30
Area	5.73	4.1	−1.63	4.46	2.77	−1.69
Total	13.85	8.19	−5.66	21.26	7.65	−13.61

TABLE 15—CHANGE IN TYPICAL SUMMER DAY VOC AND NO_X EMISSIONS IN THE SOUTH BEND-ELKHART AREA BETWEEN 2014 AND 2028 (tpd)

Source category	VOC			NO_X		
	2014	2028	Net change (2014–2028)	2014	2028	Net change (2014–2028)
Nonroad	5.74	4.44	−1.30	6.64	3.56	−3.08
Onroad	12.66	3.34	−9.32	23.35	5.09	−18.26
Point	6.23	7.46	1.23	2.71	4.12	1.41
Area	22.86	14.26	−8.60	6.14	4.90	−1.24
Total	47.49	29.50	−17.99	38.84	17.67	−21.17

TABLE 16—CHANGE IN TYPICAL SUMMER DAY VOC AND NO_X EMISSIONS IN THE LOUISVILLE AREA BETWEEN 2014 AND 2028 (tpd)

Source category	VOC			NO_X		
	2014	2028	Net change (2014–2028)	2014	2028	Net change (2014–2028)
Indiana portion of the area (Clark and Floyd counties)						
Nonroad	1.99	1.59	−0.40	2.19	1.14	−1.05
Onroad	4.38	1.25	−3.58	12.31	2.77	−9.54
Point	2.02	1.70	−0.32	4.60	6.72	2.12
Area	9.70	5.57	−4.13	0.95	1.11	0.16
Total	18.54	10.11	−8.43	20.05	11.74	−8.31
Entire Area						
Nonroad	9.61	7.94	−1.67	10.98	5.76	−5.22
Onroad	25.03	6.45	−18.58	52.13	12.78	−39.35
Point	32.49	30.58	−1.91	59.71	27.42	−32.29
Area	50.94	30.29	−20.65	10.27	10.33	0.06
Total	118.07	75.26	−42.81	133.09	56.29	−76.80

TABLE 17—CHANGE IN TYPICAL SUMMER DAY VOC AND NO_X EMISSIONS IN THE CINCINNATI AREA BETWEEN 2014 AND 2030 (tpd)

Source category	VOC			NO_X		
	2014	2030	Net change (2014–2030)	2014	2028	Net change (2014–2030)
Indiana portion of the area (Dearborn County)						
Nonroad	0.47	0.34	−0.13	0.53	0.25	−0.28
Onroad	1.76	0.34	−1.42	3.94	0.65	−3.29
Point	5.54	3.94	−1.60	9.62	1.79	−7.83
Area	1.39	1.35	−0.04	0.20	0.34	0.14
Total	9.16	5.97	−3.19	14.29	3.03	−11.26
Entire Area						
Nonroad	20.39	17.30	−3.09	22.30	8.72	−13.58
Onroad	39.23	9.71	−29.52	82.20	16.11	−66.09
Point	15.73	15.25	−0.48	91.69	41.24	−50.45
Area	79.97	47.73	−32.24	20.60	14.71	−5.89
Total	155.32	89.99	−65.33	216.79	80.78	−136.01

TABLE 18—CHANGE IN TYPICAL SUMMER DAY VOC AND NO_X EMISSIONS IN THE CHICAGO AREA BETWEEN 2014 AND 2030 (tpd)

Source category	VOC			NO_X		
	2014	2030	Net change (2014–2030)	2014	2028	Net Change (2014–2030)
Indiana portion of the area (Lake and Porter counties)						
Nonroad	18.08	8.81	−9.27	15.66	9.73	−5.93
Onroad	11.59	3.12	−8.47	28.05	6.73	−21.32
Point	12.99	17.61	4.62	71.24	67.99	−3.25
Area	20.00	15.88	−4.12	12.52	5.38	−7.14
Total	62.66	45.42	−17.24	127.47	89.83	−37.64
Entire Area						
Nonroad	94.43	91.81	−2.62	96.73	70.01	−26.72
Onroad	129.41	22.80	−106.61	258.94	71.23	−187.71
Point	51.33	57.95	6.62	146.39	141.46	−4.93
Area	225.47	201.20	−24.27	97.50	71.37	−26.13
Total	500.64	373.76	−126.88	599.57	354.07	−245.49

The maintenance demonstrations for the Indianapolis, La Porte County, South Bend-Elkhart, and the Indiana portions of the Chicago, Cincinnati, and Louisville areas show maintenance of the 1997 ozone NAAQS by providing emissions information to support the demonstration that future emissions of NO_X and VOC will remain at or below 2014 emission levels when considering both future source growth and implementation of future controls.

3. Continued Air Quality Monitoring

IDEM has committed to continue to operate an approved ozone monitoring network in the Indianapolis, La Porte County, South Bend-Elkhart, Chicago, and Louisville areas.[10] IDEM has committed to consult with EPA prior to making changes to the existing monitoring network should changes become necessary in the future. IDEM remains obligated to meet monitoring requirements and continue to quality assure monitoring data in accordance with 40 CFR part 58, and to enter all data into the Air Quality System in accordance with Federal guidelines.

4. Verification of Continued Attainment

The State of Indiana has confirmed that it has the legal authority to enforce and implement the requirements of the maintenance plans for the areas addressed in this action. This includes the authority to adopt, implement, and enforce any subsequent emission control measures determined to be necessary to correct future ozone attainment problems.

Verification of continued attainment is accomplished through operation of the ambient ozone monitoring network and the periodic update of the areas' emissions inventories. IDEM has committed to continue to operate an approved ozone monitoring network in the Indianapolis, La Porte County, South Bend-Elkhart, Chicago, Cincinnati, and Louisville maintenance areas. IDEM will not discontinue

[10] Indiana does not have any ozone monitoring site located within their portion of the Cincinnati maintenance area. Indiana will consult with EPA should changes become necessary.

operation, relocate, or otherwise change the existing ozone monitoring network other than through revisions in the network approved by EPA.

In addition, to track future levels of emissions, IDEM has committed to continue to develop and submit to EPA updated emission inventories for all source categories at least once every three years, consistent with the requirements of 40 CFR part 51, subpart A, and in 40 CFR 51.122.

5. Contingency Plan

Section 175A of the CAA requires that the state must adopt a maintenance plan, as a SIP revision, that includes such contingency measures as EPA deems necessary to assure that the state will promptly correct a violation of the NAAQS that occurs after redesignation of the area to attainment of the NAAQS. The maintenance plan must identify: The contingency measures to be considered and, if needed for maintenance, adopted and implemented; a schedule and procedure for adoption and implementation; and, a time limit for action by the state. The state should also identify specific indicators to be used to determine when the contingency measures need to be considered, adopted, and implemented. The maintenance plan must include a commitment that the state will implement all measures with respect to the control of the pollutant that were contained in the SIP before redesignation of the area to attainment in accordance with section 175A(d) of the CAA.

As required by section 175A of the CAA, Indiana has adopted a contingency plan for the Indianapolis, La Porte County, South Bend-Elkhart, Chicago, Cincinnati, and Louisville maintenance areas to address possible future ozone air quality problems. The contingency plan adopted by Indiana has two levels of response, a warning level response and an action level response.

In Indiana's plan, a warning level response will be triggered when an annual fourth high monitored value of 0.088 ppm or higher is monitored within the maintenance area. A warning level response will consist of IDEM conducting a study to determine whether the ozone value indicates a trend toward higher ozone values or whether emissions appear to be increasing. The study will evaluate whether the trend, if any, is likely to continue and, if so, the control measures necessary to reverse the trend. The study will consider ease and timing of implementation as well as economic and social impacts. Implementation of necessary controls in response to a warning level response trigger will take place within 12 months from the conclusion of the most recent ozone season.

In Indiana's plan, an action level response is triggered when a two-year average fourth high value of 0.084 ppm or greater is monitored within the maintenance area. A violation of the 1997 ozone standard within the maintenance area also triggers an action level response. In the event that the action level is triggered and is not found to be due to an exceptional event, malfunction, or noncompliance with a permit condition or rule requirement, IDEM will determine what additional control measures are needed to assure future attainment of the ozone standard. Control measures selected will be adopted and implemented within 18 months from the close of the ozone season that prompted the action level. IDEM may also consider if significant new regulations not currently included as part of the maintenance provisions will be implemented in a timely manner and would thus constitute an adequate contingency measure response.

IDEM included the following list of potential contingency measures in its maintenance plan for the Indianapolis, La Porte County, South Bend-Elkhart, Cincinnati, and Louisville areas:

1. Lower reid vapor pressure gasoline program.
2. Broaden the geographic applicability of existing measures.
3. Adoption of VOC reasonably available control technology (RACT) on existing sources covered by EPA Control Technique Guidelines issued after the 1990 CAA.
4. Application of VOC RACT to smaller existing sources.
5. Application of modern vehicle inspection/maintenance program.
6. Requirements for one or more transportation control measures sufficient to achieve at least half a percent reduction in actual area wide VOC emissions. Transportation measures will be selected from the following, based upon the factors listed above after consultation with affected local governments:

a. Trip reduction programs, including, but not limited to, employer-based transportation management plans, area wide rideshare programs, work schedule changes, and telecommuting;

b. traffic flow and transit improvements; and

c. other new or innovative transportation measures not yet in widespread use that affected local governments deem appropriate.

7. Application of alternative fuel and diesel retrofit programs for fleet vehicle operations.
8. Requirements for controls on consumer products consistent with those adopted elsewhere in the United States.
9. Requirements of VOC or NO_X emission offsets for new and modified major sources.
10. Requirements of VOC or NO_X emission offsets for new and modified minor sources.
11. Increasing the ratio of emission offsets required for new sources.
12. Requirements for VOC or NO_X controls on new minor sources.

IDEM included the following list of potential contingency measures in its maintenance plan for the Chicago area:

(1) Requirements for enhancements to the vehicle emission testing program (increased weight limit, addition of diesel vehicles, etc.).
(2) Asphalt paving (lower VOC formulation).
(3) Diesel exhaust retrofits.
(4) Traffic flow improvements.
(5) Idle reduction programs.
(6) Adoption of portable fuel container regulations (state-wide).
(7) Park and ride facilities.
(8) Rideshare/carpool program.
(9) Requirements for VOC capture/trade program for major stationary sources.
(10) Application of NO_X RACT.

To qualify as a contingency measure, emissions reductions from that measure must not be factored into the emissions projections used in the maintenance plan.

EPA has concluded that Indiana's maintenance plan adequately addresses the five basic components of a maintenance plan. Thus, EPA finds that the maintenance plan SIP revisions submitted by IDEM for the Indianapolis, La Porte County, and South Bend-Elkhart areas and the Indiana portions of the Chicago, Cincinnati, and Louisville areas meet the requirements of section 175A of the CAA.

B. Transportation Conformity

Transportation conformity is required by section 176(c) of the CAA. Conformity to a SIP means that transportation activities will not produce new air quality violations, worsen existing violations, or delay timely attainment of the NAAQS (CAA 176(c)(1)(B)). EPA's conformity rule at 40 CFR part 93 requires that transportation plans, programs and projects conform to SIPs and establish the criteria and procedures for determining whether they conform. The conformity rule generally requires a

demonstration that emissions from the Regional Transportation Plan and the Transportation Improvement Program (TIP) are consistent with the motor vehicle emissions budget (MVEB) contained in the control strategy SIP revision or maintenance plan (40 CFR 93.101, 93.118, and 93.124). A MVEB is defined as ''that portion of the total allowable emissions defined in the submitted or approved control strategy implementation plan revision or maintenance plan for a certain date for the purpose of meeting reasonable further progress milestones or demonstrating attainment or maintenance of the NAAQS, for any criteria pollutant or its precursors, allocated to highway and transit vehicle use and emissions'' (40 CFR 93.101).

The South Coast II court decision upheld EPA's revocation of the 1997 ozone NAAQS, which was effective on April 6, 2015. EPA's current transportation conformity regulation requires a regional emissions analysis only during the time period beginning one year after a nonattainment designation for a particular NAAQS until the effective date of revocation of that NAAQS (40 CFR 93.109(c)). Therefore, pursuant to the conformity regulation, a regional emissions analysis using MVEBs is not required for conformity determinations for the 1997 ozone NAAQS because that NAAQS has been revoked (80 FR 12264). As no regional emissions analysis is required for the maintenance areas in Indiana, transportation conformity for the 1997 ozone NAAQS can be demonstrated by a Metropolitan Planning Organization and the State's Department of Transportation for transportation plans and TIPs by showing that the remaining criteria contained in Table 1 in 40 CFR 93.109, and 40 CFR 93.108 have been met.

IV. Proposed Action

Under section 175A of the CAA and for the reasons set forth above, based on Indiana's representations and commitments set forth above, EPA is proposing to approve the second maintenance plans for the 1997 ozone NAAQS for the Indianapolis, La Porte County, and South Bend-Elkhart areas and the Indiana portions of the Chicago, Cincinnati, and Louisville areas, submitted by IDEM on June 20, 2019, as a revision to the Indiana SIP. These maintenance plans are designed to keep these areas in attainment of the 1997 ozone NAAQS through the second 10-year maintenance period.

V. Statutory and Executive Order Reviews

Under the CAA, 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 proposed 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 proposed 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);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because it is not a significant regulatory action under Executive Order 12866;
- 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 disproportionate human health or environmental effects with practical, appropriate, 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).

List of Subjects in 40 CFR Part 52

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

Dated: September 11, 2019.

Cheryl L. Newton,

Acting Regional Administrator, Region 5.

[FR Doc. 2019–20846 Filed 9–24–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R01–OAR–2019–0348; FRL–10000–09-Region 1]

Air Plan Approval; Connecticut; Regional Haze Five Year Progress Report

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve the Connecticut regional haze progress report submitted as a State Implementation Plan (SIP) revision on June 30, 2015. This revision addresses the provisions of the Clean Air Act and its implementing regulations that require states to submit periodic reports describing progress on reasonable progress goals established for regional haze and a determination of adequacy of the state's existing regional haze SIP. Connecticut's progress report notes that Connecticut has made substantial progress toward meeting the emissions reduction expected for the first regional planning period. The report also notes that visibility in the federal Class I areas that may be affected by emissions from Connecticut is improving. In addition, the nearby federal Class I areas have already met the applicable reasonable progress goals for 2018. The EPA is proposing approval of Connecticut's determination that the state's existing regional haze SIP requires no further substantive revision at this time in order to achieve the goals for visibility improvement and emission reductions.

DATES: Written comments must be received on or before October 25, 2019.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R01–OAR–2019–0348 at *https://www.regulations.gov.* For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. For either manner of submission, the 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. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www.epa.gov/dockets/commenting-epa-dockets.* Publicly available docket materials are available at *https://www.regulations.gov* or at the U.S. Environmental Protection Agency, EPA Region 1 Regional Office, Office of Air and Radiation, Air Quality Branch, 5 Post Office Square—Suite 100, Boston, MA. EPA requests that if at all possible, you contact the contact listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Anne K. McWilliams, Air Quality Branch, U.S. Environmental Protection Agency, EPA Region 1, 5 Post Office Square—Suite 100, (Mail code 05–2), Boston, MA 02109—3912, tel. (617) 918–1697, email *mcwilliams.anne@epa.gov.*

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

Table of Contents

I. Background and Purpose
II. EPA's Evaluation of Connecticut's SIP Revision
A. Regional Haze Progress Report
B. Determination of Adequacy of Existing Regional Haze Plan
III. Proposed Action
IV. Statutory and Executive Order Reviews

I. Background and Purpose

States are required to submit a progress report in the form of a SIP revision that evaluates progress towards the reasonable progress goals (RPGs) for each mandatory Class I federal area [1] (Class I area) within the state and each Class I area outside the state which may be affected by emissions from within the state [40 CFR 51.308(g)]. In addition, the provisions of 40 CFR 51.308(h) require states to submit, at the same time as the 40 CFR 51.308(g) progress report, a determination of adequacy of the state's existing regional haze SIP. The progress report SIP for the first planning period is due five years after submittal of the initial regional haze SIP. On November 19, 2009, Connecticut submitted the state's first regional haze SIP in accordance with 40 CFR 51.308.[2] On June 30, 2015, Connecticut submitted, as a revision to its SIP, a progress report which details the progress made in the first planning period toward the implementation of the Long Term Strategy (LTS) outlined in the 2009 regional haze submittal, the visibility improvement measured at Class I areas that may be affected by emissions from Connecticut, and a determination of the adequacy of the state's existing regional haze SIP. The EPA is proposing to approve Connecticut's June 30, 2015 submittal.

II. EPA's Evaluation of Connecticut's SIP Revision

Connecticut submitted a SIP revision that contained a report on progress made in the first implementation period toward reasonable progress goals for all Class I areas that may be affected by emissions from sources in the state (also known as a regional haze five-year progress report). This progress report SIP submittal also included a determination that the state's existing regional haze SIP requires no further substantive revisions at this time in order to achieve the established goals for visibility improvement and emissions reductions for 2018. Connecticut is a member of the Mid-Atlantic/Northeast Visibility Union (MANE–VU).[3] The MANE–VU area contains seven Class I areas in four states: Moosehorn Wilderness Area, Acadia National Park, and Roosevelt Campobello International Park in Maine; Presidential Range/Dry River Wilderness Area and Great Gulf Wilderness Area in New Hampshire; Brigantine Wilderness Area in New Jersey; and Lye Brook Wilderness Area in Vermont. There are no Class I areas in Connecticut. Through source apportionment modeling, MANE–VU assisted states in determining their contribution to the visibility impairment of each Class I area in the MANE–VU region and nearby Class I areas outside of MANE–VU.

However, as a member of MAVE–VU, Connecticut agreed to reduce emissions by at least the amount obtained by the measures in the coordinated course of action established by MANE–VU. These strategies, designed to assure reasonable progress toward preventing any future, and remedying any existing anthropogenic visibility in the mandatory Class I areas within the MANE–VU region, are commonly referred to as the MANE–VU ''ask.'' This request (or ''ask'') includes: a timely implementation of the best available retrofit technology (BART) requirements, 90 percent or more reduction in sulfur dioxide (SO_2) at 167 electrical generating units (EGUs or ''units'') identified by MANE–VU (or comparable alternative measures),[4] lower sulfur fuels requirement (with limits specified for each state) and continued evaluation of other control measures.[5] In brief, Connecticut is on track to fulfill the MANE–VU ''ask'' by implementing the lower sulfur fuels strategy and adopting and implementing an alternative to BART.

[1] Areas designated as mandatory Class I federal areas consist of national parks exceeding 6,000 acres, wilderness areas and national memorial parks exceeding 5,000 acres, and all international parks that were in existence on August 7, 1977 (42 U.S.C. 7472(a)). Listed at 40 CFR part 81, subpart D.

[2] On April 26, 2013, EPA approved the Connecticut regional haze SIP submittal. See 79 FR 39322, July 10, 2014.

[3] MANE–VU is a collaborative effort of the state governments, Tribal governments, and various federal agencies established to initiate and coordinate activities associated with the management of regional haze, visibility and other air quality issues in the Northeastern United States. Member state and tribal governments include: Connecticut, Delaware, the District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Penobscot Indian Nation, Rhode Island, St. Regis Mohawk Tribe and Vermont.

[4] Connecticut was not found to have any of the MANE–VU identified 167 EGU stacks.

[5] The MANE–VU ''ask'' was structured around the finding that SO_2 emissions were the dominate visibility impairing pollutant at Northeastern Class I areas and electrical generating units comprised the largest SO_2 emission sector. See Northeast States for Coordinated Air Use Management (NESCAUM), ''Regional Haze and Visibility in the Northeast and Mid-Atlantic States'' (January 31, 2001), *available at https://www.nescaum.org/documents/regional-haze-and-visibility-in-the-northeast-and-mid-atlantic-states/#.*

A. Regional Haze Progress Report

This section includes the EPA's analysis of Connecticut's progress report SIP submittal and an explanation of the basis of the proposed approval.

The 2009 Connecticut regional haze SIP included these key measures: (1) The adoption of low sulfur fuels requirements for residual and distillate oil for heating and off-road diesel, and (2) an EGU alternative to BART. EPA's analysis of the Connecticut regional haze SIP for the first planning period can be found at 78 FR 5158 (January 24, 2013). Connecticut's low sulfur fuels requirements may be found in the Regulations of Connecticut State Agencies (RCSA) sections 22a–174–19, 22a–174–19a and 22a–174–19b and Connecticut General Statute (CGS) section 16a–21a.[6]

Rather than implementing BART, Connecticut chose to implement an alternative to BART that was determined to achieve greater progress toward natural visibility conditions than BART. The Connecticut alternative to BART applies not only to the original seven BART units, but also to an additional 66 units in the state. *See* 77 FR 17373 (March 26, 2012). Since the 2009 SIP submittal, 15 units have been added to the alternative to BART program and six units have retired. However, the 73 alternative to BART units only emitted a total of 1,491 tons of SO_2 in 2014, which is 11.5% of the 13,005 tons of SO_2 from the original 53 units identified as subject to BART in 2002.[7] Similarly, for nitrogen oxides (NO_X), the alternative to BART program has achieved a 3,947 ton, or 66%, reduction in NO_X emissions between 2002 and 2014.

The Connecticut alternative to BART for NO_X relies in large part on non-ozone season NOx limits and Reasonable Available Control Technology (RACT) determinations. At the time of EPA's rulemaking on the Connecticut regional haze SIP, the Clean Air Interstate Rule (CAIR) was still in effect, and the state's NO_X BART alternative relied, in part, on the ozone season CAIR. CAIR represented a small part of Connecticut's BART alternative, and Connecticut's actual ozone season NO_X emissions from the BART alternative sources are currently below the levels contemplated by CAIR. Additional discussion can be found in the preamble to the EPA's final approval of the Connecticut's regional haze plan. *See* 79 FR 39322 (July 10, 2014).

In August 2011, the federal CAIR program was replaced by the federal Cross State Air Pollution Rule (CSAPR). 76 FR 48208 (August 8, 2011). CSAPR did not include Connecticut in its ozone season program because EPA analyses showed that the state does not emit ozone-season NO_X at a level that contributes significantly to non-attainment, or interferes with maintenance, of the 1997 ozone National Ambient Air Quality Standards (NAAQS) in any other state. EPA made the same finding when it promulgated the CSAPR Update for the 2008 ozone NAAQS. 81 FR 74504 (October 26, 2016).

While EPA is no longer implementing the ozone-season CAIR, Connecticut's 2014 total annual NO_X emissions from the alternative to BART sources were 1,954 tons, substantially less than the previous CAIR ozone-season cap of 2,691 tons NO_X. It should be noted that Connecticut's alternative to BART sources are still subject to non-ozone season NO_X limits and RACT determinations.

EPA is proposing approval of Connecticut's determination that the existing implementation plan requires no further substantive revision at this time in order to achieve the goals for visibility improvement and emissions reductions. While Connecticut does not contribute to visibility impairment in any Class I area, Connecticut is making progress toward attaining the state's estimated LTS emission reductions.

During the development of the regional haze SIP for the first planning period, MANE–VU and Connecticut determined that SO_2 was the greatest contributor to anthropogenic visibility impairment at nearby Class I areas. Therefore, the bulk of the visibility improvement achieved in the first planning period was expected to be from the reductions of SO_2 emissions. Table 4.1 of the 2015 progress report presents data from statewide Connecticut emission inventories developed for the years 2002, 2008, 2011 and projected inventories for 2018 for SO_2, NO_X, volatile organic compounds (VOCs),[8] and fine particulates with a diameter less than 2.5 micrometers ($PM_{2.5}$). From 2002 to 2011, the state achieved an overall 60% reduction in SO_2 emissions from 38,534 tons per year to 15,333 tons per year. Area sources[9] comprise the largest portion of the Connecticut SO_2 inventory (18,454 tons SO_2 in 2002). While SO_2 emission reductions achieved by 2011 do not meet the projection for 2018, once lower sulfur home heating oil is fully implemented, we expect additional SO_2 reductions from the area source sector.

For NO_X, total emissions were reduced from 115,213 tons NO_X per year to 72,828 tons NO_X per year[10] from 2002 to 2011. For the point source[11] sector, from 2002 to 2011, NO_X emissions were reduced from 12,868 tons per year to 6,403 tons per year, meeting the 2018 projection of 10,919 tons per year. While overall NO_X reductions achieved by 2011 do not meet the estimate for 2018, additional reduction is expected to result from motor vehicle fleet turnover between 2011 and 2018.

Finally, from 2002 to 2011, point source $PM_{2.5}$ emissions were reduced from 17,363 tons per year to 16,545 tons per year. While $PM_{2.5}$ emissions from area sources increased slightly during this period, additional reductions are expected with the implementation of lower sulfur in fuel oil.

EPA finds that Connecticut has adequately addressed the applicable provisions under 40 CFR 51.308(g). Connecticut compared the most recently updated emission inventory data available at the time of the development of the progress report with baseline emissions inventory data from its regional haze SIP. The progress report adequately details the 2011 SO_2, NO_X, and $PM_{2.5}$ reductions achieved by sector thus far in the regional haze planning period.

The provisions under 40 CFR 51.308(g) also require states with Class I areas within their borders to provide information on current visibility conditions and on the difference between current visibility conditions and baseline visibility conditions expressed in terms of five-year averages of these annual values. Connecticut has

[6] *See* 81 FR 33134 (May 25, 2016), 79 FR 39322 (July 10, 2014), and 81 FR 35626 (July 3, 2016).

[7] The SO_2 alternative to BART strategy reduces the sulfur in fuel oil requirements for subject sources from 0.5% sulfur residual oil to 0.3% sulfur residual oil. *See* 77 FR 17373 (March 26, 2012).

[8] VOCs were not found to contribute substantially to visibility impairment in the East.

[9] An area source means any small residential, governmental, institutional, commercial, or industrial fuel combustion operations; onsite solid waste disposal facility; motor vehicles, aircraft vessels, or other transportation facilities or other miscellaneous sources identified through inventory techniques similar to those described in the ''AEROS Manual series, Vol. II AEROS User's Manual,'' EPA–450/2–76–029 December 1976. *See* 40 CFR 51.100(l)

[10] The on-road sector is the dominate source of NO_X emissions. In 2011, the on-road sector accounted for 36,659 tons NO_X emissions.

[11] A point source is any stationary source in which the actual emissions are in excess of 100 tons per year of a pollutant in a region containing an area whose 1980 urban place population was greater than one million or any stationary source with actual emissions in excess of 25 tons per year in an area with a 1980 urban place population less than one million. *See* 40 CFR 51.100(k).

no Class I areas, but the Class I areas that may be affected by emissions from Connecticut have visibility conditions better than baseline conditions and conditions predicted for 2018. The Interagency Visual Environmental monitoring program (IMPROVE) [12] provides data on the air pollutants that constitute regional haze. Tables 1 and 2 below show the progress from the five-year average visibility of the 2000 to 2004 baseline period through the most recent 2009 to 2013 five-year period for the 20% haziest days and 20% clearest days. Connecticut concludes that all the included Class I areas are on track to meet the 2018 reasonable progress goals.

EPA notes the substantial improvement in visibility at the MANE–VU Class I areas. These Class I areas have already met the reasonable progress goals for the first regional haze planning period.

In its progress report SIP, Connecticut concludes the elements and strategies relied on in its original regional haze SIP are adequate to enable neighboring states to meet all established RPGs.

TABLE 1—20% HAZIEST DAYS BASELINE, REASONABLE PROGRESS GOALS, AND OBSERVED VISIBILITY IN DECIVIEWS (dv)

Class I area IMPROVE * site	Baseline (2000–2004)	Reasonable progress goal (2018)	5-Year average observed (2009–2013)	Met the 2018 progress goal?
Acadia National Park (ME)	22.9	19.4	17.93	Yes.
Brigantine Wilderness (NJ)	29.01	25.1	23.75	Yes.
Great Gulf Wilderness (NH)	22.8	19.1	16.66	Yes.
Presidential Range-Dry River Wilderness (NH).				
Lye Brook Wilderness (VT)	24.4	20.9	18.78	Yes.
Moosehorn Wilderness (ME)	21.7	19.0	16.83	Yes.
Roosevelt Campobello International Park (ME).				

TABLE 2—20% CLEANEST DAYS BASELINE, REASONABLE PROGRESS GOALS, AND OBSERVED VISIBILITY IN DECIVIEWS (dv)

Class I area IMPROVE * site	Baseline (2000–2004)	Reasonable progress goal (2018)	5-Year average observed (2009–2013)	Met the 2018 progress goal?
Acadia National Park (ME)	8.78	8.3	7.02	Yes.
Brigantine Wilderness (NJ)	14.33	14.3	12.25	Yes.
Great Gulf Wilderness (NH)	7.7	7.2	5.86	Yes.
Presidential Range-Dry River Wilderness (NH).				
Lye Brook Wilderness (VT)	6.4	5.5	4.9	Yes.
Moosehorn Wilderness (ME)	9.2	8.6	6.7	Yes.
Roosevelt Campobello International Park (ME).				

* Data from NESCAUM, *Tracking Visibility Progress 2004–2011* (April 30, 2013, rev. May 24, 2014*), available at http://www.nescaum.org/documents/manevu-trends-2004-2011-report-final-20130430.pdf/.*

EPA proposes to conclude that Connecticut has adequately addressed the provisions of 40 CFR 51.308(g). The progress report compared the most recent updated emission inventory data available at the time of the development of the progress report with the baseline emissions used in the modeling for the regional haze SIP. In its progress report, Connecticut described improving visibility trends using data from the IMPROVE network and the downward emission trend of key pollutants in the state.

Connecticut does not have any Class I areas and is not required to monitor for visibility-impairing pollutants. The Connecticut visibility monitoring strategy relies upon Class I area participation in the IMPROVE network. EPA proposes to find that Connecticut has adequately addressed the requirements for a monitoring strategy for regional haze purposes to determine no further modifications to the monitoring program are necessary.

B. Determination of Adequacy of Existing Regional Haze Plan

In its progress report, Connecticut submitted a negative declaration to EPA regarding the need for additional actions or emission reductions in Connecticut beyond those already in place and those to be implemented by 2018 as detailed in the state's regional haze plan.

In the 2015 progress report submittal, Connecticut determined that the existing regional haze SIP needs no further substantive revision at this time to achieve the emission reductions expected for the first planning period. Emission reduction trends are on track to meet Connecticut's estimated 2018 emissions. Connecticut is implementing non-ozone season NO_X limits, revised RACT, and low sulfur fuel requirements. The state continues to evaluate additional NO_X control strategies; however, the 2011 total alternative to BART annual NO_X emission of 1,602 tons was well below the now defunct CAIR ozone season cap of 2,691 tons NO_X.

EPA proposes to conclude that Connecticut has adequately addressed the provisions under 40 CFR 51.308(h) because visibility trends at nearby Class I areas and Connecticut emission trends are on track to meet the goals for the first regional haze planning period. Therefore, no substantive revisions to the SIP are needed at this time to ensure that Connecticut meets its share of visibility improvement included in the downwind states' reasonable progress goals.

III. Proposed Action

EPA is proposing to approve Connecticut's June 30, 2015 determination that the existing

[12] *http://vista.cira.colostate.edu/improve/.*

implementation plan requires no further substantive revision at this time in order to achieve established goals for visibility improvement and emissions reductions. EPA is soliciting public comments on the issues discussed in this notice or on other relevant matters. These comments will be considered before taking final action. Interested parties may participate in the Federal rulemaking procedure by submitting written comments to this proposed rule by following the instructions listed in the **ADDRESSES** section of this **Federal Register**.

IV. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this proposed 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 proposed 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);
- Is not expected to be an Executive Order 13771 regulatory action because this action is not significant under Executive Order 12866;
- 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 Clean Air Act; 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).

List of Subjects in 40 CFR Part 52

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

Dated: September 19, 2019.

Dennis Deziel,

Regional Administrator, EPA Region 1.

[FR Doc. 2019–20778 Filed 9–24–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 191 and 194

[EPA–HQ–OAR–2019–0534; FRL–10000–12–OAR]

Review Process To Determine Whether the Waste Isolation Pilot Plant Continues To Comply With the Disposal Regulations and Compliance Criteria

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability; official opening of public comment period.

SUMMARY: The Environmental Protection Agency (EPA, or the Agency) intends to evaluate whether the Waste Isolation Pilot Plant (WIPP) continues to comply with the Agency's environmental radiation protection standards for the disposal of radioactive waste. Pursuant to the 1992 WIPP Land Withdrawal Act (LWA), as amended, the U.S. Department of Energy (DOE, or the Department) must submit documentation of continued compliance with the EPA's standards for disposal and other statutory requirements every five years after the initial receipt of transuranic waste at WIPP. The Agency requests public comment on all aspects of the DOE's application.

DATES: The comment period opened on September 25, 2019, and will remain open beyond the time when the EPA notifies the DOE that the recertification application is complete, which will be specified in a future **Federal Register** document. Announcements will be published in the **Federal Register** to provide information on the Agency's completeness determination and final recertification decision.

ADDRESSES: You may send comments, identified by Docket ID No. EPA–HQ–OAR–2019–0534, by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov/* (our preferred method). Follow the online instructions for submitting comments.
- *Email: a-and-r-Docket@epa.gov.* Include Docket ID No. EPA–HQ–OAR–2019–0534 in the subject line of the message.
- *Mail:* U.S. Environmental Protection Agency, Air and Radiation Docket, EPA Docket Center, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.
- *Hand Delivery/Courier:* EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Docket Center's hours of operations are 8:30 a.m.–4:30 p.m., Monday–Friday (except Federal Holidays).

Instructions: All submissions received must include the Docket ID No. for this notice of availability. Comments received may be posted without change to *https://www.regulations.gov/,* including any personal information provided. For detailed instructions and additional information on submitting comments, see the **SUPPLEMENTARY INFORMATION** section of this document.

A copy of the DOE's 2019 Compliance Recertification Application (CRA) is linked on the EPA's WIPP website (*https://www.epa.gov/radiation/certification-and-recertification-wipp#2019*).

FOR FURTHER INFORMATION CONTACT: Ray Lee, Office of Radiation and Indoor Air, Radiation Protection Division, Center for Radiation Information and Outreach, Mail Code 6608T, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, Washington, DC 20460; telephone number: 202–343–9463; fax

number: 202–343–2305; email address: *lee.raymond@epa.gov.*

SUPPLEMENTARY INFORMATION: The DOE's 2019 CRA was received by the EPA on March 19, 2019, and a copy is linked on the EPA's WIPP website in **ADDRESSES**. The EPA will determine when the DOE has provided a complete application; the Agency's completeness determination will be conveyed to the DOE and published in the **Federal Register**. The EPA will evaluate the ''complete'' application in determining whether the WIPP facility continues to comply with the radiation protection standards for disposal. The Agency requests public comment on all aspects of the DOE's application.

I. Public Participation

Written Comments

Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2019–0534, at *https://www.regulations.gov* (our preferred method), or the other methods identified in the **ADDRESSES** section. Once submitted, comments cannot be edited or removed from the docket. The 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. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

II. Background

The WIPP was authorized in 1980, under section 213 of the DOE National Security and Military Applications of Nuclear Energy Authorization Act of 1980 (Pub. L. 96–164, 93 Stat. 1259, 1265), ''for the express purpose of providing a research and development facility to demonstrate the safe disposal of radioactive wastes resulting from the defense activities and programs of the United States.'' The WIPP is a disposal system for transuranic (TRU) radioactive waste. Developed by the DOE, the facility is located near Carlsbad in southeastern New Mexico. TRU waste is emplaced 2,150 feet underground in an ancient layer of salt that will eventually ''creep'' and encapsulate the waste containers.

The 1992 WIPP LWA (Pub. L. 102–579) [1] limits radioactive waste disposal in the WIPP to TRU radioactive wastes generated by defense-related activities. TRU waste is defined as waste containing more than 100 nano-curies per gram of alpha-emitting radioactive isotopes, with half-lives greater than twenty years and atomic numbers greater than 92. The Act further stipulates that radioactive waste shall not be TRU waste if such waste also meets the definition of high-level radioactive waste, has been specifically exempted from regulation with the concurrence of the Administrator, or has been approved for an alternate method of disposal by the Nuclear Regulatory Commission. The TRU radioactive waste proposed for disposal in the WIPP consists of materials such as rags, equipment, tools, protective gear and sludges that have become contaminated during atomic energy defense activities. The radioactive component of TRU waste consists of man-made elements created during the process of nuclear fission, chiefly isotopes of plutonium. Some TRU waste is contaminated with hazardous wastes regulated under the Resource Conservation and Recovery Act (RCRA; 42 U.S.C. 6901–6992k). The waste proposed for disposal at the WIPP derives from Federal facilities across the United States, including locations in Colorado, Idaho, New Mexico, Nevada, Ohio, South Carolina, Tennessee and Washington.

The WIPP must meet the EPA's generic disposal standards at 40 CFR part 191, subparts B and C, for high-level and TRU radioactive waste. These standards limit releases of radioactive materials from disposal systems for radioactive waste and require implementation of measures to provide confidence for compliance with the radiation release limits. Additionally, the regulations limit radiation doses to members of the public and protect ground water resources by establishing maximum concentrations for radionuclides in ground water. To help in determining whether the WIPP facility meets these disposal standards, the Agency issued the 1997 WIPP Compliance Criteria (40 CFR part 194), which provides guidance for interpretation and implementation of the disposal standards specifically for the WIPP site. The Compliance Criteria—along with its accompanying preamble and supporting documents—describe what information the DOE must provide and how the EPA evaluates WIPP's performance and provides ongoing independent oversight. The Agency implements its environmental radiation protection standards, 40 CFR part 191, by applying the WIPP Compliance Criteria, 40 CFR part 194, to the disposal of TRU radioactive waste at the WIPP. For more information about 40 CFR part 191, refer to **Federal Register** documents published in 1985 (50 FR 38066, Sep. 19, 1985) and 1993 (58 FR 66398, Dec. 20, 1993). For more information about 40 CFR part 194, refer to **Federal Register** documents published in 1996 (61 FR 5224, Feb. 9, 1996) and 1995 (60 FR 5766, Jan. 30, 1995).

Using the process outlined in the WIPP Compliance Criteria, the EPA determined on May 18, 1998 (63 FR 27354), that the DOE had demonstrated that the WIPP complied with the Agency's radioactive waste disposal regulations at subparts B and C of 40 CFR part 191. The EPA's certification determination permitted the WIPP to begin accepting TRU waste for disposal, provided that other applicable conditions and environmental regulations were met.

Since the 1998 certification decision, the EPA has conducted ongoing independent technical review and inspections of all WIPP activities related to compliance with the Agency's disposal regulations. The initial certification decision identified the starting (baseline) conditions for the WIPP site and established the waste and facility characteristics necessary to ensure proper disposal in accordance with the regulations. At that time, the EPA and the DOE understood that future information and knowledge gained from the actual operations of the WIPP would result in changes to best practices and procedures for the facility.

In recognition of this, section 8(f) of the amended WIPP LWA requires the EPA to evaluate all changes in conditions or activities at the WIPP every five years to determine if the facility continues to comply with the Agency's disposal regulations. This determination is not subject to standard rulemaking procedures or judicial review, as stated in the aforementioned section of the WIPP LWA.

The first recertification process began with the DOE's submittal of the initial CRA, which was received by the Agency on March 26, 2004. The EPA deemed the CRA–2004 to be complete on

[1] The 1992 WIPP Land Withdrawal Act was amended by the ''Waste Isolation Pilot Plant Land Withdrawal Act Amendments,'' which were part of the National Defense Authorization Act for Fiscal Year 1997 (Pub. L. 104–201).

September 29, 2005, and published its first WIPP recertification decision on March 29, 2006 (71 FR 18010).

The EPA received the DOE's second CRA on March 24, 2009. The Agency deemed the CRA–2009 to be complete on June 29, 2010, and published the second WIPP recertification decision on November 18, 2010 (75 FR 70584).

The EPA received the Department's third CRA on March 26, 2014. The Agency deemed the CRA–2014 to be complete on March 10, 2017, and published the third WIPP recertification decision on July 10, 2017 (82 FR 33106).

The EPA received the Department's fourth CRA on March 19, 2019. After the EPA has determined that the application is complete, the Agency will review the CRA–2019 to ensure that all of the changes made at the WIPP since the third recertification process have been accurately reflected and that the facility will continue to safely contain TRU radioactive waste. An approved CRA–2019 (along with any supplemental completeness information submitted by the DOE) would serve as the baseline for the next recertification that will occur starting in 2024.

With today's notice, the Agency solicits public comment on the DOE's documentation of whether the WIPP facility continues to comply with the disposal regulations. An electronic copy of the application is available for review and linked on the EPA's WIPP website (*https://www.epa.gov/radiation/certification-and-recertification-wipp#2019*). Additional background information related to the Agency's recertification activities is available in the public dockets and on this website. The EPA will evaluate DOE's complete application and make a determination whether the WIPP continues to comply with the radiation protection standards for disposal. The EPA will consider public comment and other information relevant to the WIPP's compliance. The Agency is most interested in public comment on issues where changes to the disposal system have occurred that may potentially impact the WIPP's ability to remain in compliance with requirements in the EPA's disposal regulations, as well as any areas where the public believes that changes have occurred that have not been identified by the DOE.

The EPA's first step in the recertification process is a ''completeness'' determination of DOE's application. The EPA will make this completeness determination as a first step in its more extensive technical review of the application. This determination is based on a number of the Agency's WIPP-specific guidances, most notably, the ''Compliance Application Guidance'' (CAG; EPA Pub. 402–R–95–014) and ''Guidance to the U.S. Department of Energy on Preparation for Recertification of the Waste Isolation Pilot Plant with 40 CFR parts 191 and 194'' (Docket A–98–49, Item II–B3–14; December 12, 2000). Both guidance documents include guidelines regarding: (1) Content of certification/recertification applications; (2) documentation and format requirements; (3) time frame and evaluation process; and (4) change reporting and modification. The Agency developed these guidance documents to assist the DOE with the preparation of any compliance application for the WIPP. It is the EPA's intent that these guidance documents give the DOE and the public a general understanding of the information that is expected to be included in a ''complete'' application of compliance. However, the DOE does not have to resubmit information already supplied to the EPA in prior recertification applications. The focus of each recertification is on any changes to the disposal system since the previous recertification decision. The EPA may request additional information as necessary from the DOE to ensure the completeness of the CRA.

Once the 2019 recertification application is deemed complete, the EPA will provide the DOE with written notification of its completeness determination and publish a **Federal Register** document announcing this determination. All correspondence between the EPA and the DOE regarding the completeness of the CRA–2019, and any additional information sent by the DOE, such as the supplementary results and calculations planned for submittal in December 2019, will be placed in the public docket (via *www.regulations.gov*) and linked on the Agency's WIPP website (*https://www.epa.gov/radiation/certification-and-recertification-wipp#2019*).

The EPA will make a final decision as to whether the WIPP continues to meet the disposal regulations after each of the aforementioned steps (*i.e.,* technical analysis of the application, issuance of a notice on the CRA–2019's completeness in the **Federal Register**, and analyses of public comment) have been completed. As required by the LWA, the Agency will make a final recertification decision within six months of issuing its completeness determination.

List of Subjects in 40 CFR Parts 191 and 194

Environmental protection, Radiation protection, Transuranic radioactive waste, Waste isolation pilot plant, Waste treatment and disposal.

Dated: September 12, 2019.

Jonathan D. Edwards,

Director, Office of Radiation and Indoor Air.

[FR Doc. 2019–20319 Filed 9–24–19; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL MARITIME COMMISSION

46 CFR Part 545

[Docket No. 19–05]

RIN 3072–AC76

Interpretive Rule on Demurrage and Detention Under the Shipping Act

AGENCY: Federal Maritime Commission.

ACTION: Notice of proposed rulemaking; extension of comment period.

SUMMARY: The Federal Maritime Commission is seeking public comment on its interpretation of the Shipping Act prohibition against failing to establish, observe, and enforce just and reasonable regulations and practices relating to or connected with receiving, handling, storing, or delivering property with respect to demurrage and detention. Specifically, the Commission is providing guidance as to what it will consider in assessing whether a demurrage or detention practice is unjust or unreasonable. Upon consideration of the request of the Agriculture Transportation Coalition (AgTC), the Commission has determined to extend the comment period in this matter to October 31, 2019.

DATES: Comments on the notice of proposed rulemaking, published on September 17, 2019 (84 FR 48850), are due on or before October 31, 2019.

ADDRESSES: You may submit comments by the following methods:

- *Email: secretary@fmc.gov*. Include in the subject line: ''Docket 19–05, Demurrage & Detention Comments.'' Comments should be attached to the email as a Microsoft Word or text-searchable PDF document. Only non-confidential and public versions of confidential comments should be submitted by email.
- *Mail:* Rachel E. Dickon, Secretary, Federal Maritime Commission, 800 North Capitol Street NW, Washington, DC 20573–0001.

FOR FURTHER INFORMATION CONTACT: Rachel E. Dickon, Secretary; Phone:

(202) 523–5725; Email: *secretary@fmc.gov*.

Rachel Dickon,

Secretary.

[FR Doc. 2019–20790 Filed 9–24–19; 8:45 am]

BILLING CODE 6731–AA–P

Notices

Federal Register

Vol. 84, No. 186

Wednesday, September 25, 2019

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.

AGENCY FOR INTERNATIONAL DEVELOPMENT

Board for International Food and Agricultural Development Notice of Meeting; Correction

AGENCY: U.S. Agency for International Development.

ACTION: Notice; correction.

SUMMARY: The U.S. Agency for International Development published a document in the **Federal Register** of 2019–20311 concerning notification of a public meeting. The document omitted the meeting date, October 15, 2019.

FOR FURTHER INFORMATION CONTACT: Clara Cohen, 202–712–0119.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of 09/19/2019 2019–20311, on p. 49245, in the second sentence, correct the text to read:

The meeting will be held October 15 2019 from 8:30 a.m. to 4:20 p.m. CDT at the Hotel Downtown Marriott in Des Moines Iowa.

Clara Cohen,

Designated Federal Officer, BIFAD.

[FR Doc. 2019–20763 Filed 9–24–19; 8:45 am]

BILLING CODE 6116–02–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Doc. No. AMS–FGIS–19–0027 E]

Opportunity for Designation in the South Carolina Area

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice.

SUMMARY: The Agricultural Marketing Service (AMS) is temporarily extending the South Carolina Department of Agriculture's (SCDA) designation as provider of Federal Grain Inspection Service (FGIS) official services for the State of South Carolina, until December 31, 2019. AMS administers FGIS programs.

DATES: This designation is effective September 25, 2019. Interim designation is extended through December 31, 2019.

FOR FURTHER INFORMATION CONTACT: Jacob Thein, Compliance Officer, FGIS, AMS, USDA, 10383 North Ambassador Drive, Kansas City, MO 64153; phone: (816) 866–2223; or email: *FGISQACD@ams.usda.gov.*

SUPPLEMENTARY INFORMATION: Section 7(f) of the United States Grain Standards Act (7 U.S.C. 71 *et seq.*) (USGSA) authorizes the Secretary to designate a qualified applicant to provide official grain inspection services in a specified area after determining, among other things, that the applicant is better able than any other applicant to provide such official services (7 U.S.C. 79(f)(1)(B)). Under section 7(g) of the USGSA, designations of official agencies are effective for no longer than five years, unless terminated by the Secretary, and may be renewed according to the criteria and procedures prescribed in section 7(f) of the USGSA.

SCDA is currently designated as interim official inspection service provider for the South Carolina area, pending an AMS designation decision for an official service provider. As announced in the **Federal Register** on June 25, 2019 (84 FR 29839), SCDA's interim designation was scheduled to expire on September 30, 2019. The June 25, 2019, **Federal Register** notice also invited interested persons or governmental agencies to apply for designation as official inspection service provider for the geographic area currently served by SCDA. The application period closed July 25, 2019. AMS received three applications, two from state agencies (SCDA and North Carolina Department of Agriculture), and one from a private agency (D.R. Schaal Agency, Inc.).

AMS has not completed its review of the three applications. AMS, accordingly, requires additional time to complete the review and evaluation of information submitted by the applicants. Therefore, AMS is temporarily extending SCDA's interim designation until December 31, 2019.

Authority: 7 U.S.C. 71–87k.

Dated: September 20, 2019.

Bruce Summers,

Administrator, Agricultural Marketing Service.

[FR Doc. 2019–20864 Filed 9–24–19; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Doc No. AMS–SC–19–0079; SC19–33/35–1]

Notice of Request for Renewal of a Recordkeeping Burden; Correction

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Correction.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Agricultural Marketing Service (AMS) is issuing a correction to the notice published in the **Federal Register** on February 20, 2019 (Vol. 84, No. 34, pages 5046–5047). The previously published notice, which informed the public of AMS's request to the Office of Management and Budget (OMB) for renewal of a recordkeeping burden for the information collection for the Export Fruit Acts covering exports of apples and grapes, referenced an incorrect set of burden calculations. Current burden calculations are included in the **SUPPLEMENTARY INFORMATION** section below.

Additional Information: Contact Andrew Hatch, Chief, Program Services Branch, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, Stop 0237, Room 1406–S, Washington, DC 20250–0237; Telephone (202) 720–6862 or Email: *andrew.hatch@usda.gov.*

Small businesses may request information on complying with the regulation and responding to this notice by contacting Richard Lower, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, Stop 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202) 720–8938, or Email: *richard.lower@usda.gov.*

SUPPLEMENTARY INFORMATION:

Title: Export Fruit Regulations—Export Apple Act (7 CFR part 33) and the Export Grape and Plum Act (7 CFR part 35).

OMB Number: 0581–0143.

Expiration Date of Approval: September 30, 2019.

Type of Request: Request for Renewal of a Recordkeeping Burden.

Estimate of Burden: Public recordkeeping burden for this collection of information is estimated to *average 0.058 hours per response.*

Respondents (Recordkeepers): Apple and grape export shippers and carriers.

Estimated Number of Respondents: 200 (150 shippers and carriers of exported apples and 50 shippers and carriers of exported grapes).

Estimated Number of Responses: 160,350.

Estimated Number of Responses per Respondents: 801.75.

Estimated Total Annual Burden on Respondents: 9,311.00 hours.

Dated: September 19, 2019.

Bruce Summers,

Administrator, Agricultural Marketing Service.

[FR Doc. 2019–20748 Filed 9–24–19; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

September 19, 2019.

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 October 25, 2019 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), *OIRA_Submission@omb.eop.gov* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Food and Nutrition Service

Title: National School Lunch Program.

OMB Control Number: 0584–0006.

Summary of Collection: Section 10 of the Child Nutrition Act of 1966 (42 U.S.C. 1779) requires the Secretary of Agriculture to prescribe such regulations as deemed necessary to carry out this Act and the Richard B. Russell National School Lunch Act (NSLA) (42 U.S.C. 1751 *et seq.*). The NSLA, as amended, authorizes the National School Lunch Program (NSLP) to safeguard the health and well-being of the Nation's children and provide free or reduced-price school lunches to eligible students through subsidies to schools. As required, the Secretary of Agriculture issued 7 CFR part 210, which sets forth policies and procedures for the administration and operation of the NSLP.

Need and Use of the Information: This ongoing information collection is required to administer and operate this program in accordance with the NSLA. The Program is administered at the State agency and school food authority (SFA)/local education agency (LEA) levels and States, SFAs/LEAs, and schools under this Act are required to keep accounts and records as may be necessary to enable FNS to determine whether the program is in compliance with this Act and the regulations. Program operations include the submission of applications and agreements and monthly reports of program participation and numbers of meals served submitted from monthly claims for reimbursement. Records maintained include documentation of payment of monthly claims, annual data from Program monitoring reviews, and menu and food production records. In addition to reporting and maintaining records, the States and SFAs/LEAs have publication notification requirements as well. State agencies must post summaries of the most recent administrative review results of SFAs on their websites. LEAs must inform the public annually about the content and implementation of local school wellness policies and must conduct triennial assessments of schools' compliance with the local school wellness policies and inform the public about the progress. FNS uses this information to properly monitor State agency and SFA/LEA compliance.

Description of Respondents: State, Local, or Tribal Government.

Number of Respondents: 115,935.

Frequency of Responses: Recordkeeping; Reporting; Third party disclosure: On occasion, Quarterly, Monthly, and Annually.

Total Burden Hours: 9,808,439.

Food and Nutrition Service

Title: Generic Clearance for the Development of Nutrition Education Messages and Products for the General Public.

OMB Control Number: 0584–0523.

Summary of Collection: The Food and Nutrition Consumer Service, Center for Nutrition Policy and Promotion (CNPP) of the U.S. Department of Agriculture conducts consumer research to identify key issues of concern related to understanding and use of the *Dietary Guidelines for Americans* (DGA), as well as the tools and resources used to implement the Dietary Guidelines—previously known as the *MyPyramid* food guidance system. The *Dietary Guidelines,* a primary source of dietary health information, are issued jointly by the USDA and Health and Human Services and serve as the cornerstone of Federal nutrition policy and form the basis for nutrition education efforts of these agencies. After the release of the 2010 DGA a new communication initiative built around USDA's new *MyPlate* icon, including the resources at ChooseMyPlate.gov, was launched. *MyPlate* is a visual cue supported by Dietary Guidelines messages to help consumer make better food choices.

Need and use of the Information: CNPP will collect information to develop practical and meaningful nutrition and physical activity guidance for Americans to help improve their health. The collected information will also be used to expand the knowledge base concerning how the *Dietary Guidelines for Americans* recommendations and messages supporting *MyPlate* are understood and how they can be used by consumers to improve balance of their food intake with physical energy expenditure for good health. If this information is not collected, USDA's ability to incorporate messages and materials that are practical, meaningful, and relevant for the intended audience in any proposed update of the Dietary Guidelines for Americans or related resources at *Choosemyplate.gov* will be impaired.

Description of Respondents: Individuals or households..

Number of Respondents: 174,300.

Frequency of Responses: Reporting: Other (as desired).

Total Burden Hours: 37,065.

Food and Nutrition Service

Title: Generic Clearance to Conduct Formative Research.

OMB Control Number: 0584–0524.

Summary of Collection: This information collection is based on Section 19 of the Child Nutrition Act of 1966 (42 U.S.C. 1787) Section 5 of the Richard B. Russell National School Lunch Act (42 U.S.C. 1754) and Section 11(f) of the Food and Nutrition Act of 2008 (7 U.S.C. 2020). This information collection will conduct research in support of FNS' goal of delivering science-based nutrition education to targeted audiences. From development through testing of materials and tools with the target audience, FNS plans to conduct data collections that involve formative research including focus groups, interviews (dyad, triad, telephone, *etc.*), surveys and Web-based collection tools.

Need and use of the Information: Obtaining formative input and feedback is fundamental to FNS' success in delivering science-based nutrition messages and reaching diverse segments of the population in ways that are meaningful and relevant. This includes conferring with the target audience, individuals who serve the target audience, and key stakeholders on the communication strategies and interventions that will be developed and on the delivery approaches that will be used to reach consumers. The formative research and testing activities described will help in the development of effective education and promotion tools and communication strategies. Collection of this information will increase FNS' ability to formulate nutrition education interventions that resonate with the intended target population, in particular low-income families.

Description of Respondents: Individuals or households; Not for-profit institutions; Farms; State, Local or Tribal Government.

Number of Respondents: 120,500.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 46,781.

Food and Nutrition Service

Title: Supplemental Nutrition Assistance Program Employment and Training Program Performance Measurement, Monitoring and Reporting Requirements.

OMB Control Number: 0584–0614.

Summary of Collection: This is an extension, without change, of a currently approved collection. In accordance with Section 16(h)(5) of the Food and Nutrition Act (FNA), as amended by section 4022 of the Agriculture Act of 2014, and 7 CFR 273.7(c)(17) the Department requires that State agencies report outcome data for the Supplemental Nutrition Employment Program (SNAP) Employment and Training (E&T) programs. In order for FNS to monitor the effectiveness of E&T programs State agencies are required to report outcome data on five separate reporting measures: (1) The number and percentage of E&T participants who retain employment 2 quarters and 4 quarters after completing E&T; (2) the median wages for participants with earnings 2 quarters after completion of E&T; (3) the number and percentage of participants that completed a training, education, work experience or on-the-job training component; (4) certain unique characteristics of SNAP E&T participants; and (5) additional reporting requirements for State agencies that pledge to serve all at-risk Able-bodied Adults without Dependents (ABAWDs). State agencies are also required to identify appropriate reporting measures for each proposed component that serves a threshold number of participants of at least 100 a year. State agencies identify the reporting measures for these components in State agencies' E&T plans and report the outcome data to the Food and Nutrition Service (FNS) through State agencies' annual reports. State agencies are required to report outcome data annually.

Need and Use of the Information: With this information, FNS is able to identify more, and less, successful E&T practices and provide technical assistance to State agencies to improve their E&T programs.

Description of Respondents: State, Local, or Tribal Governments;

Number of Respondents: 53.

Frequency of Responses: Reporting; annually.

Total Burden Hours: 12,233 for reporting.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2019–20730 Filed 9–24–19; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

September 20, 2019.

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 October 25, 2019 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725—17th Street NW, Washington, DC 20502. Commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Copies of the submission(s) may be obtained by calling (202) 720–8958.

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.

Foreign Agricultural Service

Title: CCC's Facility Guarantee Program (FGP).

OMB Control Number: 0551–0032.

Summary of Collection: Under the authority of 7 CFR part 1493, subpart C, the Facility Guarantee Program (FGP) offers credit guarantees to facilitate the financing of U.S. manufactured goods and services to improve or establish

agriculture infrastructure in emerging markets. Sales under FGP are considered normal commercial sales. The Foreign Agricultural Service (FAS) will collect information in a letter format via mail or facsimile.

Need and Use of the Information: FAS will collect information to determine eligibility for FGP benefits and to ensure CCC that all participants have a business office in the U.S. and are not debarred or suspended from participating in government programs. FAS will use the application to determine a project's eligibility for FGP coverage and to determine the impact on U.S. agricultural trade. The information requested will provide CCC with adequate information to meet statutory requirements. If the information were not collected CCC would be unable to determine if export sales under the FGP would be eligible for coverage or, if coverage conformed to program requirements.

Description of Respondents: Business or other for-profit.

Number of Respondents: 18.

Frequency of Responses: Recordkeeping; Reporting; On occasion.

Total Burden Hours: 361.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2019–20857 Filed 9–24–19; 8:45 am]

BILLING CODE 3410–10–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S–185–2019]

Foreign-Trade Zone 61—San Juan, Puerto Rico, Application for Subzone, Pueblo, Inc., Guaynabo, Puerto Rico

An application has been submitted to the Foreign-Trade Zones Board (the Board) by the Department of Economic Development and Commerce, grantee of FTZ 61, requesting subzone status for the facility of Pueblo, Inc., located in Guaynabo, Puerto Rico. 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 Board (15 CFR part 400). It was formally docketed on September 19, 2019.

The proposed subzone (5.0785 acres) is located at Diana Street #14 (within the Amelia Distribution Center) in Guaynabo, Puerto Rico. No authorization for production activity has been requested at this time. The proposed subzone would be subject to the existing activation limit of FTZ 61.

In accordance with the 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 Board's Executive Secretary and sent to: *ftz@trade.gov.* The closing period for their receipt is November 4, 2019. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to November 19, 2019.

A copy of the application will be available for public inspection in the ''Reading Room'' section of the Board's website, which is accessible via *www.trade.gov/ftz.*

FOR FURTHER INFORMATION CONTACT: Camille Evans at *Camille.Evans@trade.gov* or (202) 482–2350.

Dated: September 19, 2019.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2019–20814 Filed 9–24–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–58–2019]

Foreign-Trade Zone 262—Southaven, Mississippi; Application for Reorganization Under Alternative Site Framework

An application has been submitted to the Foreign-Trade Zones (FTZ) Board by the Northern Mississippi FTZ, Inc., grantee of FTZ 262, requesting authority to reorganize the zone under the alternative site framework (ASF) adopted by the FTZ Board (15 CFR 400.2(c)). The ASF is an option for grantees for the establishment or reorganization of zones and can permit significantly greater flexibility in the designation of new subzones or ''usage-driven'' FTZ sites for operators/users located within a grantee's ''service area'' in the context of the FTZ Board's standard 2,000-acre activation limit for a zone. The application was submitted pursuant to the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally docketed on September 19, 2019.

FTZ 262 was approved by the FTZ Board on October 1, 2004 (Board Order 1353, 69 FR 60841, October 13, 2004) and expanded on December 21, 2005 (Board Order 1431, 70 FR 77374–77375, December 30, 2005).

The current zone includes the following site: *Site 1* (680 acres)—DeSoto Trade Center, located between Interstate 55 and US Highway 51 just south of Church Road, Southaven.

The grantee's proposed service area under the ASF would be DeSoto County, Mississippi, as described in the application. If approved, the grantee would be able to serve sites throughout the service area based on companies' needs for FTZ designation. The application indicates that the proposed service area is within and adjacent to the Memphis Customs and Border Protection port of entry.

The applicant is requesting authority to reorganize its existing zone to include its existing site as a ''magnet'' site. No subzones/usage-driven sites are being requested at this time. The application would have no impact on FTZ 262's previously authorized subzones.

In accordance with the FTZ Board's regulations, Camille Evans of the FTZ Staff is designated examiner to evaluate and analyze the facts and information presented in the application and case record and to report findings and recommendations to the FTZ Board.

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 November 25, 2019. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to December 9, 2019.

A copy of the application will be available for public inspection in the ''Reading Room'' 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* or (202) 482–2350.

Dated: September 20, 2019.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2019–20820 Filed 9–24–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–59–2019]

Foreign-Trade Zone (FTZ) 43—Battle Creek, Michigan; Notification of Proposed Production Activity; DENSO Manufacturing Michigan, Inc. (Automotive HVAC and Engine Cooling Products), Battle Creek, Michigan

DENSO Manufacturing Michigan, Inc. (DMMI) submitted a notification of proposed production activity to the FTZ Board for its facility in Battle Creek, Michigan. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on September 9, 2019.

The DMMI facility is located within FTZ 143. The facility is used for production of automotive HVAC and engine cooling components and systems. Pursuant to 15 CFR 400.14(b), FTZ activity would be limited to the specific foreign-status materials and components and specific finished products described in the submitted notification (as described below) and subsequently authorized by the FTZ Board.

Production under FTZ procedures could exempt DMMI from customs duty payments on the foreign-status components used in export production. On its domestic sales, for the foreign-status materials/components noted below, DMMI would be able to choose the duty rates during customs entry procedures that apply to: Fan assemblies; blower assemblies; shroud assemblies; HVAC units for automotive use; filter bases, heater cores, condensers, tubes, connectors, evaporators, joint blocks and separator sheets for automotive HVAC use; motor vehicle radiators; tubes, conduction assemblies, tanks, coolers, radiator assemblies, core plates, condensers, cores and core assemblies for use in motor vehicle radiators; and, oil coolers, duct assemblies and vents for use in motor vehicles (duty rate ranges from 1.4 to 2.5%). DMMI would be able to avoid duty on foreign-status components which become scrap/waste. Customs duties also could possibly be deferred or reduced on foreign-status production equipment.

The components and materials sourced from abroad include: Automotive compressor oil; brazing compound; various plastic tubes, pipes and hoses (ethylene; propylene; polyvinyl chloride; rigid; flexible; not reinforced without fittings; with fittings; and, reinforced); plastic fittings; self-adhesive strips, gaskets and seals; various plastic labels (ethylene and propylene); vulcanized fiber plastic seals; styrene plastic insulators; various plastic components (lids; caps; plugs; covers; valve stops; brackets; clamps; bushings; guides; doors; pipes; and, gaskets); various plates, sheets and strips (cellular and non-cellular rubber); various profiles, gaskets and seals (cellular and non-cellular rubber); various rubber tubes, pipes and hoses (not reinforced without fittings; not reinforced with fittings; and, reinforced with nylon braiding or polyester or aramid fibers without fittings); cellular rubber seals; various vulcanized rubber components (seals; o-rings; bushings; grommets; insulators; and, pipes); hard rubber bushings; paper name plates/labels; various wire (zinc plated or coated; stainless steel; and, alloy steel); circular cross-section alloy steel tubes, pipes and other hollows; various iron or steel components (seamless pipes; threaded self-tapping screws; bolts and their nuts/washers; machine screws; screws or bolts; threaded bolts or studs; threaded nuts; u-nuts; washers; pins; clamps; and, inserts, clips, clamps and seat cocks); various aluminum or aluminum alloy components (wire rolls; rectangular or square sheets; sheets; and, tubes and pipes); aluminum tube couplings, connectors, and pins; brackets, fin guards, supports and clamps of iron, steel, aluminum or zinc; brazing rings; fuel, lubricating or cooling pumps; hydraulic fluid, roller or other pumps; compressors; motors, fans and heat shields; fan shrouds, fan shroud inserts and spring clips; automotive HVAC units; various components for automotive HVAC units (caps; filter bases; heater cores; clips; filters; condensers; nylon dryer bags; pipes, hoses and tubes; evaporators; joint blocks; separator sheets and plates; tanks and cooling cases; connectors; cup plates; and, receiver assemblies); intercoolers and intercooler assemblies; intercooler support assemblies; intercooler ducts; air filters; air refrigerant filters; various valves (solenoid; regulator; and, expansion); ballcock mechanisms; valve magnets; valves with electrical, hydraulic, pneumatic or thermostatic actuators; various components for valves (cable controls; seat cocks; lever subassemblies; plates; damper subassemblies; and, shaft subassemblies); various valve components (doors; shafts; film; packing; and, tube and accessory assemblies); ball studs; electric motors under 18.65W; DC motors; electric heaters; various resistors (fixed and wire wound); thermistors; contactors and relays; boards, panels, modules and other controllers and control assemblies; transistors; integrated circuits; wire harnesses; radiators and radiator assemblies; various radiator components (aluminum plates; tubes and pipes; conduction assemblies; caps; tanks and reserve tanks; oil coolers; core plates; condensers; cores; coolers; and, core subassemblies); various automotive components (oil coolers; hoses; clamps; duct assemblies; and, vents); thermostats; pressure switches; and, pressure sensors (duty rate ranges from duty-free to 8.6%; $0.84/bbl). The request indicates that certain materials/components are subject to special duties under Section 232 of the Trade Expansion Act of 1962 (Section 232) or Section 301 of the Trade Act of 1974 (Section 301), depending on the country of origin. The applicable Section 232 and Section 301 decisions require subject merchandise to be admitted to FTZs in privileged foreign status (19 CFR 146.41).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary and sent to: *ftz@trade.gov.* The closing period for their receipt is November 4, 2019.

A copy of the notification will be available for public inspection in the ''Reading Room'' section of the Board's website, which is accessible via *www.trade.gov/ftz.*

For further information, contact Juanita Chen at *juanita.chen@trade.gov* or 202–482–1378.

Dated: September 20, 2019.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2019–20819 Filed 9–24–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S–186–2019]

Foreign-Trade Zone 29—Louisville, Kentucky; Application for Subzone Expansion; Hitachi Automotive Systems America, Inc., Harrodsburg, Kentucky

An application has been submitted to the Foreign-Trade Zones Board (the Board) by the Louisville & Jefferson County Riverport Authority, grantee of FTZ 29, requesting an expansion of Subzone 29F on behalf of Hitachi Automotive Systems America, Inc. in Harrodsburg, Kentucky. 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 Board (15 CFR part 400). It was formally docketed on September 19, 2019.

Subzone 29F currently consists of the following sites: Site 1 (50 acres) 955 Warwick Road, Harrodsburg; Site 2 (1.56 acres) 601 Robinson Road, Harrodsburg; Site 3 (1.4 acres) 110 Morgan Soaper Road, Harrodsburg; and, Site 4 (20 acres) 1150 Mayde Road, Berea. The proposed expansion would add 34 acres to existing Site 1. No authorization for additional production activity has been requested at this time. The subzone would be subject to the existing activation limit of FTZ 29.

In accordance with the Board's regulations, Elizabeth Whiteman 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 Board's Executive Secretary and sent to: *ftz@trade.gov.* The closing period for their receipt is November 4, 2019. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to November 19, 2019.

A copy of the application will be available for public inspection in the ''Reading Room'' section of the Board's website, which is accessible via *www.trade.gov/ftz.*

For further information, contact Elizabeth Whiteman at *Elizabeth.Whiteman@trade.gov* or (202) 482–0473.

Dated: September 19, 2019.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2019–20818 Filed 9–24–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–887]

Carbon and Alloy Steel Threaded Rod From India: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Postponement of Final Determination, and Extension of Provisional Measures

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that carbon and alloy steel threaded rod (CASTR) from India is being, or is likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is January 1, 2018 through December 31, 2018. Interested parties are invited to comment on this preliminary determination.

DATES: Applicable September 25, 2019.

FOR FURTHER INFORMATION CONTACT: Jerry Huang or Annathea Cook, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4047 or (202) 482–0250, respectively.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 733(b) of the Tariff Act of 1930, as amended (the Act). Commerce published the notice of initiation of this investigation on March 19, 2019.[1] On June 14, 2019, Commerce postponed the preliminary determination of this investigation and the revised deadline is now September 19, 2019.[2] For a complete description of the events that followed the initiation of this investigation, *see* the Preliminary Decision Memorandum.[3] A list of topics included in the Preliminary Decision Memorandum is included as Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov,* and to all parties in the Central Records Unit, Room B8024 of the main Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.* The signed and the electronic versions of the Preliminary Decision Memorandum are identical in content.

Scope of the Investigation

The product covered by this investigation is CASTR from India. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

In accordance with the preamble to Commerce's regulations,[4] the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage (scope).[5] Certain interested parties commented on the scope of the investigation as it appeared in the *Initiation Notice.* For a summary of the product coverage comments and rebuttal responses submitted to the record for this investigation, and accompanying discussion and analysis of all comments timely received, *see* the Preliminary Scope Decision Memorandum.[6] The scope case briefs were due on August 28, 2019, 30 days after the publication of *CASTR from China Preliminary CVD Determination.*[7] There will be no further opportunity for comments on scope-related issues.[8]

Methodology

Commerce is conducting this investigation in accordance with section 731 of the Act. Commerce has calculated export prices and constructed export prices in accordance with section 772(a) and 772(b) of the Act. Commerce has calculated normal value in accordance with section 773(e) of the Act. For a full description of the methodology underlying the preliminary determination, *see* the Preliminary Decision Memorandum.

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[1] *See Carbon and Alloy Steel Threaded Rod from India, Taiwan, Thailand, and the People's Republic of China: Initiation of Less-Than-Fair-Value Investigations,* 84 FR 10034 (March 19, 2019) (*Initiation Notice*).

[2] *See Carbon and Alloy Steel Threaded Rod from India, Taiwan, and the People's Republic of China: Postponement of Preliminary Determinations in the Less-Than-Fair-Value Investigations,* 84 FR 27764 (June 14, 2019).

[3] *See* Memorandum, ''Decision Memorandum for the Preliminary Determination in the Less-Than-Fair-Value Investigation of Carbon and Alloy Steel Threaded Rod from India,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[4] *See Antidumping Duties; Countervailing Duties; Final Rule,* 62 FR 27296, 27323 (May 19, 1997).

[5] *See Initiation Notice*.

[6] *See* Memorandum, ''Carbon and Alloy Steel Threaded Rod from India, Taiwan, Thailand, and the People's Republic of China: Scope Comments Decision Memorandum for the Preliminary Determinations,'' dated July 22, 2019.

[7] The scope case briefs were due 30 days after the publication of *Carbon and Alloy Steel Threaded Rod from the People's Republic of China: Preliminary Affirmative Countervailing Duty Determination and Alignment of Final Determination With Final Antidumping Duty Determination,* 84 FR 36578 (July 29, 2019) (*CASTR from China Preliminary CVD Determination*). *See* the Preliminary Scope Decision Memorandum at 3. The deadline for the scope case briefs was Wednesday, August 28, 2019. Because the deadline for rebuttal briefs fell on Monday, September 2, 2019, a Federal holiday, the actual deadline for the scope rebuttal briefs was Tuesday, September 3, 2019. *See* 19 CFR 351.303(b)(1) (''For both electronically filed and manually filed documents, if the applicable due date falls on a non-business day, the Secretary will accept documents that are filed on the next business day.'').

[8] Parties were already permitted the opportunity to file scope case briefs. Case briefs, other written comments, and rebuttal briefs should not include scope-related issues. *See* Preliminary Scope Decision Memorandum at 3.

Particular Market Situation Allegation

On July 18, 2019, we received a cost-based particular market situation allegation (PMS) from Vulcan Threaded Products, Inc. (the petitioner).[9] On August 27, 2019, we sent the petitioner a supplemental questionnaire regarding its PMS allegation.[10] The petitioner submitted a response on September 4, 2019.[11] We preliminarily find that the revised allegation is sufficient to warrant further analysis. We also intend to issue additional questions to address remaining deficiencies regarding the quantitative analysis. We will then evaluate the response and make a determination on the PMS allegation in a post-preliminary determination. Additionally, we have accepted the factual information in support of the allegation and have further established a deadline for the submission of factual information to rebut, clarify or correct the allegation in a memo to the file dated concurrently with this preliminary determination.[12]

All-Others Rate

Sections 733(d)(1)(ii) and 735(c)(5)(A) of the Act provide that in the preliminary determination, Commerce shall determine an estimated weighted-average dumping margin (the ''all-others'' rate) for all exporters and producers not individually examined. This rate shall be an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding rates that are zero and *de minimis,* or determined entirely under section 776 of the Act. For the preliminary determination, the only rate that is not zero, *de minimis,* or based entirely on facts otherwise available is the rate calculated for Mangal Steel Enterprises Limited (Mangal). Consequently, the margin calculated for Mangal is assigned as the rate for all other producers and exporters.

Preliminary Determination

Commerce preliminarily determines that the following estimated weighted-average dumping margins exist:

Exporter/producer	Estimated weighted-average dumping margin (percent)	Cash deposit rate (adjusted for export subsidy offset) (percent)
Daksh Fasteners	* 2.04	0.00
Mangal Steel Enterprise Limited	2.04	0.00
All Others	2.04	0.00

* *See* the Preliminary Decision Memorandum for how this rate was selected.

Suspension of Liquidation

In accordance with section 733(d)(2) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise, as described in Appendix I, entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**.

Further, pursuant to section 733(d)(1)(B) of the Act and 19 CFR 351.205(d), Commerce will instruct CBP to require a cash deposit equal to the estimated weighted-average dumping margin as described above, as follows: (1) The cash deposit rate for the respondents listed above will be equal to the company-specific estimated weighted-average dumping margins determined in this preliminary determination; (2) if the exporter is not a respondent identified above, but the producer is, then the cash deposit rate will be equal to the company-specific estimated weighted-average dumping margin established for that producer of the subject merchandise; and (3) the cash deposit rate for all other producers and exporters will be equal to the all-others estimated weighted-average dumping margin.

To determine the cash deposit rate, Commerce normally adjusts the estimated weighted-average dumping margin by the amount of domestic subsidy pass-through and export subsidies determined in a companion countervailing duty (CVD) proceeding when CVD provisional measures are in effect. Accordingly, where Commerce has made a preliminary affirmative determination for domestic subsidy pass-through or export subsidies, Commerce has offset the calculated estimated weighted-average dumping margin by the appropriate rate(s). Any such adjusted rates may be found in the chart of estimated weighted-average dumping margins in the Preliminary Determination section of this notice.

Should provisional measures in the companion CVD investigation expire prior to the expiration of provisional measures in this LTFV investigation, Commerce will direct CBP to begin collecting cash deposits at a rate equal to the estimated weighted-average dumping margins calculated in this preliminary determination unadjusted for the passed-through domestic subsidies or for export subsidies at the time the CVD provisional measures expire.

These suspension of liquidation instructions will remain in effect until further notice.

Disclosure

Commerce intends to disclose to interested parties the calculations performed in connection with this preliminary determination within five days of its public announcement or, if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Verification

As provided in section 782(i)(1) of the Act, Commerce intends to verify information relied upon in making its final determination.

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the last final verification report is issued in this

[9] *See* Petitioner's Letter, ''Carbon and Alloy Steel Threaded Rod from India: Particular Market Situation Allegation,'' dated July 18, 2019.

[10] *See* Commerce's Letter, ''Antidumping Duty Investigation of Carbon and Alloy Steel Threaded Rod from India: Particular Market Situation Allegation Supplemental Questions,'' dated August 27, 2019.

[11] *See* Petitioner's Letter, ''Carbon and Alloy Steel Threaded Rod from India: Response to Particular Market Situation Allegation Supplemental Questions,'' dated September 4, 2019.

[12] *See* Memorandum, ''Less-Than-Fair-Value Investigation of Carbon and Alloy Steel Threaded Rod from India: Comment Schedule for the Particular Market Situation Allegation,'' dated September 19, 2019.

investigation. Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than five days after the deadline date for case briefs.[13] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this investigation are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at the U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

Postponement of Final Determination and Extension of Provisional Measures

Section 735(a)(2) of the Act provides that a final determination may be postponed until not later than 135 days after the date of the publication of the preliminary determination if, in the event of an affirmative preliminary determination, a request for such postponement is made by exporters who account for a significant proportion of exports of the subject merchandise, or in the event of a negative preliminary determination, a request for such postponement is made by the petitioners. Pursuant to 19 CFR 351.210(e)(2), Commerce requires that requests by respondents for postponement of a final antidumping determination be accompanied by a request for extension of provisional measures from a four-month period to a period not more than six months in duration. and 19 CFR 351.210(e)(1) further provides that Commerce may grant the request, unless Commerce finds compelling reasons to deny the request.

On August 21, 2019, pursuant to 19 CFR 351.210(e), Mangal requested that Commerce postpone the final determination and that provisional measures be extended to a period not to exceed six months.[14] In accordance with section 735(a)(2)(A) of the Act and 19 CFR 351.210(b)(2)(ii), because (1) the preliminary determination is affirmative; (2) the requesting exporter account for a significant proportion of exports of the subject merchandise; and (3) no compelling reasons for denial exist, Commerce is postponing the final determination and extending the provisional measures from a four-month period to a period not greater than six months. Accordingly, Commerce's final determination will be issued no later than 135 days after the date of publication of this preliminary determination.

International Trade Commission (ITC) Notification

In accordance with section 733(f) of the Act, Commerce will notify the ITC of its preliminary determination. If the final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after the final determination whether these imports are materially injuring, or threaten material injury to, the U.S. industry.

Notification to Importers

This notice also serves as an initial reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation. 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 to Interested Parties

This determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act and 19 CFR 351.205(c).

Dated: September 19, 2019.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The merchandise covered by the scope of the investigation is carbon and alloy steel threaded rod. Steel threaded rod is certain threaded rod, bar, or studs, of carbon or alloy steel, having a solid, circular cross section of any diameter, in any straight length. Steel threaded rod is normally drawn, cold-rolled, threaded, and straightened, or it may be hot-rolled. In addition, the steel threaded rod, bar, or studs subject to the investigation are non-headed and threaded along greater than 25 percent of their total actual length. A variety of finishes or coatings, such as plain oil finish as a temporary rust protectant, zinc coating (*i.e.,* galvanized, whether by electroplating or hot-dipping), paint, and other similar finishes and coatings, may be applied to the merchandise.

Steel threaded rod is normally produced to American Society for Testing and Materials (ASTM) specifications ASTM A36, ASTM A193 B7/B7m, ASTM A193 B16, ASTM A307, ASTM A320 L7/L7M, ASTM A320 L43, ASTM A354 BC and BD, ASTM A449, ASTM F1554–36, ASTM F1554–55, ASTM F1554 Grade 105, American Society of Mechanical Engineers (ASME) specification ASME B18.31.3, and American Petroleum Institute (API) specification API 20E. All steel threaded rod meeting the physical description set forth above is covered by the scope of the investigation, whether or not produced according to a particular standard.

Subject merchandise includes material matching the above description that has been finished, assembled, or packaged in a third country, including by cutting, chamfering, coating, or painting the threaded rod, by attaching the threaded rod to, or packaging it with, another product, or any other finishing, assembly, or packaging operation that would not otherwise remove the merchandise from the scope of the investigations if performed in the country of manufacture of the threaded rod.

Carbon and alloy steel threaded rod are also included in the scope of the investigation whether or not imported attached to, or in conjunction with, other parts and accessories such as nuts and washers. If carbon and alloy steel threaded rod are imported attached to, or in conjunction with, such non-subject merchandise, only the threaded rod is included in the scope.

Excluded from the scope of the investigation are: (1) Threaded rod, bar, or studs which are threaded only on one or both ends and the threading covers 25 percent or less of the total actual length; and (2) stainless steel threaded rod, defined as steel threaded rod containing, by weight, 1.2 percent or less of carbon and 10.5 percent or more of chromium, with our without other elements.

Excluded from the scope of the antidumping investigation on steel threaded rod from the People's Republic of China is any merchandise covered by the existing antidumping order on Certain Steel Threaded Rod from the People's Republic of China. *See Certain Steel Threaded Rod from the People's Republic of China: Notice of Antidumping Duty Order,* 74 FR 17154 (April 14, 2009).

Specifically excluded from the scope of the investigation is threaded rod that is imported as part of a package of hardware in conjunction with a ready-to-assemble piece of furniture.

Steel threaded rod is currently classifiable under subheadings 7318.15.5051, 7318.15.5056, and 7318.15.5090 of the

[13] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements).

[14] *See* Mangal's Letter, ''Antidumping Investigation of Carbon and Alloy Steel Threaded Rod from India: Request for Postponement of Final Determination,'' dated August 21, 2019.

Harmonized Tariff Schedule of the United States (HTSUS). Subject merchandise may also enter under subheading 7318.15.2095 and 7318.19.0000 of the HTSUS. The HTSUS subheadings are provided for convenience and U.S. Customs purposes only. The written description of the scope is dispositive.

Appendix II

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Period of Investigation
IV. Scope of the Investigation
V. Scope Comments
VI. Product Characteristics
VII. Selection of Respondents
VIII. Affiliation
IX. Discussion of the Methodology
X. All-Others Rate
XI. Adjustment to Cash Deposit Rate for Export Subsidy
XII. Verification
XIII. Recommendation

[FR Doc. 2019–20811 Filed 9–24–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–104]

Alloy and Certain Carbon Steel Threaded Rod From the People's Republic of China: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Postponement of Final Determination and Extension of Provisional Measures

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that Alloy and Certain Carbon Steel Threaded Rod (ACSTR) from the People's Republic of China (China) is being, or is likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is July 1, 2018 through December 31, 2018. Interested parties are invited to comment on this preliminary determination.

DATES: Applicable September 25, 2019.

FOR FURTHER INFORMATION CONTACT: Joshua Poole or Andre Gziryan, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1293 or (202) 482–2201, respectively.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 733(b) of the Tariff Act of 1930, as amended (the Act). Commerce published the notice of initiation of this investigation on March 19, 2019.[1] On June 14, 2019, Commerce postponed the preliminary determination of this investigation and the revised deadline is now September 19, 2019.[2] For a complete description of the events that followed the initiation of this investigation, *see* the Preliminary Decision Memorandum.[3] A list of topics included in the Preliminary Decision Memorandum is included as Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov,* and to all parties in the Central Records Unit, room B8024 of the main Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.*

Scope of the Investigation

The product covered by this investigation is ACSTR from China. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

In accordance with the preamble to Commerce's regulations,[4] the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage (*i.e.,* scope).[5] Certain interested parties commented on the scope of the investigation as it appeared in the *Initiation Notice.* For a summary of the product coverage comments and rebuttal responses submitted to the record for this investigation, and accompanying discussion and analysis of all comments timely received, *see* the Preliminary Scope Decision Memorandum.[6] The scope case briefs were due on August 28, 2019, 30 days after the publication of *CASTR from China Preliminary CVD Determination.*[7] There will be no further opportunity for comments on scope-related issues.[8]

Because there is an existing antidumping duty (AD) order on carbon steel threaded rod from China, on September 3, 2019, the petitioner clarified for the record that with respect to ACSTR from the China AD investigation only, the products covered are alloy and certain steel threaded rod. Accordingly, we consulted with the petitioner to revise the scope of the China AD Investigation to reflect the petitioner's intent concerning the products that should be covered. We provided all interested parties an opportunity to comment on the revised scope.[9] No parties commented on the proposed revised scope with respect to the China AD investigation only.

Commerce is preliminarily modifying the scope language as it appeared in the *Initiation Notice. See* the revised scope in Appendix I to this notice.

Methodology

Commerce is conducting this investigation in accordance with section 731 of the Act. Commerce has calculated export prices in accordance with section 772(a) of the Act. Because China is a non-market economy, within the meaning of section 771(18) of the Act, Commerce has calculated normal value (NV) in accordance with section

[1] *See Carbon and Alloy Steel Threaded Rod from India, Taiwan, Thailand, and the People's Republic of China: Initiation of Less-Than-Fair-Value Investigations,* 84 FR 10034 (March 19, 2019) (*Initiation Notice*).

[2] *See Carbon and Alloy Steel Threaded Rod From India, Taiwan, and the People's Republic of China: Postponement of Preliminary Determinations in the Less-Than-Fair-Value Investigations,* 84 FR 27764 (June 14, 2019).

[3] *See* Memorandum, ''Decision Memorandum for the Preliminary Determination in the Less Than Fair Value Investigation of Alloy Steel Threaded Rod from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[4] *See Antidumping Duties; Countervailing Duties, Final Rule,* 62 FR 27296, 27323 (May 19, 1997).

[5] *See Initiation Notice.*

[6] *See* Memorandum, ''Carbon and Alloy Steel Threaded Rod from India, Taiwan, Thailand, and the People's Republic of China: Scope Comments Decision Memorandum for the Preliminary Determinations,'' dated July 22, 2019 (Preliminary Scope Decision Memorandum).

[7] The scope case briefs were due 30 days after the publication of *Carbon and Alloy Steel Threaded Rod from the People's Republic of China: Preliminary Affirmative Countervailing Duty Determination and Alignment of Final Determination With Final Antidumping Duty Determination,* 84 FR 36578 (July 29, 2019) (*CASTR from China Preliminary CVD Determination*). *See* the Preliminary Scope Decision Memorandum at 3. The deadline for the scope case briefs was Wednesday, August 28, 2019. Because the deadline for rebuttal briefs fell on Monday, September 2, 2019, a Federal holiday, the actual deadline for the scope rebuttal briefs was Tuesday, September 3, 2019. *See* 19 CFR 351.303(b)(1) (''For both electronically filed and manually filed documents, if the applicable due date falls on a non-business day, the Secretary will accept documents that are filed on the next business day.'').

[8] Parties were already permitted the opportunity to file scope case briefs. Case briefs, other written comments, and rebuttal briefs should not include scope-related issues. *See* Preliminary Scope Decision Memorandum at 3.

[9] *See* Memorandum, ''Phone Conversation with counsel for Vulcan Threaded Products Inc.,'' dated September 6, 2019 (Proposed Revised Scope Memo).

773(c) of the Act. In addition, pursuant to section 776(a) and (b) of the Act, Commerce has relied on facts otherwise available, with adverse inferences, for the China-wide entity. For a full description of the methodology underlying Commerce's preliminary determination, *see* the Preliminary Decision Memorandum.

Combination Rates

In the *Initiation Notice,*[10] Commerce stated that it would calculate producer/exporter combination rates for the respondents that are eligible for a separate rate in this investigation. Policy Bulletin 05.1 describes this practice.[11] In this investigation, we calculated producer/exporter combination rates for respondents eligible for separate rates.

Preliminary Determination

Commerce preliminarily determines that the following estimated weighted-average dumping margins exist:

Exporter	Producer	Estimated weighted-average dumping margin (percent)	Cash deposit rate (adjusted for subsidy offsets) (percent)
Ningbo Zhongjiang High Strength Bolts Co., Ltd	Ningbo Zhongjiang High Strength Bolts Co., Ltd	27.07	16.53
Zhejiang Junyue Standard Part Co., Ltd	Zhejiang Junyue Standard Part Co., Ltd	4.81	0.00
Cooper & Turner (Ningbo) International Trading Co., Ltd.	Zhejiang Cooper & Turner Fasteners Co Ltd	21.04	10.50
Cooper & Turner (Ningbo) International Trading Co., Ltd.	Zhejiang Morgan Brother Technology Co., Ltd	21.04	10.50
Cooper & Turner (Ningbo) International Trading Co., Ltd.	Zhejiang Huiyou Import & Export Co., Ltd	21.04	10.50
EC International (Nantong) Co., Ltd	Ningbo Zhongjiang High Strength Bolts Co., Ltd	21.04	10.50
EC International (Nantong) Co., Ltd	Ningbo Zhenghai Yongding Fasteners Manufacture Co., LTD.	21.04	10.50
EC International (Nantong) Co., Ltd	Zhejiang Junyue Standard Part Co., Ltd	21.04	10.50
EC International (Nantong) Co., Ltd	Haiyan Qinshan Rubber Factory	21.04	10.50
IFI & Morgan Ltd	Zhejiang Morgan Brother Technology Co., Ltd	21.04	10.50
Jiaxing Genteel Import & Export Co., Ltd	Ningbo Zhenhai Zhongbiao Standard Parts Factory	21.04	10.50
Ningbo Dingtuo Imp. & Exp. Co., Ltd	Ningbo Jinding Fastening Piece Co., Ltd	21.04	10.50
Zhejiang Heiter Mfg & Trade Co., Ltd	Zhejiang Golden Automotive Fastener Co., Ltd	21.04	10.50
Ningbo Jinding Fastening Piece Co., Ltd	Ningbo Jinding Fastening Piece Co., Ltd	21.04	10.50
Ningbo Qunli Fastener Manufacture Co., Ltd	Ningbo Qunli Fastener Manufacture Co., Ltd	21.04	10.50
Nantong Runyou Metal Products Co., Ltd	Nantong Runyou Metal Products Co., Ltd	21.04	10.50
Ningbo Shareway Import & Export, Co., Ltd	Zhejiang Junyue Standard Parts Co., Ltd	21.04	10.50
Ningbo Xingsheng Oil Pipe Fittings Manufacture Co., Ltd.	Ningbo Xingsheng Oil Pipe Fittings Manufacture Co., Ltd.	21.04	10.50
Ningbo Zhenghai Yongding Fastener Co., Ltd	Ningbo Zhenghai Yongding Fastener Co., Ltd	21.04	10.50
RMB Fasteners Ltd	Zhejiang Morgan Brother Technology Co., Ltd	21.04	10.50
Zhejiang Morgan Brother Technology Co., Ltd	Zhejiang Morgan Brother Technology Co., Ltd	21.04	10.50
China-Wide Entity[12]		59.45	48.91

Suspension of Liquidation

In accordance with section 733(d)(2) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise as described in Appendix I, entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**, as discussed below. Further, pursuant to section 733(d)(1)(B) of the Act and 19 CFR 351.205(d), Commerce will instruct CBP to require a cash deposit equal to the estimated weighted average amount by which normal value exceeds U.S. price, as indicated in the chart above as follows: (1) For the producer/exporter combinations listed in the table above, the cash deposit rate is equal to the estimated weighted-average dumping margin listed for that combination in the table; (2) for all combinations of Chinese producers/exporters of merchandise under consideration that have not established eligibility for their own separate rates, the cash deposit rate will be equal to the estimated weighted-average dumping margin established for the China-wide entity; and (3) for all third-county exporters of merchandise under consideration not listed in the table above, the cash deposit rate is the cash deposit rate applicable to the Chinese producer/exporter combination (or the China-wide entity) that supplied that third-country exporter.

To determine the cash deposit rate, Commerce normally adjusts the estimated weighted-average dumping margin by the amount of domestic subsidy pass-through and export subsidies determined in a companion countervailing duty (CVD) proceeding when CVD provisional measures are in effect. Accordingly, Commerce has made a preliminary affirmative determination for an export subsidy adjustment, however, Commerce has not made a preliminary affirmative determination for a domestic subsidy pass-through adjustment in this investigation.[13] Commerce has offset the

[10] *See Initiation Notice* at 10038.

[11] *See* Enforcement and Compliance's Policy Bulletin No. 05.1, regarding, ''Separate-Rates Practice and Application of Combination Rates in Antidumping Investigations involving Non-Market Economy Countries,'' (April 5, 2005) (Policy Bulletin 05.1), available on Commerce's website at *http://enforcement.trade.gov/policy/bull05-1.pdf.*

[12] Commerce preliminarily determined that Jiaxing Xingcheng Electronics Co., Ltd., Ningbo Panxiang Imp & Exp Co., Ltd., Ningbo Zhonglian Fastener Co., Ltd., and Ningbo Zhong Xin Angora Spinning Mill failed to establish their eligibility for a separate rate and, therefore, preliminarily determined that these companies are part of the China-wide entity. *See* Preliminary Decision Memorandum.

[13] *See* sections, ''Adjustment Under Section 777A of the Act'' and ''Adjustment to Cash Deposit Rate for Export Subsidies'' in the Preliminary Decision Memorandum.

calculated estimated weighted-average dumping margin by the appropriate rate. Any such adjusted rates may be found in the chart of estimated weighted-average dumping margins in the Preliminary Determination Section above.

Should provisional measures in the companion CVD investigation expire prior to the expiration of provisional measures in this LTFV investigation, Commerce will direct CBP to begin collecting cash deposits at a rate equal to the estimated weighted-average dumping margins calculated in this preliminary determination unadjusted for the export subsidies at the time the CVD provisional measures expire.

These suspension of liquidation instructions will remain in effect until further notice.

Disclosure

Commerce intends to disclose to interested parties the calculations performed in connection with this preliminary determination within five days of its public announcement or, if there is no public announcement, within five days of the date of publication of this notice in the **Federal Register**, accordance with 19 CFR 351.224(b).

Verification

As provided in section 782(i)(1) of the Act, Commerce intends to verify information relied upon in making its final determination.

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the last final verification report is issued in this investigation. Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than five days after the deadline date for case briefs.[14] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this investigation are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at the U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC, 20230, at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

Postponement of Final Determination and Extension of Provisional Measures

Section 735(a)(2) of the Act provides that a final determination may be postponed until not later than 135 days after the date of the publication of the preliminary determination if, in the event of an affirmative preliminary determination, a request for such postponement is made by exporters who account for a significant proportion of exports of the subject merchandise, or in the event of a negative preliminary determination, a request for such postponement is made by the petitioners. Pursuant to 19 CFR 351.210(e)(2), Commerce requires that requests by respondents for postponement of a final antidumping determination be accompanied by a request for extension of provisional measures from a four-month period to a period not more than six months in duration.

On August 2, 2019 and August 8, 2019 respectively, pursuant to 19 CFR 351.210(e), Zhejiang Junyue Standard Part Co., Ltd. and Ningbo Zhongjiang High Strength Bolts Co., Ltd. requested that Commerce postpone the final determination and that provisional measures be extended to a period not to exceed six months.[15] In accordance with section 735(a)(2)(A) of the Act and 19 CFR 351.210(b)(2)(ii), because (1) the preliminary determination is affirmative; (2) the requesting exporters account for a significant proportion of exports of the subject merchandise; and (3) no compelling reasons for denial exist, Commerce is postponing the final determination and extending the provisional measures from a four-month period to a period not greater than six months. Accordingly, Commerce's final determination will be issued no later than 135 days after the date of publication of this preliminary determination.

International Trade Commission Notification

In accordance with section 733(f) of the Act, Commerce will notify the International Trade Commission (ITC) of its preliminary determination of sales at LTFV. If the final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after the final determination whether these imports of the subject merchandise are materially injuring, or threaten material injury to, the U.S. industry.

Notification to Interested Parties

This determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act and 19 CFR 351.205(c).

Dated: September 19, 2019.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The merchandise covered by the scope of this investigation is alloy and certain carbon steel threaded rod. Alloy and certain carbon steel threaded rod are certain threaded rod, bar, or studs, of carbon or alloy steel, having a solid, circular cross section of any diameter, in any straight length. Alloy and certain carbon steel threaded rod are normally drawn, cold-rolled, threaded, and straightened, or it may be hot-rolled. In addition, the alloy and certain carbon steel threaded rod, bar, or studs subject to this investigation are non-headed and threaded along greater than 25 percent of their total actual length. A variety of finishes or coatings, such as plain oil finish as a temporary rust protectant, zinc coating (*i.e.,* galvanized, whether by electroplating or hot-dipping), paint, and other similar finishes and coatings, may be applied to the merchandise.

Alloy Steel threaded rod is normally produced to American Society for Testing and Materials (ASTM) specifications A193 B7/B7m, A193 B16, A320 L7/L7m, A320 L43, A354 BC and BD, and F1554 Grade 105. Other specifications are Society of Automotive Engineers (SAE) specification 1429 grades 5 and 8, International Organization for Standardization (ISO) specification 898 class 8.8 and 10.9, and American Petroleum Institute (API) specification 20E. Certain carbon steel threaded rod is normally produced to ASTM specification A449. All steel threaded rod meeting the physical description set forth

[14] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements).

[15] *See* Zhejiang Junyue Standard Part Co., Ltd.'s Letter, ''Carbon and Alloy Steel Threaded Rod from the People's Republic of China—Request for Extension of Final Determination and Provisional Measures,'' dated August 2, 2019.; *see also* Ningbo Zhongjiang High Strength Bolts Co., Ltd.'s Letter, ''Zhongjiang Request for Postponement of Final Determination and Extension of Provisional Measures Period in the Antidumping Duty Investigation on Alloy Steel Threaded Rod from the People's Republic of China (A–570–104),'' dated August 8, 2019.

above is covered by the scope of this investigation, whether or not produced according to a particular standard.

Subject merchandise includes material matching the above description that has been finished, assembled, or packaged in a third country, including by cutting, chamfering, coating, or painting the threaded rod, by attaching the threaded rod to, or packaging it with, another product, or any other finishing, assembly, or packaging operation that would not otherwise remove the merchandise from the scope of the investigation if performed in the country of manufacture of the threaded rod.

Alloy and certain carbon steel threaded rod are also included in the scope of this investigation whether or not imported attached to, or in conjunction with, other parts and accessories such as nuts and washers. If carbon and alloy steel threaded rod are imported attached to, or in conjunction with, such non-subject merchandise, only the threaded rod is included in the scope.

Excluded from the scope of this investigation are: (1) Threaded rod, bar, or studs which are threaded only on one or both ends and the threading covers 25 percent or less of the total actual length; and (2) stainless steel threaded rod, defined as steel threaded rod containing, by weight, 1.2 percent or less of carbon and 10.5 percent or more of chromium, with or without other elements.

Excluded from the scope of the antidumping investigation on steel threaded rod from the People's Republic of China is any merchandise covered by the existing antidumping order on Certain Steel Threaded Rod from the People's Republic of China. See Certain Steel Threaded Rod from the People's Republic of China: Notice of Antidumping Duty Order, 74 FR 17154 (April 14, 2009).

Specifically excluded from the scope of this investigation is threaded rod that is imported as part of a package of hardware in conjunction with a ready-to-assemble piece of furniture.

Alloy and certain carbon steel threaded rod are currently classifiable under subheadings 7318.15.5051, 7318.15.5056, and 7318.15.5090 of the Harmonized Tariff Schedule of the United States (HTSUS). Subject merchandise may also enter under subheading 7318.15.2095 and 7318.19.0000 of the HTSUS. The HTSUS subheadings are provided for convenience and U.S. Customs purposes only. The written description of the scope is dispositive.

Appendix II

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Period of Investigation
IV. Scope Comments
V. Scope of the Investigation
VI. Product Characteristics
VII. Selection of Respondents
VIII. Discussion of the Methodology
IX. Adjustment Under Section 777(A)(f) of the Act
X. Adjustment to Cash Deposit Rate for Export Subsidies
XI. Recommendation

[FR Doc. 2019–20810 Filed 9–24–19; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–583–865]

Carbon and Alloy Steel Threaded Rod From Taiwan: Preliminary Affirmative Determination of Sales at Less Than Fair Value

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that Carbon and Alloy Steel Threaded Rod (CASTR) from Taiwan is being, or is likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is January 1, 2018 through December 31, 2018. Interested parties are invited to comment on this preliminary determination.

DATES: Applicable September 25, 2019.

FOR FURTHER INFORMATION CONTACT: Nicholas Czajkowski or Ethan Talbot, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1395 or (202) 482–1030, respectively.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 733(b) of the Tariff Act of 1930, as amended (the Act). Commerce published the notice of initiation of this investigation on March 19, 2019.[1] On June 14, 2019, Commerce postponed the preliminary determination of this investigation and the revised deadline is now September 19, 2019.[2] For a complete description of the events that followed the initiation of this investigation, *see* the Preliminary Decision Memorandum.[3] A list of topics included in the Preliminary Decision Memorandum is included as Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov,* and to all parties in the Central Records Unit, room B8024 of the main Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.* The signed and the electronic versions of the Preliminary Decision Memorandum are identical in content.

Scope of the Investigation

The product covered by this investigation is CASTR from Taiwan. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

In accordance with the preamble to Commerce's regulations,[4] the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage (*i.e.,* scope).[5] Certain interested parties commented on the scope of the investigation as it appeared in the *Initiation Notice.* For a summary of the product coverage comments and rebuttal responses submitted to the record for this investigation, and accompanying discussion and analysis of all comments timely received, *see* the Preliminary Scope Decision Memorandum.[6] The scope case briefs were due on August 28, 2019, 30 days after the publication of *CASTR from China Preliminary CVD Determination.*[7]

[1] *See Carbon and Alloy Steel Threaded Rod from India, Taiwan, Thailand, and the People's Republic of China: Initiation of Less-Than-Fair-Value Investigations,* 84 FR 10034 (March 19, 2019) (*Initiation Notice*).

[2] *See Carbon and Alloy Steel Threaded Rod From India, Taiwan, and the People's Republic of China: Postponement of Preliminary Determinations in the Less-Than-Fair-Value Investigations,* 84 FR 27764 (June 14, 2019).

[3] *See* Memorandum, ''Decision Memorandum for the Preliminary Determination in the Less-Than-Fair-Value Investigation of Carbon and Alloy Steel Threaded Rod from Taiwan,'' dated concurrently with, and hereby adopted by this notice (Preliminary Decision Memorandum).

[4] *See Antidumping Duties; Countervailing Duties, Final Rule,* 62 FR 27296, 27323 (May 19, 1997).

[5] *See Initiation Notic*e.

[6] *See* Memorandum ''Carbon and Alloy Steel Threaded Rod from India, Taiwan, Thailand, and the People's Republic of China: Scope Comments Decision Memorandum for the Preliminary Determinations,'' dated July 22, 2019 (Preliminary Scope Decision Memorandum).

[7] The scope case briefs were due 30 days after the publication of *Carbon and Alloy Steel Threaded Rod from the People's Republic of China: Preliminary Affirmative Countervailing Duty Determination and Alignment of Final Determination With Final Antidumping Duty Determination,* 84 FR 36578 (July 29, 2019) (*CASTR from China Preliminary CVD Determination*). *See* the Preliminary Scope Decision Memorandum at 3. The deadline for the scope case briefs was Wednesday, August 28, 2019. Because the deadline for rebuttal briefs fell on Monday, September 2, 2019, a Federal holiday, the actual deadline for the scope rebuttal briefs was Tuesday, September 3, 2019. *See* 19 CFR 351.303(b)(1) (''For both electronically filed and manually filed documents, if the applicable due date falls on a non-business

There will be no further opportunity for comments on scope-related issues.[8]

Methodology

Commerce is conducting this investigation in accordance with section 731 of the Act. Pursuant to section 776(a) and (b) of the Act, Commerce has preliminarily determined to use facts available, and to apply an adverse inference when selecting from among the facts otherwise available for Quintain Steel Co. Ltd. (Quintain Steel), Top Forever Screws Co. Ltd. (Top Forever), Fastenal Asia Pacific Ltd. TW Repres (Fastenal), QST International Corporation (QST), and Ta Chen Steel Pipe Ltd. (Ta Chen). For a full description of the methodology underlying the preliminary determination, *see* the Preliminary Decision Memorandum.

All-Others Rate

Sections 733(d)(1)(A)(ii) and 735(c)(5)(A) of the Act provide that in the preliminary determination, Commerce shall determine an estimated all-others rate for all exporters and producers not individually examined. This rate shall be an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero and *de minimis* margins, and any margins determined entirely under section 776 of the Act.

Pursuant to section 735(c)(5)(B) of the Act, if the estimated weighted-average dumping margins established for all exporters or producers individually examined are zero, *de minimis* or determined based entirely on facts otherwise available, Commerce may use any reasonable method to establish the estimated weighted-average dumping margin for all-other producers or exporters. Commerce has preliminarily determined the estimated weighted-average dumping margin for the individually examined respondent under section 776 of the Act. Consequently, pursuant to section 735(c)(5)(B) of the Act, Commerce's normal practice under these circumstances is to calculate the all-others rate as a simple average of the alleged dumping margin(s) from the petition.[9] In this investigation, only a single dumping margin was alleged in the petition, 32.26 percent (as calculated for the purposes of initiation).[10] As such, consistent with its practice, Commerce is preliminarily assigning the dumping margin alleged in the petition as the all-others rate to all exporters or producers not individually examined. For a full description of the methodology underlying Commerce's analysis, *see* the Preliminary Decision Memorandum.

Preliminary Determination

Commerce preliminarily determines that the following estimated weighted-average dumping margins exist:

Exporter or producer	Weighted-average dumping margin (percent)
Quintain Steel Co. Ltd	* 32.26
Top Forever Screws Co. Ltd.	* 32.26
Fastenal Asia Pacific Ltd. TW Repres	* 32.26
QST International Corporation	* 32.26
Ta Chen Steel Pipe Ltd	* 32.26
All Others	32.26

* Adverse Facts Available.

Suspension of Liquidation

In accordance with section 733(d)(2) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise, as described in Appendix I, entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. Further, pursuant to section 733(d)(1)(B) of the Act and 19 CFR 351.205(d), Commerce will instruct CBP to require a cash deposit equal to the estimated weighted-average dumping margin as described above, as follows: (1) The cash deposit rate for the respondents listed above will be equal to the company-specific estimated weighted-average dumping margins determined in this preliminary determination; (2) if the exporter is not a respondent identified above, but the producer is, then the cash deposit rate will be equal to the company-specific estimated weighted-average dumping margin established for that producer of the subject merchandise; and (3) the cash deposit rate for all other producers or exporters will be equal to the all others estimated weighted-average dumping margin.

Disclosure

Normally, Commerce discloses to interested parties the calculations performed in connection with a preliminary determination within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of the notice of preliminary determination in the **Federal Register**, in accordance with 19 CFR 351.224(b). However, because Commerce preliminarily applied AFA to the individually examined companies—Quintain Steel, Top Forever, Fastenal, QST, and Ta Chen—in this investigation, in accordance with section 776 of the Act, and the applied AFA rate is based solely on the highest dumping margin alleged in the petition, there are no calculations to disclose.

Verification

Because Quintain Steel, Top Forever, Fastenal, QST, and Ta Chen did not provide information requested by Commerce, and Commerce preliminarily determines that each of the examined respondents has been uncooperative, we will not conduct verification.

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than 30 days after the date of publication of the preliminary determination. Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than five days after the deadline date for case briefs.[11] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this investigation are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

day, the Secretary will accept documents that are filed on the next business day.'').

[8] Parties were already permitted the opportunity to file scope case briefs. Case briefs, other written comments, and rebuttal briefs should not include scope-related issues. *See* Preliminary Scope Decision Memorandum at 3.

[9] *See, e.g., Notice of Preliminary Determination of Sales at Less Than Fair Value: Sodium Nitrite from the Federal Republic of Germany,* 73 FR 21909, 21912 (April 23, 2008), unchanged in *Notice of Final Determination of Sales at Less Than Fair Value: Sodium Nitrite from the Federal Republic of Germany,* 73 FR 38986, 38987 (July 8, 2008), and accompanying Issues and Decision Memorandum at Comment 2; *see also, Notice of Final Determination of Sales at Less Than Fair Value: Raw Flexible Magnets from Taiwan,* 73 FR 39673, 39674 (July 10, 2008); *Steel Threaded Rod from Thailand: Preliminary Determination of Sales at Less Than Fair Value and Affirmative Preliminary Determination of Critical Circumstances,* 78 FR 79670, 79671 (December 31, 2013), unchanged in *Steel Threaded Rod from Thailand: Final Determination of Sales at Less Than Fair Value and Affirmative Final Determination of Critical Circumstances,* 79 FR 14476, 14477 (March 14, 2014).

[10] *See* Commerce's Letter, ''Antidumping Duty Investigation Initiation Checklist: Carbon and Alloy Steel Threaded Rod from Taiwan,'' dated March 13, 2019.

[11] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements).

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at the U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

Final Determination

Section 735(a)(2) of the Act provides that a final determination may be postponed until not later than 135 days after the date of the publication of the preliminary determination if, in the event of an affirmative preliminary determination, a request for such postponement is made by exporters who account for a significant proportion of exports of the subject merchandise, or in the event of a negative preliminary determination, a request for such postponement is made by the petitioner. Section 351.210(e)(2) of Commerce's regulations requires that a request by exporters for postponement of the final determination be accompanied by a request for extension of provisional measures from a four-month period to a period not more than six months in duration, and 19 CFR 351.210(e)(1) further provides that Commerce may grant the request, unless Commerce finds compelling reasons to deny the request.

On August 18, 2019, pursuant to 19 CFR 351.210(e), Ta Chen requested that Commerce postpone the final determination and agreed to extend the application of the provisional measures. However, we find that a compelling reason to deny the request to postpone the final determination exists because on August 28, 2019, Ta Chen informed Commerce that it would no longer participate in the investigation. Since there are no respondents participating in this investigation, there is no need to postpone the final determination, and we are thus compelled to deny the request. In accordance with section 735(a)(2) of the Act and 19 CFR 351.210(e)(1), because a compelling reason for denial exists, we are not granting Ta Chen's request to postpone the final determination. Therefore, we intend to issue the final determination pursuant to section 735(a)(1) of the Act and 19 CFR 351.210(b)(1).

International Trade Commission Notification

In accordance with section 733(f) of the Act, Commerce will notify the International Trade Commission (ITC) of its preliminary determination. If the final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after the final determination whether these imports are materially injuring, or threaten material injury to, the U.S. industry.

Notification to Interested Parties

This determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act and 19 CFR 351.205(c).

Dated: September 19, 2019.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The merchandise covered by the scope of the investigation is carbon and alloy steel threaded rod. Steel threaded rod is certain threaded rod, bar, or studs, of carbon or alloy steel, having a solid, circular cross section of any diameter, in any straight length. Steel threaded rod is normally drawn, cold-rolled, threaded, and straightened, or it may be hot-rolled. In addition, the steel threaded rod, bar, or studs subject to the investigation are non-headed and threaded along greater than 25 percent of their total actual length. A variety of finishes or coatings, such as plain oil finish as a temporary rust protectant, zinc coating (*i.e.,* galvanized, whether by electroplating or hot-dipping), paint, and other similar finishes and coatings, may be applied to the merchandise.

Steel threaded rod is normally produced to American Society for Testing and Materials (ASTM) specifications ASTM A36, ASTM A193 B7/B7m, ASTM A193 B16, ASTM A307, ASTM A329 L7/L7M, ASTM A320 L43, ASTM A354 BC and BD, ASTM A449, ASTM F1554–36, ASTM F1554–55, ASTM F1554 Grade 105, American Society of Mechanical Engineers (ASME) specification ASME B18.31.3, and American Petroleum Institute (API) specification API 20E. All steel threaded rod meeting the physical description set forth above is covered by the scope of the investigation, whether or not produced according to a particular standard.

Subject merchandise includes material matching the above description that has been finished, assembled, or packaged in a third country, including by cutting, chamfering, coating, or painting the threaded rod, by attaching the threaded rod to, or packaging it with, another product, or any other finishing, assembly, or packaging operation that would not otherwise remove the merchandise from the scope of the investigation if performed in the country of manufacture of the threaded rod.

Carbon and alloy steel threaded rod are also included in the scope of the investigation whether or not imported attached to, or in conjunction with, other parts and accessories such as nuts and washers. If carbon and alloy steel threaded rod are imported attached to, or in conjunction with, such non-subject merchandise, only the threaded rod is included in the scope.

Excluded from the scope of the investigation are: (1) Threaded rod, bar, or studs which are threaded only on one or both ends and the threading covers 25 percent or less of the total actual length; and (2) stainless steel threaded rod, defined as steel threaded rod containing, by weight, 1.2 percent or less of carbon and 10.5 percent or more of chromium, with our without other elements.

Excluded from the scope of the antidumping investigation on steel threaded rod from the People's Republic of China is any merchandise covered by the existing antidumping order on Certain Steel Threaded Rod from the People's Republic of China. See Certain Steel Threaded Rod from the People's Republic of China: Notice of Antidumping Duty Order, 74 FR 17154 (April 14, 2009).

Specifically excluded from the scope of the investigation is threaded rod that is imported as part of a package of hardware in conjunction with a ready-to-assemble piece of furniture.

Steel threaded rod is currently classifiable under subheadings 7318.15.5051, 7318.15.5056, and 7318.15.5090 of the Harmonized Tariff Schedule of the United States (HTSUS). Subject merchandise may also enter under subheading 7318.15.2095 and 7318.19.0000 of the HTSUS. The HTSUS subheadings are provided for convenience and U.S. Customs purposes only. The written description of the scope is dispositive.

Appendix II

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Period of Investigation
IV. Scope Comments
V. Scope of the Investigation
VI. Product Characteristics
VII. Application of Facts Available and Use of Adverse Inference
VIII. All-Others Rate
IX. Verification
X. Recommendation

[FR Doc. 2019–20812 Filed 9–24–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Notice of Scope Rulings

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: Applicable September 25, 2019.

SUMMARY: The Department of Commerce (Commerce) hereby publishes a list of scope rulings and anti-circumvention determinations made during the period October 1, 2018 through December 31, 2018. We intend to publish future lists after the close of the next calendar quarter.

FOR FURTHER INFORMATION CONTACT: Brenda E. Brown, AD/CVD Operations, Customs Liaison Unit, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: 202–482–4735.

SUPPLEMENTARY INFORMATION:

Background

Commerce regulations provide that it will publish in the **Federal Register** a list of scope rulings on a quarterly basis.[1] Our most recent notification of scope rulings was published on August 27, 2019.[2] This current notice covers all scope rulings and anti-circumvention determinations made by Enforcement and Compliance between October 1, 2018 and December 31, 2018.

Scope Rulings Made October 1, 2018 Through December 31, 2018

People's Republic of China (China)

A–570–967 and C–570–968: Aluminum Extrusions From China

Requestors: Columbia Aluminum Products, LLC; MJB Wood Group, Inc.; Worldwide Door Components, Inc.; the requestors' door thresholds are included within the scope of the antidumping duty (AD) and countervailing duty (CVD) orders on aluminum extrusions from China; December 19, 2018.

A–570–814: Carbon Steel Butt-Weld Pipe Fittings From China

Requestor: SIGMA Corporation; the SAFELET and UNILET fire-protection weld outlets it imports from China are not subject to AD order on carbon steel butt-weld pipe from China because neither the ''fish mouth'' opening nor the threaded end of SIGMA's fire-protection weld outlets can be welded end-to-end to the circular, single-plane, beveled end of a pipe or another fitting; December 11, 2018

A–570–814: Carbon Steel Butt Weld Pipe Fittings From China

Requestor: Smith-Cooper International; threaded and grooved (cooplet) weld outlets are covered by the scope of the AD order on carbon steel butt weld pipe fittings from China because the scope language can be reasonably interpreted to include cooplet weld outlets, and the descriptions of the merchandise support a conclusion that the cooplet weld outlets are subject merchandise; December 20, 2018.

A–570–881: Certain Malleable Cast Iron Pipe Fittings From China

Requestor: MCC Holdings dba Crane (Crane); stainless steel castings produced by Anhui Yingliu Electromechanical and imported by Crane are outside the scope of AD order on certain malleable cast iron pipe fittings from China because they are composed of stainless steel and not malleable cast iron. Specifically, the castings which Crane imports are stainless steel castings made to ASTM A351 Grades CF8 and CF8M standards, which specify a maximum carbon content of 0.08 percent. Furthermore, Commerce determined that cast pipe fittings made of stainless steel and not malleable cast iron, generally, are not within the scope of the AD order on certain malleable cast iron pipe fittings from China; November 1, 2018.

A–570–881: Certain Malleable Cast Iron Pipe Fittings From China

Requestor: Steel Electric Products Company, Inc. (SEPCO); Electrical conduit fittings imported by SEPCO (*i.e.,* conduit bodies, conduit nipples, and conduit couplings and connectors), are not within the scope of the AD order on malleable cast iron pipe fittings from China because they are designed and manufactured to conform to entirely different industry codes and standards and are not suitable for use in oil, gas, or sprinkler applications; December 20, 2018.

A–570–910 and C–570–911: Circular Welded Carbon Quality Steel Pipe From China

Requestor: NEXTracker Inc.; Preliminarily found that NT Torque Tubes are not covered by the scope of the AD and CVD orders on circular welded carbon quality steel pipe from China because they are excluded mechanical tubing; October 30, 2018 (Preliminary Decision).

A–570–900: Diamond Sawblades and Parts Thereof From China

Requestor: Robert Bosch Tool Corporation (Bosch); finished diamond sawblade (SM540 Diamond Wheel) produced in China and included in Bosch's Dremel Saw-Max SM–20 power tool as an accessory is within the scope of the AD order on diamond sawblades from China; November 29, 2018.

A–570–033: Large Residential Washers From China

Requestor: Army & Air Force Exchange Service; the MIDEA washing machine model MAD160S2801 is not covered by the scope of the AD order on large residential washers from China because the scope of the order specifically excludes this type of washer, *i.e.,* washers that meet all of the following conditions: (1) A vertical rotational axis; (2) top loading; (3) a drive train consisting of (a) a permanent split capacitor motor, (b) a belt drive, and (c) a flat wrap spring clutch; October 18, 2018

A–570–875: Non-Malleable Cast Iron Pipe Fittings From China

Requestor: MCC Holdings dba Crane Resistoflex (Crane); ductile iron lap joint flanges with inside diameters less than six inches (*i.e.,* product numbers C11150DI–016–1, C11150DI–024–1, C11150DI–032–1, C11150DI–048–1, and C11150DI–064–1), that Crane imports are within the scope of the AD order on non-malleable cast iron pipe fittings from China because they have inside diameters that fall within the range of the scope of the order; while ductile iron lap joint flanges with inside diameters greater than six inches (*i.e.,* product numbers C11150DI–096–1, C11150DI–128–1, C11150DI–160–1, and C11150DI–192–1), that Crane imports are outside the scope of the order because they have inside diameters that fall outside the range of scope of the AD order on non-malleable cast iron pipe fittings from China; November 19, 2018.

A–570–826: Paper Clips From China

Requestor: ACCO Brands USA LLC (ACCO); the five types of butterfly clips imported by ACCO under the following product codes/skus are not within the scope of the AD order on paper clips from China: A70726108B, A7072610, A7072620B, A7072620, and A7072643, because based on a plain reading of the language of the scope of the order, ACCO's butterfly clips are excluded from the scope of the AD order on paper clips from China; October 4, 2018.

[1] *See* 19 CFR 351.225(o).

[2] *See Notice of Scope Rulings,* 84 FR 44848 (August 27, 2019).

A–570–890: Wooden Bedroom Furniture From China

Requestor: Homewerks Worldwide, LLC; certain medicine cabinets; linen towers; space savers; and hampers are not covered by the AD order on wooden bedroom furniture from China because they are not bedroom furniture; December 19, 2018.

Anti-Circumvention Determinations Made October 1, 2018 Through December 31, 2018: China

A–570–928: Uncovered Innersprings From China

Innersprings exported from Macau to the United States, which were assembled or completed in Macau by Macao Commercial and Industrial Spring Mattress Manufacturer (Macao Commercial) and the other companies that are part of the Macao Commercial Group, used materials and/or components from China and are circumventing the AD order; December 21, 2018.

Notification to Interested Parties

Interested parties are invited to comment on the completeness of this list of completed scope inquiries and anti-circumvention determinations made during the period October 1, 2018 through December 31, 2018. Any comments should be submitted to the Deputy Assistant Secretary for AD/CVD Operations, Enforcement and Compliance, International Trade Administration, 1401 Constitution Avenue NW, APO/Dockets Unit, Room 18022, Washington, DC 20230.

This notice is published in accordance with 19 CFR 351.225(o).

Dated: September 19, 2019.

Scot T. Fullerton,

Director, Office VI for Antidumping and Countervailing Duty Operations.

[FR Doc. 2019–20817 Filed 9–24–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–010]

Certain Crystalline Silicon Photovoltaic Products From the People's Republic of China: Notice of Court Decision Not in Harmony With Final Results of Antidumping Duty Administrative Review and Notice of Amended Final Results of Antidumping Duty Administrative Review

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On July 25, 2019, the United States Court of International Trade (the Court) issued its final judgement sustaining the remand redetermination pertaining to the antidumping duty (AD) administrative review of certain crystalline silicon photovoltaic products (solar products), from the People's Republic of China (China) covering the period July 31, 2014 through January 31, 2016. The Department of Commerce (Commerce) is notifying the public that the final judgment in this case is not in harmony with Commerce's final results in the 2014–2016 AD administrative review of solar products from China and that Commerce is amending the final results with respect to AD margins assigned, as detailed below.

DATES: Applicable August 4, 2019.

FOR FURTHER INFORMATION CONTACT: Jeff Pedersen, 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) 482–2769.

SUPPLEMENTARY INFORMATION:

Background

On July 12, 2017, Commerce published the final results of the 2014–2016 AD administrative review of solar products from China.[1] In the *Final Results,* Changzhou Trina Solar Energy Co., Ltd./Trina Solar (Changzhou) Science and Technology Co., Ltd./Yangcheng Trina Solar Energy Co., Ltd./Turpan Trina Solar Energy Co., Ltd./Hubei Trina Solar Energy Co., Ltd. (collectively, Trina) was not granted an export subsidy offset because Commerce did not make a determination in the countervailing duty (CVD) investigation of certain solar products from China that the Export Buyer's Credits Program was an export subsidy.[2] However, the Court concluded that Commerce ''necessarily found'' that the Export Buyer's Credit Program was an export subsidy, and that such a finding is ''reasonably discernible'' from Commerce's description of the program.[3] On January 25, 2019, the Court remanded the *Final Results* to Commerce directing Commerce to increase Trina's U.S. selling prices by the amount countervailed to offset a particular subsidy.[4] In accordance with the Court's *Remand Order,* under respectful protest, Commerce increased Trina's U.S. selling prices by the amount countervailed to offset a subsidy that Trina received in the most recently completed segment of the corresponding CVD proceeding.[5] On July 25, 2019, the Court sustained Commerce's Remand Redetermination.[6]

Timken Notice

In its decision in *Timken,*[7] as clarified by *Diamond Sawblades,*[8] the United States Court of Appeals for the Federal Circuit (CAFC) held that, pursuant to section 516A(c) and (e) of the Tariff Act of 1930, as amended (the Act), Commerce must publish a notice of a court decision that is not ''in harmony'' with a Commerce determination and must suspend liquidation of entries pending a ''conclusive'' court decision. The Court's July 25, 2019, final judgment sustaining Commerce's Remand Redetermination constitutes a final decision of the Court that is not in harmony with Commerce's *Final Results.* This notice is published in fulfillment of the publication requirements of *Timken.* Commerce will continue the suspension of liquidation of the subject merchandise pending the expiration of the period of appeal, or if appealed, pending a final and conclusive court decision.

Amended Final Results

Because there is now a final Court decision, Commerce is amending the *Final Results.* The revised AD dumping

[1] *See Certain Crystalline Silicon Photovoltaic Products From the People's Republic of China: Final Results of Antidumping Duty Administrative Review and Final Determination of No Shipments; 2014–2016,* 82 FR 32170 (July 12, 2017) (*Final Results*), and accompanying Issues and Decision Memorandum (IDM) at Comment 2.

[2] *See Countervailing Duty Investigation of Certain Crystalline Silicon Photovoltaic Products from the People's Republic of China: Final Affirmative Countervailing Duty Determination,* 79 FR 76962 (December 23, 2014), and accompanying IDM at Comment 16, unchanged in *Certain Crystalline Silicon Photovoltaic Products from the People's Republic of China: Antidumping Duty Order; and Amended Final Affirmative Countervailing Duty an Determination and Countervailing Duty Order,* 80 FR 8592 (February 18, 2015).

[3] *See Changzhou Trina Solar Energy Co., Ltd. Et Al* v. *United States,* 359 F. Supp. 3d 1329, 1339 (CIT 2019) (*Remand Order*).

[4] *Id.* at 1342.

[5] *See Final Results of Remand Redetermination, Changzhou Trina Solar Energy Co., Ltd. Et Al* v. *United States,* Court No. 17–00199, Slip. Op. 19–12 (Court of International Trade January 25, 2019) (Remand Redetermination).

[6] *See Changzhou Trina Solar Energy Co., Ltd. Et Al* v. *United States,* Court No. 17–00199, Slip. Op. 19–92, (Court of International Trade July 25, 2019).

[7] *See Timken Co.* v. *United States,* 893 F.2d 337, 341 (Fed. Cir. 1990) (*Timken*).

[8] *See Diamond Sawblades Mfrs. Coalition* v. *United States,* 626 F. 3d 1374 (Fed. Cir. 2010) (*Diamond Sawblades*).

margin for the respondents during the period July 31, 2014 through January 31, 2016 is in the table below:

Exporter	Weighted-average dumping margin
Changzhou Trina Solar Energy Co., Ltd./Trina Solar (Changzhou) Science and Technology Co., Ltd./Yangcheng Trina Solar Energy Co., Ltd./Turpan Trina Solar Energy Co., Ltd./Hubei Trina Solar Energy Co., Ltd	3.42
BYD (Shangluo) Industrial Co., Ltd	3.42
Chint Solar (Zhejiang) Co., Ltd	3.42
Hefei JA Solar Technology Co., Ltd	3.42
Perlight Solar Co., Ltd	3.42
Shenzhen Sungold Solar Co., Ltd	3.42
Sunny Apex Development Ltd	3.42
Wuxi Suntech Power Co., Ltd	3.42

In the event the Court's ruling is not appealed or, if appealed, upheld by the CAFC, Commerce will instruct U.S. Customs and Border Protection to assess antidumping duties on unliquidated entries of subject merchandise exported by the respondents listed above based on the assessment rates calculated by Commerce in these amended final results of review.

Cash Deposit Requirements

Aside from Shenzhen Sungold Solar Co., Ltd., none of the cash deposit rates of the respondents listed above have been superseded by cash deposit rates calculated in intervening administrative reviews of the AD order on solar products from China. Thus, effective August 4, 2019, the cash deposit rate applicable to entries of subject merchandise exported by all companies listed above, aside from Shenzhen Sungold Solar Co., Ltd., is 3.42 percent. Because Shenzhen Sungold Solar Co., Ltd. lost its separate rate in the most recently completed review of this order,[9] we have not revised its cash deposit rate.

Notification to Interested Parties

This notice is issued and published in accordance with sections 516A(e), 751(a)(1), and 777(i)(1) of the Act.

Dated: September 18, 2019.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2019–20816 Filed 9–24–19; 8:45 am]

BILLING CODE 3510–DS–P

[9] *See Certain Crystalline Silicon Photovoltaic Products from the People's Republic of China: Final Results of Antidumping Duty Administrative Review; 2017–2018,* 84 FR 27764 (June 14, 2019).

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XR029

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Erickson Residence Marine Access Project in Juneau, Alaska

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

ACTION: Notice; proposed incidental harassment authorization; request for comments on proposed authorization and possible renewal.

SUMMARY: NMFS has received a request from Jim Erickson for authorization to take marine mammals incidental to the Erickson Residence Marine Access Project in Juneau, Alaska. Pursuant to the Marine Mammal Protection Act (MMPA), NMFS is requesting comments on its proposal to issue an incidental harassment authorization (IHA) to incidentally take marine mammals during the specified activities. NMFS is also requesting comments on a possible one-year renewal that could be issued under certain circumstances and if all requirements are met, as described in *Request for Public Comments* at the end of this notice. NMFS will consider public comments prior to making any final decision on the issuance of the requested MMPA authorizations and agency responses will be summarized in the final notice of our decision.

DATES: Comments and information must be received no later than October 25, 2019.

ADDRESSES: Comments should be addressed to Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service. Physical comments should be sent to 1315 East-West Highway, Silver Spring, MD 20910 and electronic comments should be sent to *ITP.Fowler@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 received electronically, including all attachments, must not exceed a 25-megabyte file size. Attachments to electronic 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: Amy Fowler, Office of Protected Resources, NMFS, (301) 427–8401. Electronic copies of the application and supporting documents, as well as a list of the references cited in this document, may be obtained online at: *https://www.fisheries.noaa.gov/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 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, a notice of a proposed incidental take authorization may be provided to the public for review.

Authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for taking for subsistence uses (where relevant). Further, NMFS must prescribe the permissible methods of taking and other ''means of effecting the least practicable adverse impact'' on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stocks for taking for certain subsistence uses (referred to in shorthand as ''mitigation''); and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth.

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 (incidental harassment authorizations 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 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 request.

Summary of Request

On May 8, 2019, NMFS received a request from Jim Erickson for an IHA to take marine mammals incidental to pile driving activities associated with a dock replacement project in Auke Bay, north of Juneau, Alaska. The application was deemed adequate and complete on August 13, 2019. Mr. Erickson's request is for take of a small number of eight species of marine mammal by Level A and Level B harassment. Neither Mr. Erickson nor NMFS expects serious injury or mortality to result from this activity and, therefore, an IHA is appropriate.

Description of Proposed Activity

Overview

Mr. Erickson is proposing to replace his private moorage facility in Auke Bay in Juneau, Alaska to provide a safer, more accessible and secure dock. The old, deteriorated dock structure will be replaced with a new, modern moorage facility. Six timber piles will be removed using a vibratory hammer, and six steel pipe piles will be installed using vibratory and impact hammers. Drilling may be required to install the larger diameter steel piles. Vibratory pile removal and installation, impact pile installation, and drilling would introduce underwater sounds at levels that may result in take, by Level A and Level B harassment, of marine mammals in Auke Bay.

Dates and Duration

Construction is expected to begin in the spring of 2020 but may occur up to December 2020. Pile driving may be intermittent during this period, depending on weather, construction and mechanical delays, and logistical constraints. Construction is expected to take up to eight days. Of those eight days, impact pile driving may occur on up to four days, vibratory pile removal and installation may occur on up to six days, and drilling may occur on up to two days. Work will occur during daylight hours only.

Specific Geographic Region

Auke Bay is an estuary at the southern end of Lynn Canal, located approximately 18 kilometers (km) (11 miles (mi)) north-northwest of downtown Juneau. The bay is one of many that lead to a larger system of glacial fjords connecting various channels with the open ocean. Auke Bay is approximately 130 km (80.7 mi) inland from the Gulf of Alaska (Figure 1). Auke Bay contains several small islands and reefs within the 11 square kilometer (km^2) (4.25 square mile (mi^2)) embayment. While most of the bay is relatively shallow, reaching depths of 40 to 60 meters (m) (131 to 197 feet (ft)), depths of more than 100 m (328 ft) are found near Coghland Island on the western side of the bay. Mr. Erickson's dock is located on the eastern shore of Auke Bay, on the Mendenhall Peninsula (see Figure 1).

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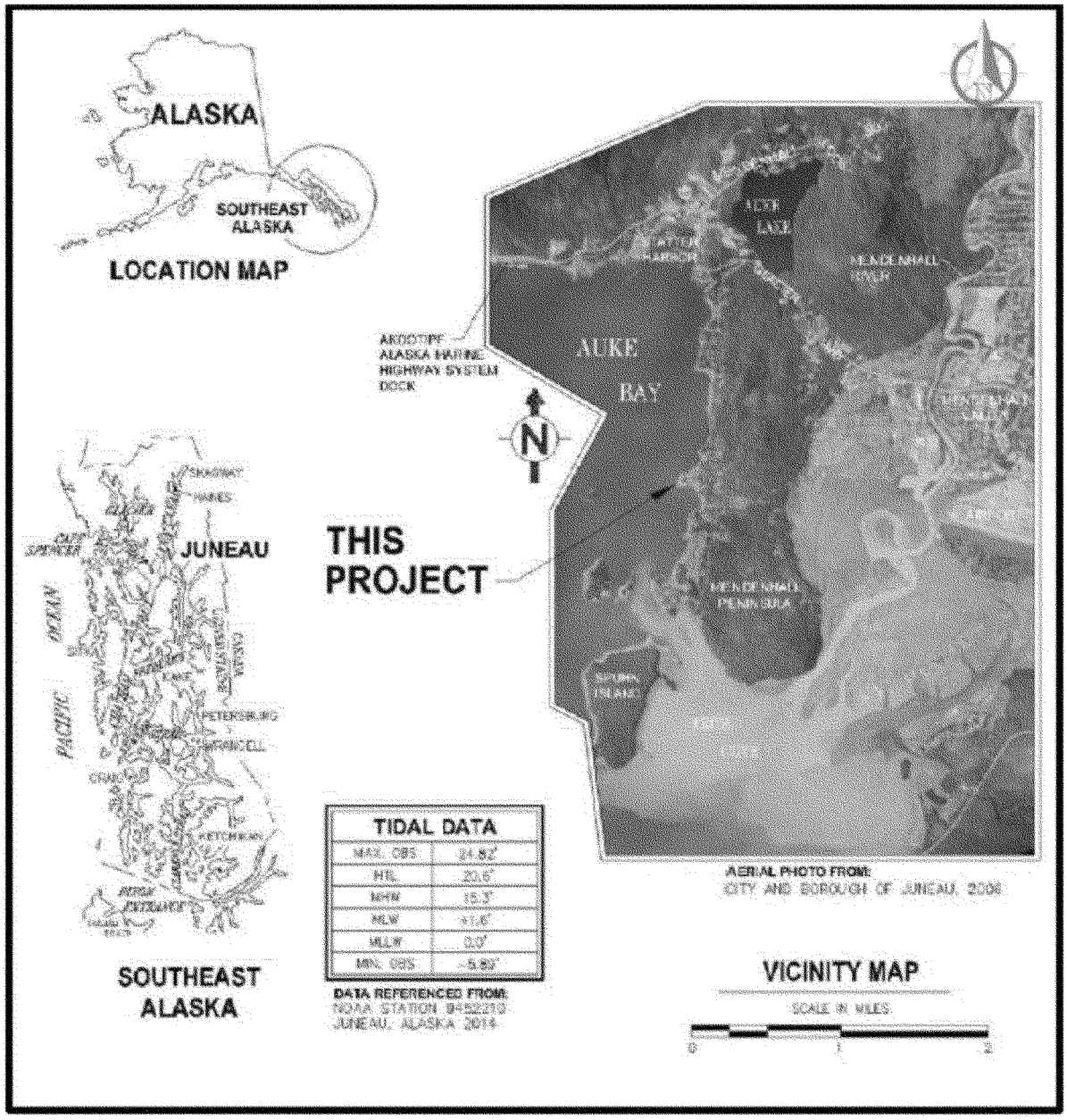

Figure 1. Project Location in Southeast Alaska.

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Detailed Description of Specific Activity

The Erickson Residence Marine Access Project involves demolishing an existing private moorage facility and replacing it with a new, modern facility consisting of a concrete retaining wall, an aluminum approach structure, and steel gangway leading to a new timber moorage float supported by steel piles. The six existing 12- to 16-inch (in) timber support piles will be extracted using a vibratory hammer. Four 12.75-in steel pipe piles and two 20-in steel pipe piles will be installed in their place. All pile removal and installation activities will be conducted from a stationary barge platform. Pile installation will primarily be done using a vibratory hammer. Due to a rock outcropping in the project vicinity, drilling may be required for the two 20-in piles, as they require more embedment to reach the necessary capacity to withstand the high lateral loads on the float. No drilling is anticipated for the four 12.75-in approach bearing piles. Impact hammers will only be used for piles that encounter soils too dense to penetrate with the vibratory hammer. Table 1 provides a summary of the expected pile removal and installation parameters.

TABLE 1—NUMBERS AND TYPES OF PILES TO BE INSTALLED AND REMOVED

Pile type	Method	Number of piles	Strikes per pile (impact driving)	Duration per pile (minutes) (vibratory driving, drilling)	Piles per day (range)	Days of activity
Pile installation:						
12.75-in steel	Vibratory installation	4	N/A	30	2–4	1–2
12.75-in steel	Impact installation		150	N/A	2–4	1–2
20-in steel	Vibratory installation	2	N/A	120	1–2	1–2
20-in steel	Impact installation		150	N/A	1–2	1–2
20-in steel	Drilling		N/A	300	1–2	1–2
Pile removal:						
12- to 16-in timber	Vibratory removal	6	N/A	15	3–6	1–2
Total piles		12			Total days	8

Demolition of the existing float and approach structures, and installation of the new float, approach, and concrete retaining wall are not expected to result in take of marine mammals and will therefore not be discussed further in this document.

Proposed mitigation, monitoring, and reporting measures are described in detail later in this document (please see *Proposed Mitigation* and *Proposed Monitoring and Reporting*).

Description of Marine Mammals in the Area of Specified Activities

Sections 3 and 4 of the application summarize available information regarding status and trends, distribution and habitat preferences, and behavior and life history, of the potentially affected species. Additional information regarding population trends and threats may be found in NMFS's Stock Assessment Reports (SARs; *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments*) and more general information about these species (*e.g.,* physical and behavioral descriptions) may be found on NMFS's website (*https://www.fisheries.noaa.gov/find-species*).

Table 2 lists all species with expected potential for occurrence in Auke Bay and summarizes information related to the population or stock, including regulatory status under the MMPA and ESA and potential biological removal (PBR), where known. For taxonomy, we follow Committee on Taxonomy (2018). PBR is defined by the MMPA as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population (as described in NMFS's SARs). While no mortality is anticipated or authorized here, PBR and annual serious injury and mortality from anthropogenic sources are included here as gross indicators of the status of the species and other threats.

Marine mammal abundance estimates presented in this document represent the total number of individuals that make up a given stock or the total number estimated within a particular study or survey area. NMFS's stock abundance estimates for most species represent the total estimate of individuals within the geographic area, if known, that comprises that stock. For some species, this geographic area may extend beyond U.S. waters. All managed stocks in this region are assessed in NMFS's U.S. Alaska and U.S. Pacific SARs. All values presented in Table 2 are the most recent available at the time of publication and are available in the 2018 SARs (Muto *et al.,* 2019; Caretta *et al.,* 2019).

TABLE 2—MARINE MAMMALS THAT COULD OCCUR IN THE PROJECT AREA

Common name	Scientific name	Stock	ESA/MMPA status; Strategic (Y/N) [1]	Stock abundance (CV, N_{min}, most recent abundance survey) [2]	PBR	Annual M/SI [3]
Order Cetartiodactyla—Cetacea—Superfamily Mysticeti (baleen whales)						
Family Eschrichtiidae						
Gray whale	Eschrichtius robustus	Eastern North Pacific	-/-; N	26,960 (0.05, 25,849, 2016).	801	138
Family Balaenopteridae (rorquals)						
Humpback whale	Megaptera novaeangliae.	Central North Pacific	T/D; Y	10,103 (0.3, 7,890, 2006).	83	26
Minke whale	Balaenoptera acutorostrada.	Alaska	-/-; N	N/A (see SAR, N/A, see SAR).	UND	0
Fin whale	Balaenoptera physalus.	Northeast Pacific	E/D; Y	see SAR (see SAR, see SAR, 2013).	5.1	0.6
Superfamily Odontoceti (toothed whales, dolphins, and porpoises)						
Family Delphinidae						
Killer whale	Orcinus orca	Alaska Resident	-/-; N	2,347 (N/A, 2347, 2012).	24	1

TABLE 2—MARINE MAMMALS THAT COULD OCCUR IN THE PROJECT AREA—Continued

Common name	Scientific name	Stock	ESA/MMPA status; Strategic (Y/N) [1]	Stock abundance (CV, N_{min}, most recent abundance survey) [2]	PBR	Annual M/SI [3]
Killer whale	Orcinus orca	Northern Resident	-/-; N	261 (N/A, 261, 2011)	1.96	0
Killer whale	Orcinus orca	West Coast Transient	-/-; N	243 (N/A, 243, 2009)	2.4	0
Family Phocoenidae (porpoises)						
Harbor porpoise	Phocoena phocoena	Southeast Alaska	-/-; Y	975 (0.10; 896; 2012)	8.9	34
Dall's porpoise	Phocoenoides dalli	Alaska	-/-; N	83,400 (0.097, N/A, 1991).	UND	38
Order Carnivora—Superfamily Pinnipedia						
Family Otariidae (eared seals and sea lions)						
Steller sea lion. Eumetopias jubatus	Eastern DPS	E/D; Y	54,267 (see SAR, 54,267, 2017)	326	252	
Steller sea lion	Eumetopias jubatus	Western DPS	-/-; N	41,638 (see SAR, 41,638, 2015).	2,498	108
California sea lion	Zalophus californianus.	U.S.	-/-; N	257,606 (N/A, 233,515, 2014).	14,011	> 321
Family Phocidae (earless seals)						
Harbor seal	Phoca vitulina	Lynn Canal/Stephens Passage.	-/-; N	9,478 (see SAR, 8,605, 2011).	155	50

1—Endangered Species Act (ESA) status: Endangered (E), Threatened (T)/MMPA status: Depleted (D). A dash (-) indicates that the species is not listed under the ESA or designated as depleted under the MMPA. Under the MMPA, a strategic stock is one for which the level of direct human-caused mortality exceeds PBR or which is determined to be declining and likely to be listed under the ESA within the foreseeable future. Any species or stock listed under the ESA is automatically designated under the MMPA as depleted and as a strategic stock.

2—NMFS marine mammal stock assessment reports online at: *www.nmfs.noaa.gov/pr/sars/.* CV is coefficient of variation; Nmin is the minimum estimate of stock abundance. In some cases, CV is not applicable.

3—These values, found in NMFS's SARs, represent annual levels of human-caused mortality plus serious injury from all sources combined (*e.g.,* commercial fisheries, ship strike). Annual M/SI often cannot be determined precisely and is in some cases presented as a minimum value or range. A CV associated with estimated mortality due to commercial fisheries is presented in some cases.

Note—Italicized species are not expected to be taken or proposed for authorization.

All species that could potentially occur in the proposed survey areas are included in Table 2. However, the spatial and temporal occurrence of gray whales and fin whales in the area is such that take is not expected to occur, and they are not discussed further beyond the explanation provided here. Sightings of gray whales and fin whales are uncommon in the inland waters of southeast Alaska. These species are typically seen closer to the open waters of the Gulf of Alaska. Take of gray whales and fin whales has not been requested nor proposed to be authorized and these species are not considered further in this document.

Steller Sea Lion

Steller sea lions are found throughout the northern Pacific Ocean, including coastal and inland waters from Russia (Kuril Islands and the Sea of Okhotsk), east to Alaska, and south to California. Steller sea lions were listed as threatened range-wide under the ESA on November 26, 1990 (55 FR 49204) but were subsequently partitioned into the eastern and western Distinct Population Segments (eDPS and wDPS, respectively). The eDPS remained classified as threatened (62 FR 24345; May 5, 1997) until it was delisted in 2013 (78 FR 66139; November 4, 2013). The wDPS (those individuals west of 144° W longitude, or Cape Suckling, AK) was upgraded to endangered status following separation of the stocks, and it remains listed as endangered.

Steller sea lions in southeast Alaska are overwhelmingly part of the eDPS; however, NMFS (2013) reports that an average of 917 individuals from the wDPS move into southeast Alaska annually. Within southeast Alaska, abundance of wDPS individuals is higher to the north and west, and lower toward the south and east. Cape Ommaney and Frederick Sound are considered the southern limit of the range for wDPS animals. While it is not possible to estimate the number of wDPS animals that are present east of the 144° W longitude boundary at any time, recent studies indicate that 18.1 percent of Steller sea lions in the Lynn Canal area may be from the wDPS (Hastings *et al.,* 2019).

Steller sea lions are opportunistic predators, feeding primarily on a wide variety of fishes and cephalopods, including Pacific herring (*Clupea pallasi*), walleye pollock (*Gadus chalogramma*), capelin (*Mallotus villosus*), Pacific sand lance (*Ammodytes hexapterus*), Pacific cod (*Gadus machrocephalus*), salmon (*Oncorhynchus* spp.), and squid (*Teuthida* spp.) (Jefferson *et al.,* 2008; Wynne *et al.,* 2011). Steller sea lions do not generally eat every day, but tend to forage every one to two days and return to haulouts to rest between foraging trips (Merrick and Loughlin 1997; Rehberg *et al.,* 2009). Most individuals that frequent Auke Bay haul out at Benjamin Island in Lynn Canal, but several other haulouts are located within 20 to 30 km (12 to 19 mi) of the project area.

The action area is not located in or near designated critical habitat for the wDPS of Steller sea lions. In southeast Alaska, critical habitat for the wDPS includes a terrestrial zone, an aquatic zone, and an in-air zone that extends 3,000 ft (0.9 km) landward, seaward, and above, respectively, any designated major rookery and major haulout. The nearest designated major haulout is located at Benjamin Island.

California Sea Lion

California sea lions typically breed on islands in southern California, western Baja California and the Gulf of California (Carretta et al 2017). During the winter, males commonly migrate to feeding grounds off California, Oregon, Washington, British Columbia and recently Southeast Alaska. Females and pups typically stay close to breeding colonies until the pups have weened. The furthest north females have been observed is off the coast of Washington and Oregon during warm water years (NMFS 2019f). California sea lions feed primarily offshore in coastal waters. They are opportunistic predators and eat a variety of prey including squid, anchovies, mackerel, rockfish and sardines (NMFS 2019f). A single California sea lion hauled out on the Statter Harbor boat ramp in Auke Bay in September of 2017.

Harbor Seal

Harbor seals range from Baja California north along the west coasts of California, Oregon, Washington, British Columbia, and southeast Alaska; west through the Gulf of Alaska, Prince William Sound, and the Aleutian Islands; and north in the Bering Sea to Cape Newenham and the Pribilof Islands. Harbor seals occur year-round in the inside passages of southeast Alaska and are regularly sighted in Auke Bay, including Statter Harbor. Groups ranging from 10 to 52 seals may be present in Auke Bay, hauled out on the western side of Coghlan Island and on Battleship Island.

Harbor seals forage on fish and invertebrates, including capelin, eulachon (*Thaleichthys pacificus*), cod, Pollock, flatfish, shrimp, octopus, and squid (Wynne 2012). They are opportunistic feeders that forage in marine, estuarine, freshwater habitats, adjusting their foraging behavior to take advantage of prey that are seasonally and locally abundant (Payne and Selzer 1989). Depending on prey availability, harbor seals conduct both shallow and deep dives while foraging (Tollit *et al.,* 1997). Harbor seals usually give birth to a single pup between May and mid-July. Birthing locations are dispersed over several haulout sites and are not confined to major rookeries (Klinkhart *et al.,* 2008).

Harbor Porpoise

The Southeast Alaska stock of harbor porpoises ranges from Cape Suckling to the Canada border (Muto *et al.,* 2018). Harbor porpoises frequent primarily coastal waters in southeast Alaska (Dalheim *et al.,* 2009) and occur most frequently in waters less than 100 m (328 ft) deep (Hobbs and Waite 2010). Harbor porpoises forage in waters less than 200 m (656 ft) deep on small pelagic schooling fish such as herring, cod, pollock, octopus, smelt, and bottom-dwelling fish, occasionally feeding on squid and crustaceans (Bjørge and Tolley 2009; Wynne *et al.,* 2011). Calving generally occurs from May to August, but can vary by region.

Dall's Porpoise

Dall's porpoises are found throughout the north Pacific, from southern Japan to southern California and north to the Bering Sea. Dall's porpoises can be found in offshore, inshore, and nearshore habitat, but prefers waters more than 183 m (600 ft) deep (Dahlheim *et al.,* 2009; Jefferson 2009). Waters over 183 m (600 ft) do not occur in Auke Bay but Dall's porpoises have been consistently observed in Lynn Canal, Stephens Passage, upper Chatham Strait, Frederick Sound, and Clarence Strait (Dahlheim *et al.,* 2000). Dall's porpoises may migrate between inshore and offshore areas and make latitudinal movements or short seasonal migrations, but these movements are generally not consistent (Jefferson 2009). If Dall's porpoises were to occur in Auke Bay, they would likely be present in March or April, given seasonal patterns observed in nearby areas of southeast Alaska (Dahlheim *et al.,* 2009). Dall's porpoises often bow-ride with vessels and may occur in Auke Bay incidentally a few times per year.

Dall's porpoises generally occur in groups of 2 to 20 individuals, but have also been recorded in groups numbering in the hundreds. Common prey include a variety of small, schooling fishes (such as herring and mackerels) and cephalopods.

Killer Whale

Killer whales have been observed in all oceans, but the highest densities occur in colder and more productive waters found at high latitudes (NMFS 2016a). Killer whales occur along the entire Alaska coast, in British Columbia and Washington inland waterways, and along the outer coasts of Washington, Oregon, and California (NMFS 2016a). There are three distinct ecotypes, or forms, of killer whales recognized in the north Pacific: Resident, transient, and offshore. The three ecotypes differ morphologically, ecologically, behaviorally, and genetically. Eight stocks of killer whales are recognized within the Pacific U.S. Exclusive Economic Zone. Of those, the Alaska Resident stock, Northern Resident stock, and West Coast Transient stock may occur in the project area (Muto *et al.,* 2018).

The Alaska Resident stock occurs from southeast Alaska to the Aleutian Islands and Bering Sea. Photo-identification studies between 2005 and 2009 identified 2,347 individuals in this stock, including approximately 121 in southeast Alaska (Muto *et al.,* 2018). The Northern Resident stock occurs from Washington north through part of southeast Alaska and consists of 261 individuals (Muto *et al.,* 2018). The West Coast Transient stock occurs from California north through southeast Alaska. Between 1975 and 2012, surveys identified 521 individual West Coast Transient killer whales but the minimum population estimate for the stock is 243 individuals (Muto *et al.,* 2018). Dahlheim *et al.,* (2009) noted a 5.2 percent annual decline in transient killer whales observed in southeast Alaska between 1991 and 2007.

No systematic studies of killer whales have been conducted in or around Auke Bay. Killer whales were observed infrequently (on 11 of 135 days) during monitoring in Hoonah, and most were recorded in deeper, offshore waters (Berger ABAM 2016). Both resident and transient killer whales were observed in southeast Alaska during all seasons during surveys between 1991 and 2007, in a variety of habitats and in all major waterways, including Lynn Canal, Icy Strait, Stephens Passage, Frederick Sound, and upper Chatham Strait (Dahlheim *et al.,* 2009). There does not appear to be strong seasonal variation in abundance or distribution of killer whales, but Dahlheim *et al.,* (2009) observed substantial variability between years during the study.

Transient killer whales hunt and feed primarily on marine mammals, including harbor seals, Dall's porpoises, harbor porpoises, and sea lions. Resident killer whale populations in the eastern north Pacific feed mainly on salmonids, showing a strong preference for Chinook salmon (NMFS 2016a). Transient killer whales are often found in long-term stable social units (pods) of 1 to 16 whales. Pod sizes in southeast Alaska vary by season, averaging 6 animals in spring, 5 in summer, and 4 in fall. Group sizes of transient whales

are generally smaller than those of resident killer whales. Resident killer whales occur in pods ranging from seven to 70 whales that are seen in association with one another more than 50 percent of the time (Dahlheim *et al.,* 2009; NMFS 2016b).

Humpback Whale

Humpback whales in the project area are from the Central North Pacific stock but may be of the Hawaii or Mexico DPS. The population of the Hawaii DPS is currently estimated at 11,398 individuals (95% confidence interval (CI) = 10,503—12,370) and the Mexico DPS is estimated at 3,264 individuals (95% CI = 2,912—3,659). The population of humpback whales from both the Hawaii and Mexico DPSs that are found in the summer feeding grounds of southeast Alaska is approximately 6,137 individuals (95% CI = 5,352—7,038) (Wade *et al.,* 2016). Humpback whales found in the project area are predominantly members of the Hawaii DPS, which is not listed under the ESA. However, based on a comprehensive photo-identification study, members of the Mexico DPS, which is listed as threatened, are known to occur in southeast Alaska. Approximately 6.1 percent (fewer than one in every 16) of all humpback whales in southeast Alaska and northern British Columbia are members of the Mexico DPS, while all others are assumed to be members of the Hawaii DPS (Wade *et al.,* 2016).

Humpback whales migrate to southeast Alaska in spring to feed after months of fasting in equatorial breeding grounds in Hawaii and Mexico. Peak abundance of humpback whales in southeast Alaska typically occurs during late summer to early fall. Most humpback whales begin returning to southern breeding grounds in fall or winter. However, due to temporal overlap between whales departing and returning, humpbacks can be found in Alaskan feeding grounds in every month of the year (Baker *et al.,* 1985; Straley 1990; Wynne and Witteveen 2009). It is also common for some humpback whales to overwinter in areas of southeast Alaska. It is thought that those humpbacks that remain in southeast Alaska do so in response to the availability of winter schools of fish, such as herring (Straley 1990).

The waters of southeast Alaska (including Auke Bay) are considered a biologically important area for feeding humpback whales between March and November (Ferguson *et al.,* 2015). In Alaska, humpback whales filter feed on small crustaceans, plankton, and small fish such as walleye pollock, Pacific sand lance, herring, eulachon, and capelin (Witteveen *et al.,* 2012). It is common to observe groups of humpback whales cooperatively bubble feeding.

Humpback whales' utilization of Auke Bay is intermittent and irregular year-round. Recent anecdotal accounts by the Juneau Deputy Harbormaster indicate that humpback whale abundance in Auke Bay has been lower over the last 18 months than in past years (Creswell, M., pers. comm.). Specific micro-habitat features of Auke Bay attract forage fish, specifically herring, and are frequented by humpback whales. Although abundance is generally higher in the summer months, the presence of prey fish is a greater determinant of the presence of humpback whales than season. Teerlink (2017) identified 179 individual humpback whales in the Juneau area based on fluke identification.

Minke Whale

Minke whales are found throughout the northern hemisphere in polar, temperate, and tropical waters (Jefferson *et al.,* 2008). The International Whaling Commission has identified three minke whale stocks in the North Pacific: One near the Sea of Japan, a second in the rest of the western Pacific (west of 180° W), and a third, less concentrated stock throughout the eastern Pacific. NMFS further splits this third stock between Alaska whales and resident whales of California, Oregon, and Washington (Muto *et al.,* 2018). Minke whales are found in all Alaska waters though there are no population estimates for minke whales in southeast Alaska.

In Alaska, minke whales feed primarily on euphausiids and walleye pollock. Minke whales are generally found in shallow, coastal waters within 200 m (656 ft) of shore (Zerbini *et al.,* 2006). No information appears to be available on the winter occurrence of minke whales in southeast Alaska. Anecdotal observations suggest that minke whales do not enter Auke Bay, and so are expected to rarely occur in the project area.

Marine Mammal Hearing

Hearing is the most important sensory modality for marine mammals underwater, and exposure to anthropogenic sound can have deleterious effects. To appropriately assess the potential effects of exposure to sound, it is necessary to understand the frequency ranges marine mammals are able to hear. Current data indicate that not all marine mammal species have equal hearing capabilities (*e.g.,* Richardson *et al.,* 1995; Wartzok and Ketten, 1999; Au and Hastings, 2008). To reflect this, Southall *et al.* (2007) recommended that marine mammals be divided into functional hearing groups based on directly measured or estimated hearing ranges on the basis of available behavioral response data, audiograms derived using auditory evoked potential techniques, anatomical modeling, and other data. Note that no direct measurements of hearing ability have been successfully completed for mysticetes (*i.e.,* low-frequency cetaceans). Subsequently, NMFS (2018) described generalized hearing ranges for these marine mammal hearing groups. Generalized hearing ranges were chosen based on the approximately 65 decibel (dB) threshold from the normalized composite audiograms, with the exception for lower limits for low-frequency cetaceans where the lower bound was deemed to be biologically implausible and the lower bound from Southall *et al.* (2007) retained. Marine mammal hearing groups and their associated hearing ranges are provided in Table 3.

TABLE 3—MARINE MAMMAL HEARING GROUPS (NMFS, 2018)

Hearing group	Generalized hearing range *
Low-frequency (LF) cetaceans (baleen whales)	7 Hz to 35 kHz.
Mid-frequency (MF) cetaceans (dolphins, toothed whales, beaked whales, bottlenose whales)	150 Hz to 160 kHz.
High-frequency (HF) cetaceans (true porpoises, *Kogia,* river dolphins, cephalorhynchid, *Lagenorhynchus cruciger* & *L. australis*).	275 Hz to 160 kHz.
Phocid pinnipeds (PW) (underwater) (true seals)	50 Hz to 86 kHz.

TABLE 3—MARINE MAMMAL HEARING GROUPS (NMFS, 2018)—Continued

Hearing group	Generalized hearing range *
Otariid pinnipeds (OW) (underwater) (sea lions and fur seals)	60 Hz to 39 kHz.

* Represents the generalized hearing range for the entire group as a composite (i.e., all species within the group), where individual species' hearing ranges are typically not as broad. Generalized hearing range chosen based on ~65 dB threshold from normalized composite audiogram, with the exception for lower limits for LF cetaceans (Southall et al. 2007) and PW pinniped (approximation).

The pinniped functional hearing group was modified from Southall *et al.* (2007) on the basis of data indicating that phocid species have consistently demonstrated an extended frequency range of hearing compared to otariids, especially in the higher frequency range (Hemilä *et al.,* 2006; Kastelein *et al.,* 2009; Reichmuth and Holt, 2013).

For more detail concerning these groups and associated frequency ranges, please see NMFS (2018) for a review of available information. Eight marine mammal species (five cetacean and three pinniped (two otariid and one phocid) species) have the reasonable potential to co-occur with the proposed survey activities. Please refer to Table 2. Of the cetacean species that may be present, two are classified as low-frequency cetaceans (*i.e.,* all mysticete species), one is classified as mid-frequency cetaceans (*i.e.,* all delphinid and ziphiid species and the sperm whale), and two are classified as high-frequency cetaceans (*i.e.,* harbor porpoise and Kogia spp.).

Potential Effects of Specified Activities on Marine Mammals and Their Habitat

This section includes a summary and discussion of the ways that components of the specified activity may impact marine mammals and their habitat. The *Estimated Take by Incidental Harassment* section later in this document includes a quantitative analysis of the number of individuals that are expected to be taken by this activity. The *Negligible Impact Analysis and Determination* section considers the content of this section, the *Estimated Take by Incidental Harassment* section, and the *Proposed Mitigation* section, to draw conclusions regarding the likely impacts of these activities on the reproductive success or survivorship of individuals and how those impacts on individuals are likely to impact marine mammal species or stocks.

Description of Sound Sources

The marine soundscape is comprised of both ambient and anthropogenic sounds. Ambient sound is defined as the all-encompassing sound in a given place and is usually a composite of sound from many sources both near and far. The sound level of an area is defined by the total acoustical energy being generated by known and unknown sources. These sources may include physical (*e.g.,* waves, wind, precipitation, earthquakes, ice, atmospheric sound), biological (*e.g.,* sounds produced by marine mammals, fish, and invertebrates), and anthropogenic sound (*e.g.,* vessels, dredging, aircraft, construction).

The sum of the various natural and anthropogenic sound sources at any given location and time—which comprise ''ambient'' or ''background'' sound—depends not only on the source levels (as determined by current weather conditions and levels of biological and shipping activity) but also on the ability of sound to propagate through the environment. In turn, sound propagation is dependent on the spatially and temporally varying properties of the water column and sea floor, and is frequency-dependent. As a result of the dependence on a large number of varying factors, ambient sound levels can be expected to vary widely over both coarse and fine spatial and temporal scales. Sound levels at a given frequency and location can vary by 10–20 dB from day to day (Richardson *et al.* 1995). The result is that, depending on the source type and its intensity, sound from the specified activity may be a negligible addition to the local environment or could form a distinctive signal that may affect marine mammals.

In-water construction activities associated with the project would include impact pile driving, vibratory pile driving, vibratory pile removal, and DTH drilling. The sounds produced by these activities fall into one of two general sound types: impulsive and non-impulsive. Impulsive sounds (*e.g.,* explosions, gunshots, sonic booms, impact pile driving) are typically transient, brief (less than 1 second), broadband, and consist of high peak sound pressure with rapid rise time and rapid decay (ANSI 1986; NIOSH 1998; ANSI 2005; NMFS 2018). Non-impulsive sounds (*e.g.* aircraft, machinery operations such as drilling or dredging, vibratory pile driving, and active sonar systems) can be broadband, narrowband or tonal, brief or prolonged (continuous or intermittent), and typically do not have the high peak sound pressure with raid rise/decay time that impulsive sounds do (ANSI 1995; NIOSH 1998; NMFS 2018). The distinction between these two sound types is important because they have differing potential to cause physical effects, particularly with regard to hearing (*e.g.,* Ward 1997 in Southall *et al.* 2007).

Two types of pile hammers would be used on this project: Impact and vibratory. Impact hammers operate by repeatedly dropping a heavy piston onto a pile to drive the pile into the substrate. Sound generated by impact hammers is characterized by rapid rise times and high peak levels, a potentially injurious combination (Hastings and Popper 2005). Vibratory hammers install piles by vibrating them and allowing the weight of the hammer to push them into the sediment. Vibratory hammers produce significantly less sound than impact hammers. Peak sound pressure levels (SPLs) may be 180 dB or greater, but are generally 10 to 20 dB lower than SPLs generated during impact pile driving of the same-sized pile (Oestman *et al.* 2009). Rise time is slower, reducing the probability and severity of injury, and sound energy is distributed over a greater amount of time (Nedwell and Edwards 2002; Carlson *et al.* 2005).

Drilling would be conducted using a DTH drill inserted through the hollow steel piles. A DTH drill is a drill bit that drills through the bedrock using a pulse mechanism that functions at the bottom of the hole. This pulsing bit breaks up rock to allow removal of debris and insertion of the pile. The head extends so that the drilling takes place below the pile. The pulsing sounds produced by the down-the-hole drilling method are continuous, however this method likely increases sound attenuation because the noise is primarily contained within the steel pile and below ground rather than impact hammer driving methods which occur at the top of the pile (R&M 2016).

The likely or possible impacts of Mr. Erickson's proposed activity on marine mammals could involve both non-acoustic and acoustic stressors. Potential non-acoustic stressors could

result from the physical presence of the equipment and personnel; however, any impacts to marine mammals are expected to primarily be acoustic in nature. Acoustic stressors include effects of heavy equipment operation during pile installation and removal.

Acoustic Impacts

The introduction of anthropogenic noise into the aquatic environment from pile installation, removal, and drilling is the primary means by which marine mammals may be harassed from Mr. Erickson's specified activity. In general, animals exposed to natural or anthropogenic sound may experience physical and psychological effects, ranging in magnitude from none to severe (Southall *et al.* 2007). In general, exposure to pile driving and drilling noise has the potential to result in auditory threshold shifts and behavioral reactions (*e.g.,* avoidance, temporary cessation of foraging and vocalizing, changes in dive behavior). Exposure to anthropogenic noise can also lead to non-observable physiological responses such an increase in stress hormones. Additional noise in a marine mammal's habitat can mask acoustic cues used by marine mammals to carry out daily functions such as communication and predator and prey detection. The effects of pile driving and drilling noise on marine mammals are dependent on several factors, including, but not limited to, sound type (*e.g.,* impulsive vs. non-impulsive), the species, age and sex class (*e.g.,* adult male vs. mom with calf), duration of exposure, the distance between the pile and the animal, received levels, behavior at time of exposure, and previous history with exposure (Wartzok *et al.* 2004; Southall *et al.* 2007). Here we discuss physical auditory effects (threshold shifts) followed by behavioral effects and potential impacts on habitat.

NMFS defines a noise-induced threshold shift (TS) as a change, usually an increase, in the threshold of audibility at a specified frequency or portion of an individual's hearing range above a previously established reference level (NMFS 2018). The amount of threshold shift is customarily expressed in dB. A TS can be permanent or temporary. As described in NMFS (2018), there are numerous factors to consider when examining the consequence of TS, including, but not limited to, the signal temporal pattern (*e.g.,* impulsive or non-impulsive), likelihood an individual would be exposed for a long enough duration or to a high enough level to induce a TS, the magnitude of the TS, time to recovery (seconds to minutes or hours to days), the frequency range of the exposure (*i.e.,* spectral content), the hearing and vocalization frequency range of the exposed species relative to the signal's frequency spectrum (*i.e.,* how animal uses sound within the frequency band of the signal; *e.g.,* Kastelein *et al.* 2014), and the overlap between the animal and the source (*e.g.,* spatial, temporal, and spectral).

Permanent Threshold Shift (PTS)—NMFS defines PTS as a permanent, irreversible increase in the threshold of audibility at a specified frequency or portion of an individual's hearing range above a previously established reference level (NMFS 2018). Available data from humans and other terrestrial mammals indicate that a 40 dB threshold shift approximates PTS onset (see Ward *et al.* 1958, 1959; Ward 1960; Kryter *et al.* 1966; Miller 1974; Ahroon *et al.* 1996; Henderson *et al.* 2008). PTS levels for marine mammals are estimates, as with the exception of a single study unintentionally inducing PTS in a harbor seal (Kastak *et al.* 2008), there are no empirical data measuring PTS in marine mammals largely due to the fact that, for various ethical reasons, experiments involving anthropogenic noise exposure at levels inducing PTS are not typically pursued or authorized (NMFS 2018).

Temporary Threshold Shift (TTS)—A temporary, reversible increase in the threshold of audibility at a specified frequency or portion of an individual's hearing range above a previously established reference level (NMFS 2018). Based on data from cetacean TTS measurements (see Southall *et al.* 2007), a TTS of 6 dB is considered the minimum threshold shift clearly larger than any day-to-day or session-to-session variation in a subject's normal hearing ability (Schlundt *et al.* 2000; Finneran *et al.* 2000, 2002). As described in Finneran (2015), marine mammal studies have shown the amount of TTS increases with cumulative sound exposure level (SEL_{cum}) in an accelerating fashion: At low exposures with lower SEL_{cum}, the amount of TTS is typically small and the growth curves have shallow slopes. At exposures with higher higher SEL_{cum}, the growth curves become steeper and approach linear relationships with the noise SEL.

Depending on the degree (elevation of threshold in dB), duration (*i.e.,* recovery time), and frequency range of TTS, and the context in which it is experienced, TTS can have effects on marine mammals ranging from discountable to serious (similar to those discussed in auditory masking, below). For example, a marine mammal may be able to readily compensate for a brief, relatively small amount of TTS in a non-critical frequency range that takes place during a time when the animal is traveling through the open ocean, where ambient noise is lower and there are not as many competing sounds present. Alternatively, a larger amount and longer duration of TTS sustained during time when communication is critical for successful mother/calf interactions could have more serious impacts. We note that reduced hearing sensitivity as a simple function of aging has been observed in marine mammals, as well as humans and other taxa (Southall *et al.* 2007), so we can infer that strategies exist for coping with this condition to some degree, though likely not without cost.

Currently, TTS data only exist for four species of cetaceans (bottlenose dolphin (*Tursiops truncatus*), beluga whale (*Delphinapterus leucas*), harbor porpoise, and Yangtze finless porpoise (*Neophocoena asiaeorientalis*)) and five species of pinnipeds exposed to a limited number of sound sources (*i.e.,* mostly tones and octave-band noise) in laboratory settings (Finneran 2015). TTS was not observed in trained spotted (*Phoca largha*) and ringed (*Pusa hispida*) seals exposed to impulsive noise at levels matching previous predictions of TTS onset (Reichmuth *et al.* 2016). In general, harbor seals and harbor porpoises have a lower TTS onset than other measured pinniped or cetacean species (Finneran 2015). Additionally, the existing marine mammal TTS data come from a limited number of individuals within these species. No data are available on noise-induced hearing loss for mysticetes. For summaries of data on TTS in marine mammals or for further discussion of TTS onset thresholds, please see Southall *et al.* (2007), Finneran and Jenkins (2012), Finneran (2015), and Table 5 in NMFS (2018). Installing piles requires a combination of impact pile driving and vibratory pile driving, and may require DTH drilling. For the project, these activities would not occur at the same time and there would likely be pauses in activities producing the sound during each day. Given these pauses and that many marine mammals are likely moving through the action area and not remaining for extended periods of time, the potential for TS declines.

Behavioral Harassment—Exposure to noise from pile driving and removal also has the potential to behaviorally disturb marine mammals. Available studies show wide variation in response to underwater sound; therefore, it is difficult to predict specifically how any

given sound in a particular instance might affect marine mammals perceiving the signal. If a marine mammal does react briefly to an underwater sound by changing its behavior or moving a small distance, the impacts of the change are unlikely to be significant to the individual, let alone the stock or population. However, if a sound source displaces marine mammals from an important feeding or breeding area for a prolonged period, impacts on individuals and populations could be significant (*e.g.,* Lusseau and Bejder 2007; Weilgart 2007; NRC 2005).

Disturbance may result in changing durations of surfacing and dives, number of blows per surfacing, or moving direction and/or speed; reduced/increased vocal activities; changing/cessation of certain behavioral activities (such as socializing or feeding); visible startle response or aggressive behavior (such as tail/fluke slapping or jaw clapping); avoidance of areas where sound sources are located. Pinnipeds may increase their haul out time, possibly to avoid in-water disturbance (Thorson and Reyff 2006). Behavioral responses to sound are highly variable and context-specific and any reactions depend on numerous intrinsic and extrinsic factors (*e.g.,* species, state of maturity, experience, current activity, reproductive state, auditory sensitivity, time of day), as well as the interplay between factors (*e.g.,* Richardson *et al.* 1995; Wartzok *et al.* 2003; Southall *et al.* 2007; Weilgart 2007; Archer *et al.* 2010). Behavioral reactions can vary not only among individuals but also within an individual, depending on previous experience with a sound source, context, and numerous other factors (Ellison *et al.* 2012), and can vary depending on characteristics associated with the sound source (*e.g.,* whether it is moving or stationary, number of sources, distance from the source). In general, pinnipeds seem more tolerant of, or at least habituate more quickly to, potentially disturbing underwater sound than do cetaceans, and generally seem to be less responsive to exposure to industrial sound than most cetaceans. Please see Appendices B–C of Southall *et al.* (2007) for a review of studies involving marine mammal behavioral responses to sound.

Disruption of feeding behavior can be difficult to correlate with anthropogenic sound exposure, so it is usually inferred by observed displacement from known foraging areas, the appearance of secondary indicators (*e.g.,* bubble nets or sediment plumes), or changes in dive behavior. As for other types of behavioral response, the frequency, duration, and temporal pattern of signal presentation, as well as differences in species sensitivity, are likely contributing factors to differences in response in any given circumstance (*e.g.,* Croll *et al.* 2001; Nowacek *et al.* 2004; Madsen *et al.* 2006; Yazvenko *et al.* 2007). A determination of whether foraging disruptions incur fitness consequences would require information on or estimates of the energetic requirements of the affected individuals and the relationship between prey availability, foraging effort and success, and the life history stage of the animal.

In 2016, ADOT&PF documented observations of marine mammals during construction activities (*i.e.,* pile driving and down-hole drilling) at the Kodiak Ferry Dock (see 80 FR 60636 for Final IHA **Federal Register** notice). In the marine mammal monitoring report for that project (ABR 2016), 1,281 Steller sea lions were observed within the behavioral disturbance zone during pile driving or drilling (*i.e.,* documented as Level B harassment take). Of these, 19 individuals demonstrated an alert behavior, 7 were fleeing, and 19 swam away from the project site. All other animals were engaged in activities such as milling, foraging, or fighting and did not change their behavior. In addition, two sea lions approached within 20 meters of active vibratory pile driving activities. Three harbor seals were observed within the disturbance zone during pile driving activities; none of them displayed disturbance behaviors. Fifteen killer whales and three harbor porpoise were also observed within the Level B harassment zone during pile driving. The killer whales were travelling or milling while all harbor porpoises were travelling. No signs of disturbance were noted for either of these species. Given the similarities in activities and habitat and the fact the same species are involved, we expect similar behavioral responses of marine mammals to the specified activity. That is, disturbance, if any, is likely to be temporary and localized (*e.g.,* small area movements). Monitoring reports from other recent pile driving projects have observed similar behaviors.

Masking—Sound can disrupt behavior through masking, or interfering with, an animal's ability to detect, recognize, or discriminate between acoustic signals of interest (*e.g.,* those used for intraspecific communication and social interactions, prey detection, predator avoidance, navigation) (Richardson *et al.* 1995). Masking occurs when the receipt of a sound is interfered with by another coincident sound at similar frequencies and at similar or higher intensity, and may occur whether the sound is natural (*e.g.,* snapping shrimp, wind, waves, precipitation) or anthropogenic (*e.g.,* pile driving, shipping, sonar, seismic exploration) in origin. The ability of a noise source to mask biologically important sounds depends on the characteristics of both the noise source and the signal of interest (*e.g.,* signal-to-noise ratio, temporal variability, direction), in relation to each other and to an animal's hearing abilities (*e.g.,* sensitivity, frequency range, critical ratios, frequency discrimination, directional discrimination, age or TTS hearing loss), and existing ambient noise and propagation conditions. Masking of natural sounds can result when human activities produce high levels of background sound at frequencies important to marine mammals. Conversely, if the background level of underwater sound is high (*e.g.* on a day with strong wind and high waves), an anthropogenic sound source would not be detectable as far away as would be possible under quieter conditions and would itself be masked. Auke Bay is home to a busy ferry terminal as well as moorage for small private vessels that transit the area on a regular basis; therefore, background sound levels in the harbor are already elevated.

Airborne Acoustic Effects—Pinnipeds that occur near the project site could be exposed to airborne sounds associated with pile driving and removal that have the potential to cause behavioral harassment, depending on their distance from pile driving activities. Cetaceans are not expected to be exposed to airborne sounds that would result in harassment as defined under the MMPA.

Airborne noise would primarily be an issue for pinnipeds that are swimming or hauled out near the project site within the range of noise levels exceeding the acoustic thresholds. We recognize that pinnipeds in the water could be exposed to airborne sound that may result in behavioral harassment when looking with their heads above water. Most likely, airborne sound would cause behavioral responses similar to those discussed above in relation to underwater sound. For instance, anthropogenic sound could cause hauled-out pinnipeds to exhibit changes in their normal behavior, such as reduction in vocalizations, or cause them to temporarily abandon the area and move further from the source. However, these animals would previously have been 'taken' because of exposure to underwater sound above the behavioral harassment thresholds, which are in all cases larger than those

associated with airborne sound. Thus, the behavioral harassment of these animals is already accounted for in these estimates of potential take. Therefore, we do not believe that authorization of incidental take resulting from airborne sound for pinnipeds is warranted, and airborne sound is not discussed further here.

Marine Mammal Habitat Effects

Mr. Erickson's construction activities could have localized, temporary impacts on marine mammal habitat by increasing in-water sound pressure levels and slightly decreasing water quality. Construction activities are of short duration and would likely have temporary impacts on marine mammal habitat through increases in underwater sound. Increased noise levels may affect acoustic habitat (see masking discussion above) and adversely affect marine mammal prey in the vicinity of the project area (see discussion below). During pile driving and drilling, elevated levels of underwater noise would ensonify the bay where both fish and mammals may occur and could affect foraging success.

In-water pile installation, pile removal, and drilling would also cause short-term effects on water quality due to increased turbidity. Local currents are anticipated to disburse suspended sediments produced by project activities at moderate to rapid rates depending on tidal stage. Mr. Erickson would employ standard construction best management practices, thereby reducing any impacts. Considering the nature and duration of the effects, combined with the measures to reduce turbidity, the impact from increased turbidity levels is expected to be discountable.

In-Water Construction Effects on Potential Foraging Habitat

The area likely impacted by the project is relatively small compared to the available habitat in the surrounding waters of Lynn Canal. Although Auke Bay is included in the designated Biologically Important Area for feeding humpback whales, humpback foraging efforts within Auke Bay itself are intermittent and irregular across seasons. Construction activities may temporarily increase turbidity resulting from suspended sediments. Any increases would be temporary, localized, and minimal. Mr. Erickson must comply with state water quality standards during these operations by limiting the extent of turbidity to the immediate project area. In general, turbidity associated with pile installation is localized to about a 25-foot radius around the pile (Everitt *et al.* 1980). Cetaceans are not expected to enter the harbor and be close enough to the project pile driving areas to experience effects of turbidity, and any pinnipeds would likely be transiting the area and could avoid localized areas of turbidity. Therefore, the impact from increased turbidity levels is expected to be discountable to marine mammals. Furthermore, pile driving and removal at the project site would not obstruct movements or migration of marine mammals.

Avoidance by potential prey (*i.e.,* fish) of the immediate area due to the temporary loss of this foraging habitat is also possible. The duration of fish avoidance of this area after pile driving stops is unknown, but a rapid return to normal recruitment, distribution and behavior is anticipated. Any behavioral avoidance by fish of the disturbed area would still leave significantly large areas of fish and marine mammal foraging habitat in the nearby vicinity in Lynn Canal.

The duration of the construction activities is relatively short, with pile driving activities expected to take only eight days. Each day, construction would occur for only a few hours during the day. Impacts to habitat and prey are expected to be temporary and minimal based on the short duration of activities.

In-Water Construction Effects on Potential Prey (Fish)

Construction activities would produce continuous (*i.e.,* vibratory pile driving) and pulsed (*i.e.* impact driving) sounds. Fish react to sounds that are especially strong and/or intermittent low-frequency sounds. Short duration, sharp sounds can cause overt or subtle changes in fish behavior and local distribution. Hastings and Popper (2005) identified several studies that suggest fish may relocate to avoid certain areas of sound energy. Additional studies have documented effects of pile driving on fish, although several are based on studies in support of large, multiyear bridge construction projects (*e.g.,* Scholik and Yan 2001, 2002; Popper and Hastings 2009). Sound pulses at received levels of 160 dB may cause subtle changes in fish behavior. SPLs of 180 dB may cause noticeable changes in behavior (Pearson *et al.* 1992; Skalski *et al.* 1992). SPLs of sufficient strength have been known to cause injury to fish and fish mortality.

The most likely impact to fish from pile driving and drilling activities at the project area would be temporary behavioral avoidance of the area. The duration of fish avoidance of this area after pile driving stops is unknown, but a rapid return to normal recruitment, distribution and behavior is anticipated. In general, impacts to marine mammal prey species are expected to be minor and temporary due to the short timeframe for the project.

Construction activities, in the form of increased turbidity, have the potential to adversely affect fish in the project area. Increased turbidity is expected to occur in the immediate vicinity (on the order of 10 feet or less) of construction activities. However, suspended sediments and particulates are expected to dissipate quickly within a single tidal cycle. Given the limited area affected and high tidal dilution rates any effects on fish are expected to be minor or negligible. In addition, best management practices would be in effect, which would limit the extent of turbidity to the immediate project area.

In summary, given the short daily duration of sound associated with individual pile driving and drilling events and the relatively small areas being affected, pile driving activities associated with the proposed action are not likely to have a permanent, adverse effect on any fish habitat, or populations of fish species. Thus, we conclude that impacts of the specified activity are not likely to have more than short-term adverse effects on any prey habitat or populations of prey species. Further, any impacts to marine mammal habitat are not expected to result in significant or long-term consequences for individual marine mammals, or to contribute to adverse impacts on their populations.

Estimated Take

This section provides an estimate of the number of incidental takes proposed for authorization through this IHA, which will inform both NMFS' consideration of ''small numbers'' and the negligible impact determination.

Harassment is the only type of take expected to result from these activities. Except with respect to certain activities not pertinent here, section 3(18) of the MMPA defines ''harassment'' as any act of pursuit, torment, or annoyance, which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

Authorized takes would primarily be by Level B harassment, as use of the vibratory and impact pile hammers and drill has the potential to result in disruption of behavioral patterns for

individual marine mammals. There is also some potential for auditory injury (Level A harassment) to result, primarily for high frequency cetacean species and phocids because predicted auditory injury zones are larger than for other hearing groups. Auditory injury is unlikely to occur for other groups. The proposed mitigation and monitoring measures are expected to minimize the severity of such taking to the extent practicable.

As described previously, no mortality is anticipated or proposed to be authorized for this activity. Below we describe how the take is estimated.

Generally speaking, we estimate take by considering: (1) Acoustic thresholds above which NMFS believes the best available science indicates marine mammals will be behaviorally harassed or incur some degree of permanent hearing impairment; (2) the area or volume of water that will be ensonified above these levels in a day; (3) the density or occurrence of marine mammals within these ensonified areas; and, (4) and the number of days of activities. We note that while these basic factors can contribute to a basic calculation to provide an initial prediction of takes, additional information that can qualitatively inform take estimates is also sometimes available (*e.g.,* previous monitoring results or average group size). Below, we describe the factors considered here in more detail and present the proposed take estimate.

Acoustic Thresholds

Using the best available science, NMFS has developed acoustic thresholds that identify the received level of underwater sound above which exposed marine mammals would be reasonably expected to be behaviorally harassed (equated to Level B harassment) or to incur PTS of some degree (equated to Level A harassment).

Level B Harassment for non-explosive sources—Though significantly driven by received level, the onset of behavioral disturbance from anthropogenic noise exposure is also informed to varying degrees by other factors related to the source (*e.g.,* frequency, predictability, duty cycle), the environment (*e.g.,* bathymetry), and the receiving animals (hearing, motivation, experience, demography, behavioral context) and can be difficult to predict (Southall *et al.,* 2007, Ellison *et al.,* 2012). Based on what the available science indicates and the practical need to use a threshold based on a factor that is both predictable and measurable for most activities, NMFS uses a generalized acoustic threshold based on received level to estimate the onset of behavioral harassment. NMFS predicts that marine mammals are likely to be behaviorally harassed in a manner we consider Level B harassment when exposed to underwater anthropogenic noise above received levels of 120 dB re 1 μPa (rms) for continuous (*e.g.,* vibratory pile-driving, drilling) and above 160 dB re 1 μPa (rms) for non-explosive impulsive (*e.g.,* seismic airguns) or intermittent (*e.g.,* scientific sonar) sources.

Mr. Erickson's proposed activity includes the use of continuous (vibratory pile driving and removal, drilling) and impulsive (impact pile driving) sources, and therefore the 120 and 160 dB re 1 μPa (rms) thresholds are applicable.

Level A harassment for non-explosive sources—NMFS' Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing (Version 2.0) (Technical Guidance, 2018) identifies dual criteria to assess auditory injury (Level A harassment) to five different marine mammal groups (based on hearing sensitivity) as a result of exposure to noise from two different types of sources (impulsive or non-impulsive). Mr. Erickson's proposed activity includes the use of impulsive (impact pile driving) and non-impulsive (vibratory pile driving and removal, drilling) source.

These thresholds are provided in Table 4. The references, analysis, and methodology used in the development of the thresholds are described in NMFS 2018 Technical Guidance, which may be accessed at *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-acoustic-technical-guidance.*

TABLE 4—THRESHOLDS IDENTIFYING THE ONSET OF PERMANENT THRESHOLD SHIFT

Hearing group	PTS onset acoustic thresholds * (received level)	
	Impulsive	Non-impulsive
Low-Frequency (LF) Cetaceans	*Cell 1:* $L_{pk,flat}$: 219 dB; $L_{E,LF,24h}$: 183 dB	*Cell 2:* $L_{E,LF,24h}$: 199 dB.
Mid-Frequency (MF) Cetaceans	*Cell 3:* $L_{pk,flat}$: 230 dB; $L_{E,MF,24h}$: 185 dB	*Cell 4:* $L_{E,MF,24h}$: 198 dB.
High-Frequency (HF) Cetaceans	*Cell 5:* $L_{pk,flat}$: 202 dB; $L_{E,HF,24h}$: 155 dB	*Cell 6:* $L_{E,HF,24h}$: 173 dB.
Phocid Pinnipeds (PW) (Underwater)	*Cell 7:* $L_{pk,flat}$: 218 dB; $L_{E,PW,24h}$: 185 dB	*Cell 8:* $L_{E,PW,24h}$: 201 dB.
Otariid Pinnipeds (OW) (Underwater)	*Cell 9:* $L_{pk,flat}$: 232 dB; $L_{E,OW,24h}$: 203 dB	*Cell 10:* $L_{E,OW,24h}$: 219 dB.

* Dual metric acoustic thresholds for impulsive sounds: Use whichever results in the largest isopleth for calculating PTS onset. If a non-impulsive sound has the potential of exceeding the peak sound pressure level thresholds associated with impulsive sounds, these thresholds should also be considered.

Note: Peak sound pressure (L_{pk}) has a reference value of 1 μPa, and cumulative sound exposure level (L_E) has a reference value of 1μPa^{2}s. In this Table, thresholds are abbreviated to reflect American National Standards Institute standards (ANSI 2013). However, peak sound pressure is defined by ANSI as incorporating frequency weighting, which is not the intent for this Technical Guidance. Hence, the subscript ''flat'' is being included to indicate peak sound pressure should be flat weighted or unweighted within the generalized hearing range. The subscript associated with cumulative sound exposure level thresholds indicates the designated marine mammal auditory weighting function (LF, MF, and HF cetaceans, and PW and OW pinnipeds) and that the recommended accumulation period is 24 hours. The cumulative sound exposure level thresholds could be exceeded in a multitude of ways (*i.e.,* varying exposure levels and durations, duty cycle). When possible, it is valuable for action proponents to indicate the conditions under which these acoustic thresholds will be exceeded.

Ensonified Area

Here, we describe operational and environmental parameters of the activity that will feed into identifying the area ensonified above the acoustic thresholds, which include source levels and transmission loss coefficient.

The sound field in the project area is the existing background noise plus additional construction noise from the proposed project. Marine mammals are expected to be affected via sound generated by the primary components of the project (*i.e.,* impact pile driving, vibratory pile driving and removal). The area ensonified above the thresholds for harassment is governed by the topography of Auke Bay and the various islands located within and around the

bay. The eastern part of Auke Bay is acoustically shadowed by Auke Cape, while Portland Island, Coghlan Island, Suedla Island, and Spuhn Island would inhibit sound transmission from reaching the more open waters toward Mansfield Peninsula (see Figure 2 in the IHA application). Additionally, vessel traffic and other commercial and industrial activities in the project area may contribute to elevated background noise levels which may mask sounds produced by the project.

The project includes vibratory removal of timber piles, vibratory and impact installation of steel pipe piles, and drilling. Source levels for these activities are based on reviews of measurements of the same or similar types and dimensions of piles available in the literature. Source levels for each activity are presented in Table 5. The source level for vibratory removal of timber piles is from in-water measurements generated by the Greenbusch Group (2018) from the Seattle Pier 62 project (83 FR 39709; April 10, 2018). Hydroacoustic monitoring results from Pier 62 determined unweighted rms ranging from 140 dB to 169 dB. NMFS analyzed source measurements at different distances for all 63 individual timber piles that were removed at Pier 62 and normalized the values to 10 m. The results showed that the median is 152 dB SPLrms. There are no literature source levels for vibratory installation of 12.75-in steel piles so source levels from vibratory installation of 12-in steel piles from the Caltrans Compendium of Pile Driving Sound Data were used as a proxy (Caltrans 2015). Similarly, as no literature source levels exist for vibratory installation of 20-in steel piles, hydroacoustic measurements of vibratory installation of 24-in steel piles from the U.S. Navy's Test Pile Project were used as a proxy (Navy 2015). Source levels for impact installation of 12.75-in piles were determined by using Caltrans measurements of impact installation of 12-in steel piles as a proxy (Caltrans 2015). Source levels for impact installation of 20-in piles are from installation of 20-in piles in the Columbia River, in similar water depths (Yurk *et al.,* 2016). Source levels for drilling are proxy from median measured source level from drilling of 24-in diameter piles at the Kodiak Ferry Terminal (Denes et al., 2016, Table 72).

TABLE 5—SOUND SOURCE LEVELS FOR PILE SIZES AND DRIVING METHODS

Pile size	Method	Source level			Literature source
		dB RMS	dB Peak	dB SEL	
12.75-in steel	Vibratory	155	171	155	Caltrans 2015 (proxy from 12-in).
20-in steel	Vibratory	161	—	—	Navy 2015 (proxy from 24-in).
12- to 16-in timber	Vibratory	152	—	—	Greenbusch Group 2018.
20-in steel	Drilling	166.2	—	—	Denes *et al.,* 2016 (proxy from 24-in).
12.75-in steel	Impact	177	192	—	Caltrans 2015 (proxy from 12-in).
20-in steel	Impact	190	205	175	Yurk *et al.,* 2016.

—indicates source level not reported.

Transmission loss (TL) is the decrease in acoustic intensity as an acoustic pressure wave propagates out from a source. TL parameters vary with frequency, temperature, sea conditions, current, source and receiver depth, water depth, water chemistry, and bottom composition and topography. The general formula for underwater TL is:

$TL = B * Log_{10} (R_1/R_2)$, where

TL = transmission loss in dB

B = transmission loss coefficient

R_1= the distance of the modeled SPL from the driven pile, and

R_2= the distance from the driven pile of the initial measurement

A practical spreading value of fifteen is often used under conditions, such as Auke Bay, where water increases with depth as the receiver moves away from the shoreline, resulting in an expected propagation environment that would lie between spherical and cylindrical spreading loss conditions. Practical spreading loss is assumed here.

TABLE 6—PILE DRIVING SOURCE LEVELS AND DISTANCES TO LEVEL B HARASSMENT THRESHOLDS

Pile size and type	Method	Source level at 10 m (dB re 1 μPa rms)	Level B threshold (dB re 1 μPa rms)	Distance to level B threshold (m)
12.75-in steel	Vibratory	155	120	2,154
20-in steel	Vibratory	161	120	5,412
12- to 16-in timber	Vibratory	152	120	1,359
20-in steel	Drilling	166.2	120	12,023
12.75-in steel	Impact	177	160	136
20-in steel	Impact	190	160	1,000

When the NMFS Technical Guidance (2016) was published, in recognition of the fact that ensonified area/volume could be more technically challenging to predict because of the duration component in the new thresholds, we developed a User Spreadsheet that includes tools to help predict a simple isopleth that can be used in conjunction with marine mammal density or occurrence to help predict takes. We note that because of some of the assumptions included in the methods used for these tools, we anticipate that isopleths produced are typically going to be overestimates of some degree, which may result in some degree of overestimate of Level A harassment take. However, these tools offer the best way to predict appropriate isopleths when more sophisticated 3D modeling methods are not available, and NMFS continues to develop ways to quantitatively refine these tools, and will qualitatively address the output where appropriate. For stationary sources (such as pile drivers), NMFS

User Spreadsheet predicts the closest distance at which, if a marine mammal remained at that distance the whole duration of the activity, it would not incur PTS. Inputs used in the User Spreadsheet, and the resulting isopleths are reported below (Table 7). Mr. Erickson anticipates that the number of piles installed or removed per day may vary due to environmental conditions and equipment availability. To calculate the Level A harassment isopleths in the User Spreadsheet, Mr. Anderson conservatively entered the maximum number of piles that may be installed in a day.

TABLE 7—USER SPREADSHEET INPUT PARAMETERS USED FOR CALCULATING LEVEL A HARASSMENT ISOPLETHS

Activity	Spreadsheet tab used	Weighting factor adjustment (kHz)	Source level at 10 m	Propagation (xLogR)	Strike duration (sec)	Strikes per pile	Driving duration for single pile (hours)	Max piles per day
Timber vibratory removal	A.1	2.5	152 dB rms	15	N/A	N/A	0.25	6
12.75-in vibratory install	A.1	2.5	155 dB rms	15	N/A	N/A	1	4
20-in vibratory install	A.1	2.5	161 dB rms	15	N/A	N/A	2	2
DTH Drilling	A.1	2.5	166.2	15	N/A	N/A	5	2
12.75-in impact	E.1	2	177 dB rms	15	0.05	150	N/A	4
20-in impact	E.1	2	175 dB SEL	15	N/A	150	N/A	2

N/A indicates not applicable.

TABLE 8—CALCULATED DISTANCES TO LEVEL A HARASSMENT ISOPLETHS

Activity	Level A harassment zone (m)				
	LF cetaceans	MF cetaceans	HF cetaceans	Phocids	Otariids
Timber vibratory removal	2.2	0.2	3.3	1.4	0.1
12.75-in vibratory install	6.9	0.6	10.1	4.2	0.3
20-in vibratory install	17.2	1.5	25.4	10.5	0.7
DTH Drilling	70.4	6.2	104.1	42.8	3.0
12.75-in impact	38.4	1.4	45.7	20.5	1.5
20-in impact	131.1	4.7	156.1	70.1	5.1

Marine Mammal Occurrence and Take Calculation and Estimation

In this section we provide the information about the presence, density, or group dynamics of marine mammals and describe how it is brought together with the information above to produce a quantitative take estimate. When available, peer-reviewed scientific publications were used to estimate marine mammal abundance in the project area. However, scientific surveys and resulting data such as population estimates, densities, and other quantitative information are lacking for most marine mammal populations and most areas of southeast Alaska, including Auke Bay. Therefore, Mr. Erickson gathered qualitative information from discussions with knowledgeable local people in the Auke Bay area, including biologists, the harbormaster, a tour operator, and other individuals familiar with marine mammals in the Auke Bay area.

Here we describe how the information provided above is brought together to produce a quantitative take estimate. Because reliable densities are not available, the applicant requests take based on the maximum number of animals that may occur in the harbor per day multiplied by the number of days of the activity.

Steller Sea Lion

Steller sea lions are common within Auke Bay but generally only occur in the area during winter. Most individuals that frequent Auke Bay haul out at Benjamin Island in Lynn Canal. The Auke Bay boating community observes Steller sea lions transiting between Auke Bay and Benjamin Island regularly during winter. Steller sea lions are not known to haul out on any beaches or structures within Auke Bay, but animals have been observed foraging within Auke Bay, and may rest in large raft groups in the water. Groups as large as 121 individuals have been observed in Auke Bay (Ridgway pers. observ.).

Mr. Erickson estimates that one large group (121 individuals) may be exposed to project-related underwater noise daily on 8 days of pile installation and removal activities, for a total of 968 exposures. As stated above, approximately 18.1 percent of Steller sea lions present in Auke Bay are expected to belong to the wDPS, for a total of 175 exposures of wDPS Steller sea lions and 793 exposures of eDPS Steller sea lions.

The largest Level A harassment zone for otariid pinnipeds extends 5.1 m from the source (Table 8). Mr. Erickson is planning to implement a minimum shutdown zone of 10 m during all pile driving activities, (see *Proposed Mitigation* section), which is expected to eliminate the potential for Level A take of Steller sea lions. Therefore, no takes of Steller sea lions by Level A harassment were requested or are proposed to be authorized.

California Sea Lion

California sea lions are rare in Southeast Alaska, but a single California sea lion was observed hauled out in Statter Harbor in September of 2017. While Statter Harbor is acoustically shadowed by the topography of Auke Bay and will not be ensonified above the Level B behavioral harassment threshold, a California sea lion could enter the Level B harassment zone within Auke Bay to forage. Therefore, Mr. Erickson estimates that a single California sea lion may enter the Level B harassment zone on each of the eight days of pile driving, for a total of eight exposures.

The largest Level A harassment zone for otariid pinnipeds extends 5.1 m from the source (Table 8). Mr. Erickson is planning to implement a minimum shutdown zone of 10 m during all pile driving activities, (see *Proposed Mitigation* section), which is expected to eliminate the potential for Level A take of California sea lions. Therefore, no takes of California sea lions by Level A harassment were requested or are proposed to be authorized.

Harbor Seal

Harbor seals are commonly sighted in the waters of the inside passages throughout southeast Alaska. Seals occur year-round within the project area and are regularly sighted in Auke Bay, including Statter Harbor.

Up to 52 seals have been observed hauled out on a dock at Fisherman's Bend within Statter Harbor (Ridgway unpubl. data) which is acoustically sheltered from the proposed pile driving activities, but it is assumed that these animals may leave the dock to forage within Auke Bay and may be exposed to noise levels in excess of the Level B harassment thresholds upon entering the water. Mr. Erickson estimates up to 52 harbor seals could be exposed to elevated sound levels on each day of pile driving, for a total of 416 exposures.

The largest Level A harassment zone for phocid pinnipeds results from impact installation of 20-in piles and extends 70.1 m from the pile (Table 8). There are no haulouts located within the Level A harassment zone and although it is unlikely that harbor seals will enter this area without detection while pile driving activities are underway, it is possible that harbor seals may approach and enter the Level A harassment zone undetected. Mr. Erickson has observed up to four harbor seals in the water near the existing dock. Therefore, Mr. Erickson estimates that up to four harbor seals may approach the site within 70 m of the source each day. Impact pile driving is expected to occur on up to four days (Table 1). For this reason, Mr. Erickson has requested take of 16 harbor seals by Level A harassment.

Harbor Porpoise

Although there have been no systematic studies or observations of harbor porpoises specific to Auke Bay, there is the potential for them to occur within the project area. Abundance data for harbor porpoises in southeast Alaska were collected during 18 seasonal surveys spanning 22 years, from 1991 to 2012. During that study, a total of 398 harbor porpoises were observed in the northern inland waters of southeast Alaska, including Lynn Canal (Dahlheim *et al.,* 2015). Mean group size of harbor porpoises in southeast Alaska varies by season. In the fall, mean group size was determined to be 1.88 harbor porpoises (Dahlheim *et al.,* 2009). However, groups of five to six harbor porpoises have been observed in Auke Bay (B. Lambert, pers. comm.). Therefore, Mr. Erickson estimates that up to six harbor porpoises may enter the Level B harassment zone on each of the eight days of pile driving, for a total of 48 exposures.

The largest Level A harassment zone extends 156.1 m from the source (Table 8). Mr. Erickson is planning to implement shutdown zones that encompass the Level A harassment zones (see *Proposed Mitigation* section). However, harbor porpoises are known to be an inconspicuous species and are challenging for protected species observers (PSOs) to sight, making any approach to a specific area potentially difficult to detect. Because harbor porpoises move quickly and elusively, it is possible that they may enter the Level A harassment zone without detection. Mr. Erickson estimates that one pair of harbor porpoises may enter the Level A harassment zone on each of the four days of impact pile driving for a total of eight potential takes by Level A harassment.

Dall's Porpoise

Dall's porpoises are not expected to occur within Auke Bay because the shallow water habitat of the bay is atypical of areas where Dall's porpoises usually occur. However, Dall's porpoises may opportunistically inhabit nearshore habitat. The largest group of Dall's porpoises observed in Auke Bay was 10 individuals in 1994. Therefore, Mr. Erickson estimates that one group of ten Dall's porpoises may enter the Level B harassment zone once during construction, for a total of ten exposures.

Mr. Erickson will implement shutdown zones for porpoises that encompass the Level A harassment zones for each pile driving activities. The largest Level A harassment zone for Dall's porpoise extends 156.1 m from the source during impact installation of 20-in steel piles (Table 8). Given the larger group size and more conspicuous rooster-tail generated by swimming Dall's porpoises, which makes them more noticeable than harbor porpoises, PSOs are expected to detect Dall's porpoises prior to them entering the Level A harassment zone. Therefore, takes of Dall's porpoises by Level A harassment have not been requested and are not proposed to be authorized.

Killer Whale

Killer whales are known visitors of the Lynn Canal area, and occasionally enter Auke Bay. Oceanus Alaska compiled sightings records reported by Juneau residents and reported an average of 25 killer whales in the area per year between 2010 and 2017. Killer whales in the project area may be of the Northern Resident, Alaska Resident, or West Coast Transient stocks. The Alaska Resident group AG pod is known to frequent the Juneau Area in groups of up to 25 individuals (B. Lambert, pers. comm.). Mr. Erickson estimates that one group of up to 25 killer whales may enter the Level B harassment zone during the eight days of pile driving for a total of 25 exposures.

Mr. Erickson will implement shutdown zones that encompass the largest Level A harassment zones for killer whales during all pile driving activities. Killer whales are generally conspicuous and PSOs are expected to detect killer whales and implement a shutdown before the animals enter the Level A harassment zone. Therefore, takes by Level A harassment have not been requested and are not proposed to be authorized.

Humpback Whale

Use of Auke Bay by humpback whales is intermittent and irregular year-round. During winter, researchers have documented 1 to 19 individual humpback whales per month in waters close to the project area, including Lynn Canal (Moran *et al.,* 2018a; Straley *et al.,* 2018). Group sizes in southeast Alaska generally range from one to four individuals (Dahlheim *et al.,* 2009). Mr. Erickson estimates that one group of up to four individuals may be present in the Level B harassment zone per day during the eight days of pile driving, for a total of 32 takes by Level B harassment.

The largest Level A harassment zone for humpback whales extends 131.1 m from the source during impact installation of 20-in piles (Table 8). Given the irregular and small presence of humpback whales in Auke Bay, along with the fact that PSOs are expected to detect humpback whales before they enter the Level A harassment zone and implement shutdowns to prevent take by Level A harassment, no Level A takes have been requested nor proposed to be authorized.

Minke Whale

Dedicated surveys for cetaceans in southeast Alaska found that minke whales were scattered throughout inland waters from Glacier Bay and Icy Strait to Clarence Strait, with small concentrations near the entrance of Glacier Bay. All sightings were of single minke whales, except for a single sighting of multiple minke whales. Surveys took place in spring, summer, and fall, and minke whales were present in low numbers in all seasons and years (Dahlheim *et al.,* 2009). Anecdotal reports have not included minke whales near Auke Bay. However, minke whales are distributed throughout a wide

variety of habitats and have been observed in nearby Glacier Bay, indicating they may potentially occur within the Level B harassment zone. Therefore, Mr. Erickson estimates that one minke whale may enter the Level B harassment zone once during the eight days of pile driving activities, for a total of one take by Level B harassment.

The Level A harassment zones for minke whales are the same as for humpback whales, and the shutdown protocols will be the same as well. Therefore, given the low occurrence of minke whales combined with the mitigation, takes by Level A harassment have not been requested and are not proposed to be authorized.

TABLE 9—ESTIMATED TAKE BY LEVEL A AND LEVEL B HARASSMENT, BY SPECIES AND STOCK

Common name	Stock	Stock abundance [a]	Level A	Level B	Total proposed take	Proposed take as percentage of stock
Humpback whale	Central North Pacific	10,103	0	32	[b] 32	0.32
Minke Whale	Alaska	N/A	0	1	1	N/A
Killer whale	Alaska Resident	2,347	0	25	25	[d] 1.06
	Northern Resident	261				[d] 9.58
	West Coast Transient	243				[d] 10.3
Harbor porpoise	Southeast Alaska	975	8	40	48	4.92
Dall's porpoise	Alaska	83,400	0	10	10	<0.1
Steller sea lion	Western U.S.	54,267	0	175	[c] 175	0.32
	Eastern U.S.	41,638	0	793	793	1.90
California sea lion	U.S.	257,606	0	8	8	<0.01
Harbor seal	Lynn Canal/Stephens Passage.	9,478	16	400	416	4.39

[a] Stock or DPS size is N_{best} according to NMFS 2018 Draft Stock Assessment Reports.
[b] For ESA section 7 consultation purposes, 6.1 percent are designated to the Mexico DPS and the remaining are designated to the Hawaii DPS; therefore, we assigned 2 Level B takes to the Mexico DPS.
[c] Based on numbers reported in Hastings *et al.* (2019) and in consultation with the Alaska Regional Office, we used an 18.1 percent distinction factor to determine the number of animals potentially from the western DPS.
[d] These percentages assume all 25 takes may occur to each individual stock, thus the percentage of one or more stocks are likely inflated as the takes would be divided among multiple stocks.

Proposed Mitigation

In order to issue an IHA under Section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to such activity, and other means of effecting the least practicable impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stock for taking for certain subsistence uses (latter not applicable for this action). NMFS regulations require applicants for incidental take authorizations to include information about the availability and feasibility (economic and technological) of equipment, methods, and manner of conducting such activity or other means of effecting the least practicable adverse impact upon the affected species or stocks and their habitat (50 CFR 216.104(a)(11)).

In evaluating how mitigation may or may not be appropriate to ensure the least practicable adverse impact on species or stocks and their habitat, as well as subsistence uses where applicable, we carefully consider two primary factors:

(1) The manner in which, and the degree to which, the successful implementation of the measure(s) is expected to reduce impacts to marine mammals, marine mammal species or stocks, and their habitat, as well as subsistence uses. This considers the nature of the potential adverse impact being mitigated (likelihood, scope, range). It further considers the likelihood that the measure will be effective if implemented (probability of accomplishing the mitigating result if implemented as planned), the likelihood of effective implementation (probability implemented as planned); and

(2) the practicability of the measures for applicant implementation, which may consider such things as cost, impact on operations, and, in the case of a military readiness activity, personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity.

Mitigation for Marine Mammals and Their Habitat

In addition to the measures described later in this section, Mr. Erickson will employ the following standard mitigation measures:

- Conduct briefings between construction supervisors and crews and the marine mammal monitoring team prior to the start of all pile driving activity, and when new personnel join the work, to explain responsibilities, communication procedures, marine mammal monitoring protocol, and operational procedures;
- For in-water heavy machinery work other than pile driving (*e.g.,* standard barges, etc.), if a marine mammal comes within 10 m, operations shall cease and vessels shall reduce speed to the minimum level required to maintain steerage and safe working conditions. This type of work could include the following activities: (1) Movement of the barge to the pile location; or (2) positioning of the pile on the substrate via a crane (*i.e.,* stabbing the pile);
- Work may only occur during daylight hours, when visual monitoring of marine mammals can be conducted;
- For those marine mammals for which Level B harassment take has not been requested, in-water pile installation/removal and drilling will shut down immediately if such species are observed within or on a path towards the monitoring zone (*i.e.,* Level B harassment zone); and
- If take reaches the authorized limit for an authorized species, pile installation will be stopped as these species approach the Level B harassment zone to avoid additional take.

The following measures would apply to ADOT&PF's mitigation requirements:

Establishment of Shutdown Zone for Level A Harassment—For all pile driving/removal and drilling activities, Mr. Erickson would establish a shutdown zone. The purpose of a shutdown zone is generally to define an area within which shutdown of activity would occur upon sighting of a marine

mammal (or in anticipation of an animal entering the defined area). These shutdown zones would be used to prevent incidental Level A exposures from impact pile driving for Steller sea lions, California sea lions, Dall's porpoises, killer whales, humpback whales, and minke whales, and to reduce the potential for such take for harbor seals and harbor porpoises. During all pile driving and removal activities, a minimum shutdown zone of 20 m would be enforced (Table 10). Shutdown zones for each specific activity are based on the Level A harassment zones and therefore vary by pile-size, type, driving method, and marine mammal hearing group (Table 10).

TABLE 10—SHUTDOWN ZONES FOR PILE DRIVING ACTIVITIES

Activity	Shutdown zone (m)				
	LF cetaceans	MF cetaceans	HF cetaceans	Phocid pinnipeds	Otariid pinnipeds
Vibratory Timber Pile Removal	10	10	10	10	10
Vibratory Pile Driving (12.75-in)	10	10	10	10	10
Vibratory Pile Driving (20-in)	20	10	30	15	10
Drilling	75	10	105	45	10
Impact Pile Driving 12.75-in	40	10	50	20	10
Impact Pile Driving 20-in	135	10	160	75	10

Establishment of Monitoring Zones for Level B Harassment—Mr. Erickson would establish monitoring zones to correlate with Level B disturbance zones or zones of influence which are areas where SPLs are equal to or exceed the 160 dB rms threshold for impact driving and the 120 dB rms threshold during vibratory driving and drilling. Monitoring zones provide utility for observing by establishing monitoring protocols for areas adjacent to the shutdown zones. Monitoring zones enable observers to be aware of and communicate the presence of marine mammals in the project area outside the shutdown zone and thus prepare for a potential cease of activity should the animal enter the shutdown zone. The proposed monitoring zones are described in Table 11. Should PSOs determine the monitoring zone cannot be effectively observed in its entirety, Level B harassment exposures will be recorded and extrapolated based upon the number of observed take and the percentage of the Level B zone that was not visible.

TABLE 11—MARINE MAMMAL MONITORING ZONES

Activity	Monitoring zone (m)
Impact installation of 12.75-in piles	135
Impact installation of 20-in piles	1,000
Vibratory timber pile removal	1,360
Vibratory installation of 21.75-in piles	2,155
Vibratory installation of 20-in piles	5,410
Drilling	12,100

Soft Start—The use of soft-start procedures are believed to provide additional protection to marine mammals by providing warning and/or giving marine mammals a chance to leave the area prior to the hammer operating at full capacity. For impact pile driving, contractors would be required to provide an initial set of strikes from the hammer at reduced energy, with each strike followed by a 30-second waiting period. This procedure would be conducted a total of three times before impact pile driving begins. Soft start would be implemented at the start of each day's impact pile driving and at any time following cessation of impact pile driving for a period of thirty minutes or longer. Soft start is not required during vibratory pile driving and removal activities.

Pre-Activity Monitoring—Prior to the start of daily in-water construction activity, or whenever a break in pile driving/removal or drilling of 30 minutes or longer occurs, PSOs will observe the shutdown and monitoring zones for a period of 30 minutes. The shutdown zone will be cleared when a marine mammal has not been observed within the zone for that 30-minute period. If a marine mammal is observed within the shutdown zone, a soft-start cannot proceed until the animal has left the zone or has not been observed for 15 minutes. If the Level B harassment zone has been observed for 30 minutes and non-permitted species are not present within the zone, soft start procedures can commence and work can continue even if visibility becomes impaired within the Level B monitoring zone. If a marine mammal permitted for Level B take is present in the Level B harassment zone, activities may begin and Level B take will be recorded. As stated above, if the entire Level B zone is not visible at the start of construction, piling or drilling activities can begin. If work ceases for more than 30 minutes, the pre-activity monitoring of both the Level B and shutdown zone will commence.

Based on our evaluation of the applicant's proposed measures, NMFS has preliminarily determined that the proposed mitigation measures provide the means effecting the least practicable impact on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Proposed Monitoring and Reporting

In order to issue an IHA for an activity, Section 101(a)(5)(D) of the MMPA states that NMFS must set forth requirements pertaining to the monitoring and reporting of such taking. The MMPA implementing regulations at 50 CFR 216.104 (a)(13) indicate that requests for authorizations must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present in the proposed action area. Effective reporting is critical both to compliance as well as ensuring that the most value is obtained from the required monitoring.

Monitoring and reporting requirements prescribed by NMFS should contribute to improved understanding of one or more of the following:

- Occurrence of marine mammal species or stocks in the area in which take is anticipated (*e.g.,* presence, abundance, distribution, density);
- Nature, scope, or context of likely marine mammal exposure to potential

stressors/impacts (individual or cumulative, acute or chronic), through better understanding of: (1) Action or environment (*e.g.,* source characterization, propagation, ambient noise); (2) affected species (*e.g.,* life history, dive patterns); (3) co-occurrence of marine mammal species with the action; or (4) biological or behavioral context of exposure (*e.g.,* age, calving or feeding areas);

- Individual marine mammal responses (behavioral or physiological) to acoustic stressors (acute, chronic, or cumulative), other stressors, or cumulative impacts from multiple stressors;
- How anticipated responses to stressors impact either: (1) Long-term fitness and survival of individual marine mammals; or (2) populations, species, or stocks;
- Effects on marine mammal habitat (*e.g.,* marine mammal prey species, acoustic habitat, or other important physical components of marine mammal habitat); and
- Mitigation and monitoring effectiveness.

Marine Mammal Visual Monitoring

Monitoring shall be conducted by NMFS-approved observers. Trained observers shall be placed from the best vantage point(s) practicable to monitor for marine mammals and implement shutdown or delay procedures when applicable through communication with the equipment operator. Observer training must be provided prior to project start, and shall include instruction on species identification (sufficient to distinguish the species in the project area), description and categorization of observed behaviors and interpretation of behaviors that may be construed as being reactions to the specified activity, proper completion of data forms, and other basic components of biological monitoring, including tracking of observed animals or groups of animals such that repeat sound exposures may be attributed to individuals (to the extent possible).

Monitoring would be conducted 30 minutes before, during, and 30 minutes after pile driving/removal and drilling activities. In addition, observers shall record all incidents of marine mammal occurrence, regardless of distance from activity, and shall document any behavioral reactions in concert with distance from piles being driven or removed. Pile driving/removal and drilling activities include the time to install or remove a single pile or series of piles, as long as the time elapsed between uses of the pile driving equipment is no more than 30 minutes.

At least two PSOs will be on duty during all pile driving activities. One PSO will be stationed at the dock site to allow full monitoring of the waters within the shutdown zones and the closest waters of the Level B harassment monitoring zones. An additional PSO will be positioned in a vessel in Auke Bay to observed the larger monitoring zones. Most of the shoreline of Auke Bay is privately owned and unavailable for PSOs to access. Additionally, PSOs cannot be stationed on the shore of the various islands in Auke Bay due to safety concerns. Therefore, a vessel-based PSO is the most practicable position for this project. Potential PSO locations are shown in Figure 2 in Mr. Erickson's Marine Mammal Monitoring Plan.

PSOs would scan the waters using binoculars, and/or spotting scopes, and would use a handheld GPS or range-finder device to verify the distance to each sighting from the project site. All PSOs would be trained in marine mammal identification and behaviors and are required to have no other project-related tasks while conducting monitoring. In addition, monitoring will be conducted by qualified observers, who will be placed at the best vantage point(s) practicable to monitor for marine mammals and implement shutdown/delay procedures when applicable by calling for the shutdown to the hammer operator. Mr. Erickson would adhere to the following observer qualifications:

(i) Independent observers (*i.e.,* not construction personnel) are required;

(ii) At least one observer must have prior experience working as an observer;

(iii) Other observers may substitute education (degree in biological science or related field) or training for experience; and

(iv) Mr. Erickson must submit observer CVs for approval by NMFS.

Additional standard observer qualifications include:

- Ability to conduct field observations and collect data according to assigned protocols;
- Experience or training in the field identification of marine mammals, including the identification of behaviors;
- Sufficient training, orientation, or experience with the construction operation to provide for personal safety during observations;
- Writing skills sufficient to prepare a report of observations including but not limited to the number and species of marine mammals observed; dates and times when in-water construction activities were conducted; dates and times when in-water construction activities were suspended to avoid potential incidental injury from construction sound of marine mammals observed within a defined shutdown zone; and marine mammal behavior; and
- Ability to communicate orally, by radio or in person, with project personnel to provide real-time information on marine mammals observed in the area as necessary.

A draft marine mammal monitoring report would be submitted to NMFS within 90 days after the completion of pile driving and removal and drilling activities. It will include an overall description of work completed, a narrative regarding marine mammal sightings, and associated PSO data sheets. Specifically, the report must include:

- Date and time that monitored activity begins or ends;
- Construction activities occurring during each observation period;
- Weather parameters (*e.g.,* percent cover, visibility);
- Water conditions (*e.g.,* sea state, tide state);
- Species, numbers, and, if possible, sex and age class of marine mammals observed;
- Description of any observable marine mammal behavior patterns, including bearing and direction of travel and distance from pile driving activity;
- Distance from pile driving activities to marine mammals and distance from the marine mammals to the observation point;
- Locations of all marine mammal observations;
- Other human activity in the area; and
- A summary of the total number of individuals of each species detected within the Level B Harassment Zone, and estimated as taken if correction factor appropriate, and the total number of individuals of each species detected within the Level A Harassment Zone and the average amount of time that they remained in that zone.

If no comments are received from NMFS within 30 days, the draft final report will constitute the final report. If comments are received, a final report addressing NMFS comments must be submitted within 30 days after receipt of comments.

In the unanticipated event that the specified activity clearly causes the take of a marine mammal in a manner prohibited by the IHA (if issued), such as an injury, serious injury or mortality, Mr. Erickson would immediately cease the specified activities and report the incident to the Chief of the Permits and Conservation Division, Office of

Protected Resources, NMFS, and the Alaska Regional Stranding Coordinator. The report would include the following information:

- Description of the incident;
- Environmental conditions (*e.g.,* Beaufort sea state, visibility);
- Description of all marine mammal observations in the 24 hours preceding the incident;
- Species identification or description of the animal(s) involved;
- Fate of the animal(s); and
- Photographs or video footage of the animal(s) (if equipment is available).

Activities would not resume until NMFS is able to review the circumstances of the prohibited take. NMFS would work with Mr. Erickson to determine what is necessary to minimize the likelihood of further prohibited take and ensure MMPA compliance. Mr. Erickson would not be able to resume pile driving activities until notified by NMFS via letter, email, or telephone.

In the event that Mr. Erickson discovers an injured or dead marine mammal, and the lead PSO determines that the cause of the injury or death is unknown and the death is relatively recent (*e.g.,* in less than a moderate state of decomposition as described in the next paragraph), Mr. Erickson would immediately report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, and the NMFS Alaska Stranding Hotline and/or by email to the Alaska Regional Stranding Coordinator. The report would include the same information identified in the paragraph above. Activities would be able to continue while NMFS reviews the circumstances of the incident. NMFS would work with Mr. Erickson to determine whether modifications in the activities are appropriate.

In the event that Mr. Erickson discovers an injured or dead marine mammal and the lead PSO determines that the injury or death is not associated with or related to the activities authorized in the IHA (*e.g.,* previously wounded animal, carcass with moderate to advanced decomposition, or scavenger damage), Mr. Erickson would report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, and the NMFS Alaska Stranding Hotline and/or by email to the Alaska Regional Stranding Coordinator, within 24 hours of the discovery. Mr. Erickson would provide photographs, video footage (if available), or other documentation of the stranded animal sighting to NMFS and the Marine Mammal Stranding Network.

Negligible Impact Analysis and Determination

NMFS has defined negligible impact as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.,* population-level effects). An estimate of the number of takes alone is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be ''taken'' through harassment, NMFS considers other factors, such as the likely nature of any responses (*e.g.,* intensity, duration), the context of any responses (*e.g.,* critical reproductive time or location, migration), as well as effects on habitat, and the likely effectiveness of the mitigation. We also assess the number, intensity, and context of estimated takes by evaluating this information relative to population status. Consistent with the 1989 preamble for NMFS's implementing regulations (54 FR 40338; September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into this analysis via their impacts on the environmental baseline (*e.g.,* as reflected in the regulatory status of the species, population size and growth rate where known, ongoing sources of human-caused mortality, or ambient noise levels).

Pile driving/removal and drilling activities associated with the project as outlined previously, have the potential to disturb or displace marine mammals. Specifically, the specified activities may result in take, in the form of Level A harassment and Level B harassment from underwater sounds generated from pile driving and removal. Potential takes could occur if individuals of these species are present in zones ensonified above the thresholds for Leval A or Level B harassment identified above when these activities are underway.

The takes from Level A and Level B harassment would be due to potential behavioral disturbance, TTS, and PTS. No mortality is anticipated given the nature of the activity and measures designed to minimize the possibility of injury to marine mammals. Level A harassment is only anticipated for harbor porpoise and harbor seal. The potential for harassment is minimized through the construction method and the implementation of the planned mitigation measures (see *Proposed Mitigation* section).

Effects on individuals that are taken by Level B harassment, on the basis of reports in the literature as well as monitoring from other similar activities, will likely be limited to reactions such as increased swimming speeds, increased surfacing time, or decreased foraging (if such activity were occurring) (*e.g.,* Thorson and Reyff 2006; HDR, Inc. 2012; Lerma 2014; ABR 2016). Most likely for pile driving, individuals will simply move away from the sound source and be temporarily displaced from the areas of pile driving and drilling, although even this reaction has been observed primarily only in association with impact pile driving. The pile driving activities analyzed here are similar to, or less impactful than, numerous other construction activities conducted in southeast Alaska, which have taken place with no known long-term adverse consequences from behavioral harassment. Level B harassment will be reduced to the level of least practicable adverse impact through use of mitigation measures described herein and, if sound produced by project activities is sufficiently disturbing, animals are likely to simply avoid the area while the activity is occurring. While vibratory driving and drilling associated with the proposed project may produce sound at distances of many kilometers from the project site, thus intruding on some habitat, the project site itself is located in a busy harbor and the majority of sound fields produced by the specified activities are close to the harbor. Therefore, we expect that animals annoyed by project sound would simply avoid the area and use more-preferred habitats.

In addition to the expected effects resulting from authorized Level B harassment, we anticipate that harbor porpoises and harbor seals may sustain some limited Level A harassment in the form of auditory injury. However, given the relatively small size of the Level A harassment zones and the anticipated effectiveness of mitigation, animals in these locations that experience PTS would likely only receive slight PTS, *i.e.,* minor degradation of hearing capabilities within regions of hearing that align most completely with the energy produced by pile driving, *i.e.,* the low-frequency region below 2 kHz, not severe hearing impairment or impairment in the regions of greatest hearing sensitivity. If hearing impairment occurs, it is most likely that the affected animal would lose a few decibels in its hearing sensitivity, which in most cases is not likely to meaningfully affect its ability to forage

and communicate with conspecifics. As described above, we expect that marine mammals would be likely to move away from a sound source that represents an aversive stimulus, especially at levels that would be expected to result in PTS, given sufficient notice through use of soft start.

Nearly all inland waters of southeast Alaska, including Auke Bay, are included in the southeast Alaska humpback whale feeding BIA (Ferguson *et al.,* 2015), though humpback whale distribution in southeast Alaska varies by season and waterway (Dahlheim *et al.* 2009). Humpback whales are present within Auke Bay intermittently and in low numbers. The area of the BIA that may be affected by the proposed project is small relative to the overall area of the BIA, and the area of suitable humpback whale habitat that is not included in the BIA. The southeast Alaska humpback whale feeding BIA is active between March and November. While the exact timing of the proposed project is unknown, Mr. Erickson's pile driving activities are expected to take only eight days. If the project were to occur between March and November, the days of activity represent a small fraction of the time the BIA is active and, thus, even if humpback whale feeding behaviors were interrupted by the activity, the disturbance would be short-term and alternative habitat and foraging opportunities are available nearby. Further, only a very small portion of the humpback stock is expected to enter the area and potentially be disturbed. Therefore, any adverse effects on humpback whales resulting from disturbances occurring in the southeast Alaska humpback whale feeding BIA are expected to be short-term and minor and not adversely impact reproduction or survival, much less the stock.

The project also is not expected to have significant adverse effects on affected marine mammals' habitat. The project activities would not modify existing marine mammal habitat for a significant amount of time. The activities may cause some fish to leave the area of disturbance, thus temporarily impacting marine mammals' foraging opportunities in a limited portion of the foraging range; but, because of the short duration of the activities and the relatively small area of the habitat that may be affected, the impacts to marine mammal habitat are not expected to cause significant or long-term negative consequences.

In summary and as described above, the following factors primarily support our preliminary determination that the impacts resulting from this activity are not expected to adversely affect the species or stock through effects on annual rates of recruitment or survival:

- No mortality is anticipated or authorized;
- The Level A harassment exposures are anticipated to result only in slight PTS, within the lower frequencies associated with pile driving;
- The anticipated incidents of Level B harassment would consist of, at worst, temporary modifications in behavior that would not result in fitness impacts to individuals;
- The area impacted by the specified activity is very small relative to the overall habitat ranges of all species, does not include ESA-designated critical habitat, and only temporally overlaps with the southeast Alaska humpback whale feeding BIA for two months of the planned six months of activity; and
- The proposed mitigation measures are expected to reduce the effects of the specified activity to the level of least practicable adverse impact.

In addition, although affected humpback whales and Steller sea lions may be from a DPS that is listed under the ESA, it is unlikely that minor noise effects in a small, localized area of habitat would have any effect on the stocks' ability to recover. In combination, we believe that these factors, as well as the available body of evidence from other similar activities, demonstrate that the potential effects of the specified activities will have only minor, short-term effects on individuals. The specified activities are not expected to impact rates of recruitment or survival and will therefore not result in population-level impacts.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the proposed monitoring and mitigation measures, NMFS preliminarily finds that the total marine mammal take from the proposed activity will have a negligible impact on all affected marine mammal species or stocks.

Small Numbers

As noted above, only small numbers of incidental take may be authorized under Sections 101(a)(5)(A) and (D) of the MMPA for specified activities other than military readiness activities. The MMPA does not define small numbers and so, in practice, where estimated numbers are available, NMFS compares the number of individuals taken to the most appropriate estimation of abundance of the relevant species or stock in our determination of whether an authorization is limited to small numbers of marine mammals. Additionally, other qualitative factors may be considered in the analysis, such as the temporal or spatial scale of the activities.

Table 8 indicates the number of animals that could be exposed to received noise levels that could cause Level A and Level B harassment for the proposed work in Auke Bay. Our analysis shows that less than 11 percent of each affected stock could be taken by harassment. The numbers of animals proposed to be taken for these stocks would be considered small relative to the relevant stock's abundances even if each estimated taking occurred to a new individual—an extremely unlikely scenario.

Based on the analysis contained herein of the proposed activity (including the proposed mitigation and monitoring measures) and the anticipated take of marine mammals, NMFS preliminarily finds that small numbers of marine mammals will be taken relative to the population size of the affected species or stocks.

Unmitigable Adverse Impact Analysis and Determination

In order to issue an IHA, NMFS must find that the specified activity will not have an ''unmitigable adverse impact'' on the subsistence uses of the affected marine mammal species or stocks by Alaskan Natives. NMFS has defined ''unmitigable adverse impact'' in 50 CFR 216.103 as an impact resulting from the specified activity: (1) That is likely to reduce the availability of the species to a level insufficient for a harvest to meet subsistence needs by: (i) Causing the marine mammals to abandon or avoid hunting areas; (ii) Directly displacing subsistence users; or (iii) Placing physical barriers between the marine mammals and the subsistence hunters; and (2) That cannot be sufficiently mitigated by other measures to increase the availability of marine mammals to allow subsistence needs to be met.

The proposed project is not known to occur in an important subsistence hunting area. Auke Bay is a developed area with regular marine vessel traffic. Of the marine mammals considered in this IHA application, only harbor seals are known to be used for subsistence in the project area. In a previous consultation with ADF&G, the Douglas Indian Association, Sealaska Heritage Institute, and the Central Council of the Tlingit and Haida Indian Tribes of Alaska, representatives indicated that the primary concern with construction activities in Statter Harbor was impacts to herring fisheries, not marine

mammals. As stated above, impacts to fish from the proposed project are expected to be localized and temporary, so are not likely to impact herring fisheries. If any tribes express concerns regarding project impacts to subsistence hunting of marine mammals, further communication between will take place, including provision of any project information, and clarification of any mitigation and minimization measures that may reduce potential impacts to marine mammals.

Based on the description of the specified activity, the measures described to minimize adverse effects on the availability of marine mammals for subsistence purposes, and the proposed mitigation and monitoring measures, NMFS has preliminarily determined that there will not be an unmitigable adverse impact on subsistence uses from [name of applicant]'s proposed activities.

Endangered Species Act (ESA)

Section 7(a)(2) of the Endangered Species Act of 1973 (ESA: 16 U.S.C. 1531 *et seq.*) requires that each Federal agency insure that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure ESA compliance for the issuance of IHAs, NMFS consults internally, in this case with the Alaska Regional Office, whenever we propose to authorize take for endangered or threatened species.

NMFS is proposing to authorize take of wDPS Steller sea lions and Mexico DPS humpback whales, which are listed under the ESA. The Permits and Conservation Division has requested initiation of section 7 consultation with NMFS' Alaska Regional Office for the issuance of this IHA. NMFS will conclude the ESA consultation prior to reaching a determination regarding the proposed issuance of the authorization.

Proposed Authorization

As a result of these preliminary determinations, NMFS proposes to issue an IHA to Mr. Erickson for conducting pile installation and removal activities between January and December 2020, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated. A draft of the proposed IHA can be found at *https://www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act.*

Request for Public Comments

We request comment on our analyses, the proposed authorization, and any other aspect of this Notice of Proposed IHA for the proposed action. We also request at this time comment on the potential renewal of this proposed IHA as described in the paragraph below. Please include with your comments any supporting data or literature citations to help inform decisions on the request for this IHA or a subsequent Renewal.

On a case-by-case basis, NMFS may issue a one-year IHA renewal with an additional 15 days for public comments when (1) another year of identical or nearly identical activities as described in the Specified Activities section of this notice is planned or (2) the activities as described in the Specified Activities section of this notice would not be completed by the time the IHA expires and a Renewal would allow for completion of the activities beyond that described in the Dates and Duration section of this notice, provided all of the following conditions are met:

- A request for renewal is received no later than 60 days prior to expiration of the current IHA.
- The request for renewal must include the following:

(1) An explanation that the activities to be conducted under the requested Renewal 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 because only a subset of the initially analyzed activities remain to be completed under the Renewal).

(2) 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.

- 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.

Dated: September 19, 2019.

Donna S. Wieting,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2019–20777 Filed 9–24–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XQ004

Fall Meeting of the Advisory Committee to the U.S. Section of the International Commission for the Conservation of Atlantic Tunas

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

ACTION: Notice of public meeting.

SUMMARY: In preparation for the 2019 International Commission for the Conservation of Atlantic Tunas (ICCAT) meeting, the Advisory Committee to the U.S. Section to ICCAT is announcing the convening of its fall meeting.

DATES: The meeting will be held on October 16–17, 2019. There will be an open session on Wednesday, October 16, 2019, from 9 a.m. through approximately 12 p.m. The remainder of the meeting will be closed to the public and is expected to end by 12 p.m. on October 17. Interested members of the public may present their views during the public comment session on October 16, 2019 or submit written comments by October 11, 2019 (see **ADDRESSES**).

ADDRESSES: The meeting will be held at the DoubleTree by Hilton Washington, DC—Silver Spring, 8727 Colesville Road, Silver Spring, Maryland 20910. Written comments should be sent via email to *terra.lederhouse@noaa.gov.* Comments may also be sent via mail to Terra Lederhouse at NMFS, Office of International Affairs and Seafood Inspection, 1315 East-West Highway, Silver Spring, MD 20910.

FOR FURTHER INFORMATION CONTACT: Terra Lederhouse, Office of International Affairs and Seafood Inspection, 301–427–8360 or at *terra.lederhouse@noaa.gov.*

SUPPLEMENTARY INFORMATION: The Advisory Committee to the U.S. Section to ICCAT will meet October 16–17, 2019, first in an open session to consider management- and research-related information on stock status of Atlantic highly migratory species and then in a closed session to discuss sensitive matters. The open session will be from 9 a.m. through 12 p.m. on October 16, 2019, including an opportunity for public comment beginning at approximately 11:30 a.m. Comments may also be submitted in writing for the Advisory Committee's consideration. Interested members of the public can submit comments by

mail or email; use of email is encouraged. All written comments must be received by October 11, 2019 (see **ADDRESSES**).

NMFS expects members of the public to conduct themselves appropriately at the open session of the Advisory Committee meeting. At the beginning of the public comment session, an explanation of the ground rules will be provided (*e.g.,* alcohol in the meeting room is prohibited, speakers will be called to give their comments in the order in which they registered to speak, each speaker will have an equal amount of time to speak and speakers should not interrupt one another). The session will be structured so that all attending members of the public are able to comment, if they so choose, regardless of the degree of controversy of the subject(s). Those not respecting the ground rules will be asked to leave the meeting.

After the open session, the Advisory Committee will meet in closed session to discuss sensitive information relating to upcoming international negotiations regarding Atlantic highly migratory species conservation and management.

Special Accommodations

The meeting location is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Terra Lederhouse at (301) 427–8360 or *terra.lederhouse@noaa.gov* at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 971 *et seq.;* 16 U.S.C. 1801 *et seq.*

Dated: September 20, 2019.

Alexa Cole,

Acting Director, Office of International Affairs and Seafood Inspection, National Marine Fisheries Service.

[FR Doc. 2019–20776 Filed 9–24–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; West Coast Region Groundfish Electronic Fish Ticket Program

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, 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 proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before November 25, 2019.

ADDRESSES: Direct all written comments to Adrienne Thomas, Government Information Specialist, NOAA, 151 Patton Avenue, Room 159, Asheville, NC 28801 (or via the internet at *PRAcomments@doc.gov*). Comments will generally be posted without change. All Personally Identifiable Information (for example, name and address) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information. You may submit attachments to electronic comments in Microsoft Word, Excel, or Adobe PDF file formats.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Jahnava Duryea at (916) 930–3725 or email at *jahnava.duryea@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for an extension of a currently approved information collection.

As part of its fishery management responsibilities, the National Oceanic and Atmospheric Administration (NOAA), National Marine Fisheries Service (NMFS) collects information to determine the amount and type of groundfish caught by fishing vessels. Electronic fish tickets are submissions of landings data from the first receiver to the Pacific States Marine Fisheries Commission (PSMFC) and NMFS. This collection supports requirements for participants of the Pacific Coast shorebased commercial groundfish fisheries (including the shorebased Individual Fishing Quota (IFQ) program, the limited entry fixed gear fishery, and the open access fixed gear fishery) to account for all landed catch and to send electronic catch data used to manage the catch allocations and limits. The respondents are principally shorebased first receivers.

II. Method of Collection

Electronic fish ticket data of landings data will be submitted from the first receiver to PSMFC. Shoreside first receivers, defined as persons who receive, purchase, or take custody, control, or possession of catch onshore directly from a vessel, are required to use a web-based, NMFS-approved electronic fish ticket program to send catch reports within 24 hours from the date of the landing. The electronic fish tickets are based on information currently required in state fish receiving tickets or landing receipts. The PSMFC currently receives and stores fish ticket data from the states. These data are maintained on the Pacific Fisheries Information Network (PacFIN) database.

III. Data

OMB Control Number: 0648–0738.

Form Number(s): None.

Type of Review: Regular submission.

Affected Public: Business or other for-profit organizations; Individuals or households; State, Local, or Tribal government.

Estimated Number of Respondents: 100.

Estimated Time per Response: 2–10 minutes. Electronic fish ticket filling and submission (Washington and California): 10 minutes. Electronic fish ticket submission (Oregon already requires electronic fish tickets, sending will be the only additional time/cost burden): 2 Minutes.

Estimated Total Annual Burden Hours: 666.

Estimated Total Annual Cost to Public: $0.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (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.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Sheleen Dumas,

Departmental Lead PRA Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2019–20766 Filed 9–24–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; Atlantic Large Whale Take Reduction Plan Regulations

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, 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 proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before November 25, 2019.

ADDRESSES: Direct all written comments to Adrienne Thomas, PRA Officer, NOAA, 151 Patton Avenue, Room 159, Asheville, NC 28801 (or via the internet at *PRAcomments@doc.gov*). Comments will generally be posted without change. All Personally Identifiable Information (for example, name and address) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information. You may submit attachments to electronic comments in Microsoft Word, Excel, or Adobe PDF file formats.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Colleen Coogan, Marine Mammal Take Reduction Team Coordinator, Greater Atlantic Regional Fisheries Office, 55 Great Republic Drive, Gloucester, MA 01930; 978–281–9181, *Colleen.Coogan@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

Type of review: regular submission (extension of a current information collection).

Any persons setting trap/pot of gillnet gear to fish commercially in some areas of the Atlantic Ocean are required to paint or otherwise mark their gear with one or two color codes, designating the type of gear and area where the gear is set. The surface buoys of this gear need to be marked to identify the vessel or fishery. These marking requirements apply in the various management areas under the Atlantic Large Whale Take Reduction Plan (ALWTRP), developed under the authority of the Marine Mammal Protection Act.

The goal of this collection of information is to enable the National Marine Fisheries Service (NMFS) to reduce injuries and deaths of large whales, especially right whales, due to incidental entanglement in United States commercial fishing gear. In order to develop fair and effective management measures, the Take Reduction Team (Team) requires comprehensive data on when, where, and how fixed gear vessels fish, and where whales become entangled in fishing gear. Last updated in 2015, the Plan requires buoy lines in fixed gear fisheries to be marked. All buoy lines must be marked with three 12 inch (30.5. 48 cm), colored marks unique to particular fishing areas: one at the top of the buoy line, one midway along the buoy line, and one at the bottom of the buoy line. No additional markings are being proposed at this time. This gear marking, when observed on entangled whales, allows fishery managers to identify the gear type and area the entangling gear may have originated from, to tailor management measures to reduce the risk of mortality and serious injury of marine mammal incidental to commercial fishing operations. Without the information provided by the gear-marking requirements informing where entanglements occur and what type of gear is involved, future management measures may be overly broad and affect more individuals than necessary. Therefore, knowing which geographic areas and fisheries pose the greatest risk to large whales will minimize the economic impact to fishermen while maximizing the benefits for these species.

II. Method of Collection

Information collected is in the form of gear marking.

III. Data

OMB Control Number: 0648–0364.

Form Number(s): None.

Type of Review: Regular submission.

Affected Public: Business or other for-profit organizations, and individuals or households.

Estimated Number of Respondents: Approximately 4,008 vessels.

Estimated Time per Response: Each mark requires approximately 5 minutes of time.

Estimated Total Annual Burden Hours: Estimated 3 burden hours each year, per vessel, for vessels who are re-marking existing gear. This results in a total of 12,024 hours per year total, for all vessels.

Estimated Total Annual Cost to Public: Estimated cost of $2.31 each year, per vessel, for vessels who are re-marking existing gear. This results in a total expense of $9,258.48 per year, for all vessels who are re-marking existing gear.

IV. Request for Comments

Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (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.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Sheleen Dumas,

Departmental Lead PRA Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2019–20769 Filed 9–24–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; Basic Requirements for Special Exception Permits and Authorizations To Take, Import, and Export Marine Mammals, Threatened and Endangered Species, and for Maintaining a Captive Marine Mammal Inventory Under the Marine Mammal Protection Act, the Fur Seal Act, and/or the Endangered Species Act

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, 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 proposed and/or continuing information

collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before November 25, 2019.

ADDRESSES: Direct all written comments to Adrienne Thomas, PRA Officer, NOAA, 151 Patton Avenue, Room 159, Asheville, NC 28801 (or via the internet at *PRAcomments@doc.gov*). Comments will generally be posted without change. All Personally Identifiable Information (for example, name and address) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information. You may submit attachments to electronic comments in Microsoft Word, Excel, or Adobe PDF file formats.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Amy Sloan or Carrie Hubard, NOAA Fisheries Office of Protected Resources, 1315 East-West Highway, Silver Spring, MD 20910, (301) 427–8401, *Amy.Sloan@noaa.gov* or *Carrie.W.Hubard@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for a revision and extension of a currently approved information collection.

The Marine Mammal Protection Act (16 U.S.C. 1361 *et seq.;* MMPA), Fur Seal Act (16 U.S.C. 1151 *et seq.;* FSA), and Endangered Species Act (16 U.S.C. 1531 *et seq.;* ESA) prohibit certain activities affecting marine mammals and endangered and threatened species, with exceptions. Pursuant to Section 104 of the MMPA and Section 10(a)(1)(A) of the ESA, special exception permits may be obtained for scientific research and enhancing the survival or recovery of a species or stock of marine mammals or endangered or threatened species. Section 104 of the MMPA also provides for Letters of Confirmation under a General Authorization for scientific research and permits for commercial and educational photography of marine mammals that involve only Level B harassment of marine mammals; permits for capture and/or import of marine mammals for public display; and inventory reporting pertaining to marine mammals in public display facilities.

The regulations pertaining to permits and associated reporting requirements under the MMPA and FSA are at 50 CFR part 216; the regulations for permit requirements under the ESA are at 50 CFR part 222. The required information in this collection is used to make the determinations required by the MMPA, FSA, ESA and their implementing regulations prior to issuing a permit; to establish appropriate permit conditions; to evaluate the impacts of the proposed activity on protected species; and, to ensure compliance with the Acts. The marine mammal inventory forms ensure compliance with MMPA reporting requirements and allow NMFS to maintain the National Inventory of Marine Mammals (NIMM), as required by the MMPA.

This information collection applies to certain protected species for which NMFS is responsible: Cetaceans (whales, dolphins and porpoises) and pinnipeds (seals and sea lions); and, for ESA scientific research and enhancement permits: Sawfish (largetooth and smalltooth), sea turtles (in water), sturgeon (Atlantic and shortnose), and certain foreign ESA-listed species. This information collection may be used for future ESA-listed species.

We propose to revise the currently-approved special exception permit application instructions to: (1) Improve readability by changing the font, adding color, removing jargon, eliminating extraneous text, incorporating bullets and numbered lists, and reorganizing sentence structure; (2) be more user-friendly by consolidating pages, shortening and moving background information to the end, and removing sections that don't apply to specific permit types; (3) eliminate the requirement for applicants to provide scientific names of protected species; (4) update the information required to use unmanned aircraft systems; (5) reduce time spent asking for additional information from applicants by eliminating the requirement for proposed take numbers to be included in both the narrative and table sections of the application; (6) require most permit personnel to use a specialized qualifications form instead of submitting resumes, thus reducing time spent clarifying personnel experience; (7) provide examples of qualification forms for different personnel types; (8) provide detailed procedure options for those requesting parts permits; (9) put questions about potential effects to the environment in plain language; (10) improve organizational structure of the public display instructions, since those applicants do not submit via our online system; and (11) include examples of take tables for import and capture from the wild in the public display instructions. In addition, we propose to remove the requirement that permit applicants provide the name and contact information of Authorized Recipients who may receive protected species parts. Moving forward, we propose to allow permit holders to designate their own Authorized Recipients, which will give them more flexibility and autonomy and will save time by removing the need to request an authorization letter. We also propose to make photography and parts permit applications accessible via our online application system known as APPS (Authorizations and Permits for Protected Species; *https://apps.nmfs.noaa.gov*).

The MMPA requires NMFS to establish and maintain an inventory of marine mammals in zoos and aquariums. On February 15, 2019, we published a **Federal Register** notice (84 FR 4443) seeking comment on policies and procedures for implementing NMFS' National Inventory of Marine Mammals (NIMM). We extended the public comment period to July 31, 2019 (84 FR 15593). After review and consideration of public comments (available at: *https://www.regulations.gov/docket?D=NOAA-NMFS-2019-0012*), we are proposing certain inventory reporting revisions. Public access to NIMM is not the subject of this notice and is not addressed here. We will provide a separate opportunity to comment on public access to NIMM. This notice only pertains to inventory reporting requirements.

In addition to providing holders of marine mammals (*i.e.,* Owners and Facilities) electronic forms to complete and submit marine mammal inventory information via email, fax, or mail (as is currently done), we propose to make the online inventory, NIMM, accessible to holders of marine mammals for those who would like to report their inventory information online. We propose revisions to the current inventory form known as the marine mammal data sheet (MMDS) to (1) define birth and clarify that a birth must be reported if the marine mammal is born alive, no matter how long it lives; (2) clarify that stillbirths are not required to be reported; and (3) standardize reporting of cause of death (when determined) to include a simple, two-tier system that reflects the primary body system or circumstance of the cause of death (Tier 1) with the significant findings underlying that body system or circumstance (Tier 2). This information could also be entered in the online format noted above. Below we respond to comments received regarding these three points during the February 15 to July 31, 2019 comment period on NIMM.

Birth and Stillbirth: Several commenters opposed the reporting of stillbirths, suggested we modify our proposed definition of birth to clarify it only pertains to live animals, and remove any reference to reporting stillbirths in the cause of death section of the MMDS. We have done so in the proposed revised MMDS. One comment suggested that a stillbirth should be reported as a birth and that such information has scientific and welfare value. While we acknowledge that information in the inventory is of value to the U.S. Department of Agriculture, Animal and Plant Health Inspection Service (the agency with oversight for the humane handling care, treatment and transportation of marine mammals), we believe that the intent of the inventory is to track individual marine mammals over their lifetime. The inventory requires both birth and death information for each animal. We interpret this to imply that a marine mammal must be born alive to enter the inventory. We also propose to clarify on the MMDS that a birth of a live marine mammal must be reported regardless of how long the animal lives, as some zoos and aquariums have interpreted the requirement to report births as only including marine mammals in the inventory if they live for 30 days.

Cause of Death: Some commenters supported the proposed two-tier system cause of death reporting as a ''much-needed improvement'' and an ''innovative method of standardizing and reporting'' to allow ''enough detail to accurately characterize the event.'' We received suggestions to improve the accuracy of the cause of death information, which we have incorporated into the revised MMDS. Once a body system or circumstance is selected for the underlying cause of death (Tier 1), multiple selections can be made from the associated Tier 2 level. However, because we are seeking the primary body system or circumstance to be reported, and due to associated programming challenges, we propose that only a single Tier 1 factor may be selected at this time.

We also received opposing comments to the use of the two-tier system, including that it exceeded the required statement of ''cause of death,'' was ''too complicated,'' should only have one tier, and could only be based on findings that would be developed through a necropsy. We first clarify that we do not require necropsy reports be submitted to the inventory to report cause of death. The MMPA states that cause of death must be reported ''when determined,'' implying that analyses be performed (such as necropsy and tissue analysis, as is standard when determining cause of death), before reporting it to the inventory. As one commenter noted, cause of death reporting has been ''uneven and variable'' via *ad libitum* reports of death as provided in a text field. For example, we have received reports with vague information such as ''expired after a prolonged illness'' compared to reports with information such as ''metastatic squamous cell carcinoma.'' The two-tier system provides a mechanism to provide a standardized, simple statement of the cause of death (*e.g.,* Liver [Tier 1 Body System]; Cancer/Neoplastic—Primary [Tier 2 Significant Finding]).

Additional Comments: Regarding additional comments we received such as on historical information in NIMM and providing a mechanism for zoos and aquariums to verify the accuracy of their information in NIMM, we propose to address those comments in a separate notice prior to making NIMM available for online reporting by marine mammal holders. As mentioned previously, public access to NIMM will be addressed in a separate notice.

II. Method of Collection

Currently-approved permit applications, permit report form information, and inventory forms are available as downloadable Word or PDF versions online at *https://www.fisheries.noaa.gov/permits-and-forms#protected-resources* or via email. Respondents may submit all applications, forms, and reports by email, facsimile, or mail. Respondents may currently also submit scientific research and enhancement permit applications (including parts permit applications) and Letters of Intent under the General Authorization online via APPS. Reports for most permits can be submitted online via APPS.

Under the proposed revision, in addition to the modes of access and submission listed above, photography permit applications would be made available online via APPS, a simplified parts permit application module would be developed in APPS, and marine mammal inventory reporting would be made available online via NIMM.

III. Data

OMB Control Number: 0648–0084.

Form Number(s): None.

Type of Review: Regular submission (revision and extension of previously-approved collection).

Affected Public: Individuals; Business or other for-profit organizations; Not-for-profit institutions; State, Local, or Tribal government; Federal government.

Estimated Number of Respondents: 415. This is the estimated total number, annually, of persons or organizations anticipated to (1) apply for an MMPA, FSA, and/or ESA permit or authorization; (2) submit annual permit reports and modification requests; and (3) submit marine mammal inventory reports. This number is, respectively, based on (1) the number of permit applications anticipated to be received annually (from reviewing data from 2016–2018); (2) the number of current permit holders required to submit annual reports and who may request to modify their permit; and (3) the total number of currently active marine mammal facilities subject to inventory reporting requirements.

Estimated Time per Response: The estimated *average* amount of time it takes to complete each information collection instrument is as follows. Scientific research permit applications, 50 hours; public display permit applications, 30 hours; photography permit applications, 10 hours; General Authorization Letters of Intent, 10 hours; major permit modification requests, 35 hours; minor permit modification requests, 3 hours; scientific research permit reports, 12 hours; scientific research parts only permit reports, 8 hours; General Authorization reports, 8 hours; public display permit reports, 2 hours; photography permit reports, 2 hours; public display inventory reporting, 2 hours; and general record keeping, 2 hours per each type.

Estimated Total Annual Burden Hours: 6,711.

Estimated Total Annual Cost to Public: $1,000 in recordkeeping/reporting costs. This represents costs for mailing in applications, forms, and reports. The majority of respondents use electronic submission formats but some still mail in applications, forms, and reports. This estimate excludes time required to complete the applications, forms, and reports, and any equipment such as computers needed to complete them.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (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.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Sheleen Dumas,

Departmental Lead PRA Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2019–20767 Filed 9–24–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; Estuary Habitat Restoration Program Inventory [Formerly National Estuaries Restoration Inventory]

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, 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 proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before November 25, 2019.

ADDRESSES: Direct all written comments to Adrienne Thomas, PRA Officer, NOAA, 151 Patton Avenue, Room 159, Asheville, NC 28801 (or via the internet at *PRAcomments@doc.gov*). Comments will generally be posted without change. All Personally Identifiable Information (for example, name and address) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information. You may submit attachments to electronic comments in Microsoft Word, Excel, or Adobe PDF file formats.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Julia Royster, Office of Habitat Conservation, Restoration Center, 1315 East-West Highway, Silver Spring, MD 20910, 301–427–8686, or *julia.royster@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for a revision and renewal of a currently approved bi-annual information collection. The Estuary Restoration Act of 2000 established an Estuary Habitat Restoration Program that provides funding to restoration projects. Funded projects are required to complete the collection tool so project information (*e.g.,* location, habitat type, goals, status, monitoring information) can be included in the Estuary Habitat Restoration Program database mandated by the Estuary Restoration Act of 2000. The benefit of data collection is to document the restoration actions implemented, as well as the monitoring results to understand the success of each project. Estuary habitat restoration program project information will be submitted by habitat restoration project managers and will be accessible to the public via internet. The collection method includes paper or electronic forms, not web-based data entry.

II. Method of Collection

Respondents have a choice of either electronic or paper forms. Methods of submittal include email of electronic forms, and mail and facsimile transmission of paper forms.

III. Data

OMB Control Number: 0648–0479.

Form Number(s): None.

Type of Review: Regular submission (revision and extension of a currently approved collection).

Affected Public: Non-profit institutions; State, local, or tribal government.

Estimated Number of Respondents: 20.

Estimated Time per Response: Data entry of new projects, 4 hours; updates to existing projects, 2 hours.

Estimated Total Annual Burden Hours: 100.

Estimated Total Annual Cost to Public: $100 in recordkeeping/reporting costs.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (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.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Sheleen Dumas,

Departmental Lead PRA Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2019–20768 Filed 9–24–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XU003

Marine Fisheries Advisory Committee Meeting

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

ACTION: Notice of open public meeting.

SUMMARY: This notice sets forth the proposed schedule and agenda of a forthcoming meeting of the Marine Fisheries Advisory Committee (MAFAC). The members will discuss and provide advice on issues outlined under **SUPPLEMENTARY INFORMATION** below.

DATES: The meeting will be held October 15 and 16, 2019, from 8:30 a.m. to 5 p.m., and October 17, from 8:30 a.m. to 1 p.m.

ADDRESSES: The meeting will be held at the Sheraton Silver Spring Hotel, 8777 Georgia Ave., Silver Spring, MD 20910; 301–589–0800.

FOR FURTHER INFORMATION CONTACT: Heidi Lovett, MAFAC Assistant Director; 301–427–8034; email: *Heidi.Lovett@noaa.gov.*

SUPPLEMENTARY INFORMATION: As required by section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. 2, notice is hereby given of a meeting of MAFAC. The MAFAC was established by the Secretary of Commerce (Secretary), and, since 1971, advises the Secretary on all living marine resource matters that are the responsibility of the Department of Commerce. The complete charter and

summaries of prior meetings are located online at *http://www.nmfs.noaa.gov/ocs/mafac/.*

Matters To Be Considered

This meeting time and agenda are subject to change. The meeting is convened to hear presentations and updates and to discuss policies and guidance on the following topics: Seafood promotion and marketing in the U.S.; role of the new senior advisor for seafood strategy; recreational fisheries engagement and electronic reporting; wind development in the marine environment; and electronic monitoring policies and implementation. MAFAC will receive updates on the phase 2 work of Columbia Basin Partnership Task Force, NMFS scientific enterprise, and the budget outlook for FY2020. MAFAC will discuss various administrative and organizational matters, and meetings of subcommittees and working groups will be convened.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Heidi Lovett; 301–427–8034 by October 7, 2019.

Dated: September 19, 2019.

Jennifer Lukens,

Director for the Office of Policy, National Marine Fisheries Service.

[FR Doc. 2019–20740 Filed 9–24–19; 8:45 am]

BILLING CODE 3510–22–P

COMMODITY FUTURES TRADING COMMISSION

Agency Information Collection Activities: Notice of Intent To Extend Collection 3038–0096, Swap Data Recordkeeping and Reporting Requirements

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice.

SUMMARY: The Commodity Futures Trading Commission (''CFTC'' or ''Commission'') is announcing an opportunity for public comment on the proposed renewal of an information collection by the agency. Under the Paperwork Reduction Act (''PRA''), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment. This notice solicits comments on the swap data recordkeeping and reporting requirements on the following entities: Swap Dealers (''SDs''), Major Swap Participants (''MSPs''), and swap counterparties that are neither swap dealers nor major swap participants (''non-SD/MSP counterparties'').

DATES: Comments must be submitted on or before November 25, 2019.

ADDRESSES: You may submit comments, identified by ''Extension of Information Collection Pertaining to Swap Data Recordkeeping and Reporting Requirements, OMB Control No. 3038–0096,'' by any of the following methods:

- The Agency's website, at *http://comments.cftc.gov/.* Follow the instructions for submitting comments through the website.
- *Mail:* Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.
- *Hand Delivery/Courier:* Same as Mail above.

Please submit your comments using only one method. All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to *http://www.cftc.gov.*

FOR FURTHER INFORMATION CONTACT: Meghan Tente, Special Counsel, Division of Market Oversight, Commodity Futures Trading Commission, (202) 418–5785, email: *mtente@cftc.gov,* and refer to OMB Control No. 3038–0096.

SUPPLEMENTARY INFORMATION: Under the PRA, 44 U.S.C. 3501 *et seq.,* Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of Information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3 and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA, 44 U.S.C. 3506(c)(2)(A), requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed information collection, including each proposed extension of an existing information collection, before submitting the collection to OMB for approval. To comply with this requirement, the CFTC is publishing notice of a proposed extension of the currently approved information collection listed below. An agency may not conduct or sponsor, and a person is not required to respond to, an information collection unless it displays a currently valid OMB control number.

Title: Swap Data Recordkeeping and Reporting Requirements (OMB Control No. 3038–0096). This is a request for extension of a currently approved information collection.

Abstract: The information collection is needed to ensure that the CFTC and other regulators have access to swap data as required by the Commodity Exchange Act, as amended by the Dodd-Frank Wall Street Reform and Consumer Protection Act (''Dodd-Frank Act''). The Dodd-Frank Act directed the CFTC to adopt rules providing for the reporting of data relating to swaps. In 2012, the CFTC adopted Regulation 45, which imposes recordkeeping and reporting requirements relating to pre-enactment and historical swaps.

With respect to the collection of information, the CFTC invites comments on:

- Whether the proposed collection of information is necessary for the proper performance of the functions of the CFTC, including whether the information will have a practical use;
- The accuracy of the CFTC's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Ways to enhance the quality, usefulness, and clarity of the information to be collected; and
- Ways to minimize the burden of collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology; *e.g.,* permitting electronic submission of responses.

You should submit only information that you wish to make available publicly. If you wish the CFTC to consider information that you believe is exempt from disclosure under the Freedom of Information Act (FOIA), a petition for confidential treatment of the exempt information may be submitted according to the procedures established in § 145.9 of the CFTC's regulations.[1]

The CFTC reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse or remove any or all of your submission from *http://www.cftc.gov* that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the Information Correction Request will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other

[1] 17 CFR 145.9.

applicable laws, and may be accessible under FOIA.

Burden Statement: Provisions of CFTC Regulations 45.2, 45.3, 45.4, 45.5, 45.6, 45.7, and 45.14 result in information collection requirements within the meaning of the PRA. With respect to the ongoing reporting and recordkeeping burdens associated with swaps, the CFTC believes that SDs, MSPs, and non-SD/MSP counterparties incur an annual time burden of 2,279,312 hours. This time-burden represents a proportion of the burden respondents incur to operate and maintain their swap data recordkeeping and reporting systems.

Respondents/Affected Entities: Swap Dealers, Major Swap Participants, and other counterparties to a swap transaction (*i.e.,* end-user, non-SD/non-MSP counterparties).

Estimated number of respondents: 1,732.

Estimated average burden hours per respondent: 1,316.

Estimated total annual burden hours on respondents: 2,279,312 hours.

Frequency of collection: Ongoing.

There are no capital costs or operating and maintenance costs associated with this collection.

(Authority: 44 U.S.C. 3501 *et seq.*)

Dated: September 19, 2019.

Robert Sidman,

Deputy Secretary of the Commission.

[FR Doc. 2019–20749 Filed 9–24–19; 8:45 am]

BILLING CODE 6351–01–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Application Package for AmeriCorps National Civilian Community Corps (NCCC) Member Experience Survey; Proposed Information Collection; Comment Request

AGENCY: Corporation for National and Community Service.

ACTION: Notice.

SUMMARY: The Corporation for National and Community Service (CNCS) has submitted a public information collection request (ICR) entitled AmeriCorps National Civilian Community Corps (NCCC) Member Experience Survey for review and approval in accordance with the Paperwork Reduction Act.

DATES: Comments may be submitted, identified by the title of the information collection activity, by October 25, 2019.

ADDRESSES: Direct written comments and/or suggestions regarding the items contained in this Notice to the Attention: CNCS Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of Notice publication.

FOR FURTHER INFORMATION CONTACT: Copies of this ICR, with applicable supporting documentation, may be obtained by calling the Corporation for National and Community Service, Jacob Sgambati, at 202–606–6930 or by email to *jsgambati@cns.gov.*

SUPPLEMENTARY INFORMATION: The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of CNCS, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions;
- Propose ways to enhance the quality, utility, and clarity of the information to be collected; and
- Propose 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

A 60-day Notice requesting public comment was published in the **Federal Register** on July 11, 2019 at 84 FR 33063. This comment period ended September 9, 2019. No public comments were received from this Notice.

Title of Collection: AmeriCorps NCCC Member Experience Survey.

OMB Control Number: 3045–0181

Type of Review: Renewal.

Respondents/Affected Public: Current/prospective AmeriCorps NCCC Members.

Total Estimated Number of Annual Responses: 2,000.

Total Estimated Number of Annual Burden Hours: 173 Hours.

Abstract: The AmeriCorps NCCC Member Experience Survey is completed by AmeriCorps members who have been a part of an AmeriCorps NCCC team. Each year, AmeriCorps NCCC engages teams of members in projects in communities across the United States. Service projects, which typically last from six to eight weeks, address critical needs in natural and other disasters, infrastructure improvement, environmental stewardship and conservation, energy conservation, and urban and rural development. Members construct and rehabilitate low-income housing, respond to natural disasters, clean up streams, help communities develop emergency plans, and address other local needs.

CNCS seeks to renew the current information collection. The revisions are intended to be used in the same manner as the existing survey. The information collection will otherwise be used in the same manner as the existing application. CNCS also seeks to continue using the current application until the revised application is approved by OMB. The current application is due to expire on December 31, 2019.

Dated: September 19, 2019.

Jacob Sgambati,

Acting Deputy Director.

[FR Doc. 2019–20726 Filed 9–24–19; 8:45 am]

BILLING CODE 6050–28–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

[Docket Number DARS–2019–0040; OMB Control Number 0704–0441]

Information Collection Requirement; Defense Federal Acquisition Regulation Supplement (DFARS); Quality Assurance; Submission for OMB Review; Comment Request

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Notice.

SUMMARY: The Defense Acquisition Regulations System has submitted to the Office of Management and Budget (OMB) for clearance, the following proposed revision and extension of a collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by October 25, 2019.

SUPPLEMENTARY INFORMATION:

Title and OMB Number: Defense Federal Acquisition Regulation Supplement (DFARS) Part 246, Quality Assurance, and related clauses at 252.246; OMB Control Number 0704–0441.

Affected Public: Businesses or other for-profit and not-for-profit institutions.

Respondent's Obligation: Required to obtain or retain benefits.

Frequency: On occasion.

Type of Request: Revision and extension.

Number of Respondents: 34,842.

Responses per Respondent: ~1.55.

Annual Responses: 122,024.

Average Burden per Response: ~17.05.

Annual Burden Hours: 2,075,685 (includes 39,075 reporting hours and 2,036,610 recordkeeping hours).

Needs and Uses: The information collections under OMB Control Number 0704–0441 pertain to all information that offerors or contractors must submit related to DFARS contract quality assurance programs. This renewal includes the incorporation of OMB Control Number 0704–0541.

a. 252.246–7003, Notification of Potential Safety Issues. Contracting officers require timely notification of potential safety defects so that (1) systems and equipment likely affected by the situation can be readily identified, and (2) appropriate engineering investigation and follow-on actions can be taken to establish and mitigate risk.

b. 252.246–7005, Notice of Warranty Tracking of Serialized Items. The information provided by offerors under this provision alerts contracting officers in those cases where the offeror is proposing to provide a warranty for an individual contract line item for which DoD has not specified a warranty in the solicitation. The warranty notice will permit the Government to recognize and utilize any warranty after contract award.

c. 252.246–7006, Warranty Tracking of Serialized Items, implements section 818 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2012 (Pub. L. 112–81 as amended by section 817 of the NDAA for FY 2015 (Pub. L. 113–291). The information provided by contractors allows DoD to track warranties for item unique item identification (IUID) required items in the IUID registry to obtain maximum utility of warranties provided on contracted items. The identification and enforcement of warranties is essential to the effectiveness and efficiency of DoD's material readiness. Providing visibility and accountability of warranty data associated with acquired goods, from the identification of the requirement to the expiration date of the warranted item, significantly enhances DoD's ability to take full advantage of warranties, resulting in—

(1) Reduced costs;

(2) Ability to recognize benefits included at no additional cost;

(3) Ability to compare performance against Government-specified warranties; and

(4) Identification of sufficient durations for warranties for specific goods.

d. 252.246–7008, Sources of Electronic Parts. The notification and documentation requirements are necessary to comply with statute. The contracting officer will use the information to ensure that the contractor performs the traceability of parts, additional inspection, testing, and authentication required when an electronic part is not obtained from a trusted supplier. The Government may also use this information to more actively perform acceptance.

Comments and recommendations on the proposed information collection should be sent to Ms. Jasmeet Seehra, DoD Desk Officer, at *Oira_submission@omb.eop.gov.* Please identify the proposed information collection by DoD Desk Officer and the Docket ID number and title of the information collection

You may also submit comments, identified by docket number and title, by the following method: *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

DoD Clearance Officer: Ms. Angela James. Requests for copies of the information collection proposal should be sent to Ms. James at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Jennifer Lee Hawes,

Regulatory Control Officer, Defense Acquisition Regulations System.

[FR Doc. 2019–20845 Filed 9–24–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

[Docket Number DARS–2019–0044; OMB Control Number 0704–0434]

Information Collection Requirement; Defense Federal Acquisition Regulation Supplement (DFARS); Radio Frequency Identification Advance Shipment Notices; Submission for OMB Review; Comment Request

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Notice.

SUMMARY: The Defense Acquisition Regulations System has submitted to OMB for clearance, the following proposed revision of a collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by October 25, 2019.

SUPPLEMENTARY INFORMATION: *Title, Associated Form, and OMB Number:* Defense Federal Acquisition Regulation Supplement (DFARS); Radio Frequency Identification Advance Shipment Notices; OMB Control Number 0704–0434.

Affected Public: Businesses or other for-profit and not-for-profit institutions.

Respondent's Obligation: Required to obtain or retain benefits.

Frequency: On Occasion.

Type of Request: Revision.

Number of Respondents: 5,217.

Responses per Respondent: 3,782.

Annual Responses: 19,732,850.

Average Burden per Response: Approximately 1.16 seconds.

Annual Burden Hours: 6,358.

Needs and Uses: The clause at DFARS 252.211–7006, Passive Radio Frequency Identification, requires the contractor to ensure that the data on each passive RFID tag are unique and conform to the requirements that they are readable and affixed to the appropriate location on the specific level of packaging in accordance with MIL–STD–129 tag placement specifications. The contractor shall encode an approved RFID tag using the appropriate instructions at the time of contract award. Regardless of the selected encoding scheme, the contractor is responsible for ensuring that each tag contains a globally unique identifier. The contractor shall electronically submit advance shipment notices with the RFID tag identification in advance of the shipment in accordance with the procedures at *https://wawf.eb.mil/.* DoD uses advance shipment notices for the shipment of material containing Radio Frequency Identification (RFID) tag data. DoD receiving personnel use the advance shipment notice to associate the unique identification encoded on the RFID tag with the corresponding shipment. Use of the RFID technology permits DoD an automated and sophisticated end-to-end supply chain that has increased visibility of assets and permits delivery of supplies to the warfighter more quickly.

Comments and recommendations on the proposed information collection should be sent to Ms. Jasmeet Seehra, DoD Desk Officer, at *Oira_submission@omb.eop.gov.* Please identify the proposed information collection by DoD

Desk Officer and the Docket ID number and title of the information collection.

You may also submit comments, identified by docket number and title, by the following method: *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

DoD Clearance Officer: Ms. Angela James. Requests for copies of the information collection proposal should be sent to Ms. James at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Jennifer Lee Hawes,

Regulatory Control Officer, Defense Acquisition Regulations System.

[FR Doc. 2019–20844 Filed 9–24–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

TRICARE; Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); Adoption of Medicare's Home Health Value-Based Purchasing (HHVBP) Adjustments for Reimbursement Under TRICARE's Home Health Prospective Payment System Demonstration

AGENCY: Office of the Secretary, Department of Defense.

ACTION: Notice of TRICARE's adoption of Medicare's Home Health Value-Based Purchasing Model as a Demonstration.

SUMMARY: This notice describes the adoption of Medicare's Home Health Value-Based Purchasing (HHVBP) adjustments for reimbursement under TRICARE's Home Health Prospective Payment System (HH PPS). In recognition that the Defense Health Agency (DHA) strongly supports the implementation of value-based incentive programs, in accordance with Section 705(a) of National Defense Authorization Act (NDAA) for Fiscal Year 2017, the adoption of this model establishes a new value-based initiative within the TRICARE program, based on Medicare's similar pilot. In the Medicare HHVBP model, the Centers for Medicare and Medicaid Services (CMS) determines a payment adjustment up to the maximum percentage, upward or downward, based on the Home Health Agency's (HHA) Total Performance Score (TPS). As a result, the model incentivizes quality improvements and encourages efficiency. States selected for participation in the Medicare HHVBP model include Arizona, Florida, Iowa, Maryland, Massachusetts, Nebraska, North Carolina, Tennessee, and Washington.

CMS cannot release HHVBP adjustment factors to TRICARE, so Home Health Agencies (HHAs) in the participating states will be required to send their annual payment adjustment reports to the applicable TRICARE contractors prior to January 1 each year. Failure to submit the required payment adjustment documentation would result in full application of the negative adjustment factor for the calendar year. This requirement allows TRICARE to mirror Medicare's HHVBP payment adjustments. The TRICARE HHVBP model will only apply to Medicare-certified HHAs in the nine participating states. Specialized HHAs that qualify for corporate services provider status but are not Medicare-certified will continue to be reimbursed under the CHAMPUS Maximum Allowable Charge (CMAC) system and will not be subject to the TRICARE HHVBP model.

DATES: This demonstration project will be effective January 1, 2020, through December 31, 2022, unless terminated earlier by Medicare or by TRICARE.

ADDRESSES: Defense Health Agency (DHA), TRICARE, Medical Benefits and Reimbursement Office, 16401 East Centretech Parkway, Aurora, CO 80011–9066.

FOR FURTHER INFORMATION CONTACT: Mr. Jahanbakhsh Badshah, Medical Benefits and Reimbursement Section, TRICARE, telephone (303) 676–3881. Questions regarding payment of specific claims should be addressed to the appropriate TRICARE contractor.

SUPPLEMENTARY INFORMATION:

A. Background

As authorized by section 1115A of the Social Security Act and finalized in the Medicare calendar year (CY) 2016 Home Health Prospective Payment System (HH PPS) final rule (80 FR 68624), CMS began testing the Home Health Value-Based Purchasing (HHVBP) Model in January 2016. The specific goals of the Model are to: (1) Provide incentives for better quality care with greater efficiency; (2) study new potential quality and efficiency measures for appropriateness in the home health setting; and (3) enhance the current public reporting process. It is expected that tying quality to payment through a system of value-based purchasing for all Medicare-certified Home Health Agencies (HHAs) providing services in the states of Arizona, Florida, Iowa, Maryland, Massachusetts, Nebraska, North Carolina, Tennessee, and Washington will improve the beneficiaries' experience and outcomes. It is also expected that payment adjustments that both reward improved quality and penalize poor performance will incentivize quality improvement and encourage efficiency. TRICARE's adoption of the HHVBP model will strengthen the impact of the incentives included within the model by adding TRICARE's market share to Medicare's. Adoption of this model by the TRICARE program will also continue DHA's efforts to transition payments to reward high-quality providers, and leverages Medicare's experience to implement the most effective value-based payment methodologies.

The distribution of payment adjustments under this HHVBP Model are based on quality performance, as measured by both achievement and improvement, across a set of quality measures constructed to minimize the burden as much as possible and improve care. The degree of the payment adjustment is dependent on the level of quality achieved or improved from the base year, with the highest upward performance adjustment going to competing HHAs with the highest overall level of performance based on either achievement or improvement in quality. The size of a competing HHA's payment adjustment for each year under the Model is dependent upon the HHA's performance with respect to that calendar year relative to other competing HHAs of similar size in the same state, and relative to its own performance during the baseline year. Medicare utilizes quarterly performance reports, annual payment adjustment reports and annual publicly available performance reports to align the competitive forces within the market to deliver care based on value. The quality performance scores and relative peer rankings are determined through the use of a baseline year and subsequent performance periods for each HHA. A payment adjustment report is provided once a year to each of the HHAs by CMS. The annual report from CMS provides the HHA's payment adjustment percentage and explains how the adjustment was determined relative to its performance scores. This is the document that the HHAs in the selected states will be required to submit to TRICARE contractors prior to the beginning of each calendar year, upon adoption of the HHVBP by TRICARE.

The Medicare model will be implemented over a total of seven years that began on January 1, 2016, and ends December 31, 2022. (However, if Medicare decides to terminate or expand the demonstration TRICARE

will follow suit as well as adopt future modifications made to the HHVBP model by Medicare, as practicable.) The HHAs were notified of their first payment adjustment being finalized, based on the 2016 performance period (January 1, 2016 to December 31, 2016) with their first payment adjustment applied January 1, 2018 through December 31, 2018. Payment adjustments will be increased incrementally over the course of the HHVBP Model as described in Table 1 below:

TABLE 1—CMS HHVBP PAYMENT ADJUSTMENTS

Performance year	Calendar year payment adjustment applied	Maximum payment adjustment (upward or downward) (percent)
2016	2018	3
2017	2019	5
2018	2020	6
2019	2021	7
2020	2022	8

For additional information on the quality measures, methodology, and considerations used for calculating the HHVBP payment adjustment percentages, please go to the CMS Innovation Center website at *https://innovation.cms.gov/initiatives/home-health-value-based-purchasing-model.*

B. TRICARE's Adoption of the Model

As a result of the statutory authority granted under Section 705 of the NDAA for Fiscal Year (FY) 2017 for development and implantation of value-based incentive programs, we evaluated the administrative feasibility of adopting HHVBP adjustments under the TRICARE HH PPS in accordance with TRICARE's statute.

Based on the complexity of the multiple reporting systems and methodology used in the calculation of TPSs and final payment adjustment percentages, it appears that the only administratively feasible means of mirroring the HHVBP payment adjustment is to obtain the required information from each HHA; *i.e.,* to require submission of the HHA's annual payment adjustment report for reimbursement in the upcoming calendar year, the process of which will be described in the implementing instructions. This would be administratively feasible, given the fact that HHAs are notified of subsequent payment adjustments in August, prior to their January 1 application date. This would give TRICARE sufficient time to load the HHVBP adjustment factors by January 1 of each subsequent calendar year. Failure to submit the required payment adjustment documentation would result in full application of the negative adjustment factor for the calendar year (*e.g.,* application of a negative 6 percent adjustment in payments for home health services provided in CY 20202). This would allow HHAs to continue to receive payments under the program, thus avoiding potential access to care issues/problems, while at the same time serving as a disincentive for non-compliance.

Although TRICARE will not have access to specific quarterly performance reports available to each HHA through the Center for Medicare and Medicaid Innovation (CMMI) model specific platform, it will have access to publicly available annual quality reports. These reports will provide home health industry stakeholders, including providers and suppliers that refer their patients to HHAs, with the opportunity to confirm that the beneficiaries they are referring for home health services are being provided the best possible quality of care available. The implementing instructions will also encourage the TRICARE contractors to direct care to high-quality providers when possible. TRICARE will also have access to annual payment adjustment reports focusing on both quality achievement and improvement. Submission of these reports will be required to avoid full application of the CY negative adjustment factor under the TRICARE HH PPS. Since TRICARE does not have the quality monitoring systems in place to assess its specific impact on HHAs' quality achievement and improvement, TRICARE will have to utilize Medicare's performance reports in its evaluation process. This approach permits TRICARE to leverage Medicare's dominant market share and technical expertise in evaluation quality as it relates to value-based payment methodology. In other words, an assumption can be made that quality measures experienced from TRICARE's participation in the HHVBP demonstration would be comparable to those experienced under the Medicare program, given its dominant home health market share, and the overlap in the type of services and beneficiaries that utilize the two benefits.

TABLE 2—TRICARE HOME HEALTH CLAIMS BY AGE GROUP, FY 2017

Age group	Number of claims	Percent of total claims
<19	1,000	5
19–44	3,479	18
44–64	14,740	76
65+ *	243	1
Total	19,462	100

* Home Health claims for beneficiaries aged 65 and older make up only one percent of total claims because, for Medicare-eligible beneficiaries, Medicare is the primary payer for most Home Health services and home health services have no cost-share.

TABLE 3—TRICARE HOME HEALTH CLAIMS BY SEVERITY AND AGE GROUP, FY 2017

Category based on clinical and functional severity	N	Percent	Percent of category by age group			
			<19	19–44	45–64	65+
Most Severe	3,317	17	9	1	15	20
Moderately Severe	9,288	48	64	43	48	47
Less Severe	5,339	27	9	30	28	27
Least Severe	1,518	8	18	13	6	5
Total	19,462	100	100	100	100	100

The HHVBP model applies to all Medicare-certified HHAs in each of the nine selected states, which covered approximately 25 percent of total TRICARE claims in fiscal year (FY) 2017. However, those HHAs for which Medicare-certification is not available due to the specialized beneficiary categories they serve (*e.g.,* those HHAs specializing solely in the treatment of TRICARE beneficiaries that are under the age of 18 or receiving maternity care) are exempt from the HHVBP adjustment methodology. These specialized HHAs must qualify for corporate services provider status under the Program and are paid for covered professional services under the CMAC reimbursement system, and would not participate in the TRICARE HHVBP.

C. Implementation

The new demonstration is effective January 1, 2020 and will continue until the end of Medicare's HHVBP model on December 31, 2022, unless terminated earlier by the Director, DHA, or Administrator, Centers for Medicare and Medicaid Services.

D. Evaluation

This demonstration project will assist the Department in evaluating the feasibility of incorporating the HHVBP model in the TRICARE program. Regular status reports and a full analysis of demonstration outcomes will be conducted consistent with the requirements in the TRICARE Operations Manual, Chapter 29, Section 1.

TRICARE's hypothesis is that payments that are linked to quality outcomes will:

(1) Be administratively feasible, meaning that the demonstration will be successfully implemented and administered within a reasonable margin of the DHA's estimate of this demonstration;

(2) Improve the quality of care delivered over time; and

(3) Be cost-neutral or result in modest long-term cost savings.

Success shall be defined as:

(1) Implementation and ongoing maintenance costs do not exceed 2 percent of the annual TRICARE total spend on home health care in the HHVBP demonstration states, and a high percentage of TRICARE HHAs provide their TPS scores.

(2) Measurable and statistically significant improvements in the quality of care received by TRICARE beneficiaries occurs, year-over-year, with averages from 2014–2018 serving as the baseline data period.

(3) The average acuity-adjusted home health cost per TRICARE beneficiary or episode in the HHVBP states increases at a slower rate or at the same rate compared to the same measure in the non-HHVBP states.

Following the end of each 12 months in the demonstration, DHA will measure and report the preceding data to the Director, DHA, along with a recommendation of whether to continue or discontinue the demonstration.

In the 12 months following termination of the demonstration, DHA shall make a report available to the public on the DHA website which details the findings of this demonstration, and potential next steps, if the demonstration is found to be successful in achieving the anticipated results. Continuation of the demonstration, or a transition into the Basic program reimbursement methodologies will be issued via appropriate **Federal Register** Notice or rulemaking action, and will be based on a demonstration that the pilot met the benchmarks set for success that are established in this Notice and Implementing Instructions.

Dated: September 20, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2019–20815 Filed 9–24–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 19–0H]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Arms sales notice.

SUMMARY: The Department of Defense is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: Karma Job at *karma.d.job.civ@mail.mil* or (703) 697–8976.

SUPPLEMENTARY INFORMATION: This 36(b)(5)(C) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 19–0H with attached Policy Justification.

Dated: September 20, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

JUL 0 8 2019

The Honorable Nancy Pelosi
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

Dear Madam Speaker:

Pursuant to the reporting requirements of Section 36(b)(5)(C) of the Arms Export Control Act (AECA), as amended, we are forwarding Transmittal No. 19-0H. This report relates to enhancements or upgrades from the level of sensitivity of technology or capability described in the Section 36(b)(1) AECA certification 16-01 of December 16, 2015.

Sincerely,

Charles W. Hooper
Lieutenant General, USA
Director

Enclosures:
1. Transmittal

BILLING CODE 5001–06–C

Transmittal No. 19-0H

REPORT OF ENHANCEMENT OR UPGRADE OF SENSITIVITY OF TECHNOLOGY OR CAPABILITY (SEC. 36(B)(5)(C), AECA)

(i) *Purchaser*: Taipei Economic and Cultural Representative Office (TECRO)

(ii) *Sec. 36(b)(1), AECA Transmittal No.*: 16-01

Date: December 16, 2015

Military Department: Army

(iii) *Description*: On December 16, 2015, Congress was notified by Congressional certification transmittal number 16-01, of the possible sale under Section 36(b)(1) of the Arms Export Control Act of seven hundred sixty-nine (769) TOW 2B Aero Radio Frequency (RF) Missiles (BGM-71F-Series). This proposed sale also includes fourteen (14) Radio Frequency (RF) TOW 2B Aero (BGM-71F-Series) Fly-to-Buy Missiles for lot acceptance testing, forty-six (46) Improved Target Acquisition System (ITAS) Launchers, four (4) Improved Target Acquisition System (ITAS) launcher spares, Missile Support Equipment, Government-Furnished Equipment, Technical Manuals/Publications, Spare Parts, Tool and Test Equipment, Trainers, Training, U.S. Government Technical Support/Integrated Logistical Support, Contractor Technical Support, and other associated equipment and services. The estimated total cost was $268 million. Major Defense Equipment (MDE) constituted $237 million of this total.

This transmittal notifies the inclusion of the following MDE items: 1) an additional one thousand two hundred forty (1,240) TOW 2B Aero, Radio Frequency (RF) missiles (BGM-71F-Series); 2) an additional fourteen (14) TOW 2B Aero, Radio Frequency (RF) missiles (BGM-71F-Series) Fly-to-Buy missiles; 3) an additional fifty-eight (58) Improved Target Acquisition System (ITAS); and 4) one hundred (100)

M1167A1B1 HMMWVs. Also included are missile support equipment, government-furnished equipment, technical manuals/publications, spare parts, tool and test equipment, training, U.S. Government technical support/logistical support, contractor technical support, and other related elements of logistics and program support. These inclusions will increase the MDE value by $241.2 million resulting in a new MDE cost of $478.2 million. The new total case value will be $567.2 million.

(iv) *Significance*: This notification will allow the recipient to improve its security and defensive capability.

(v) *Justification*: This proposed sale serves U.S. national, economic, and security interests by supporting the recipient's continuing efforts to modernize its armed forces and enhance its defensive capability. The proposed sale will help improve the security of the recipient and assist in maintaining political stability, military balance, and economic progress in the region.

(vi) *Sensitivity of Technology*: The statement contained in the original AECA 36(b)(1) transmittal applies to the MDE items reported here.

(vii) *Date Report Delivered to Congress*: July 8, 2019

[FR Doc. 2019–20823 Filed 9–24–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 19–39]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Arms sales notice.

SUMMARY: The Department of Defense is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: Karma Job at *karma.d.job.civ@mail.mil* or (703) 697–8976.

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 19–39 with attached Policy Justification and Sensitivity of Technology.

Dated: September 20, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

JUL 1 2 2019

The Honorable Nancy Pelosi
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

Dear Madam Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 19-39 concerning the Navy's proposed Letter(s) of Offer and Acceptance to the Government of the Greece for defense articles and services estimated to cost $600 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

Charles W. Hooper
Lieutenant General, USA
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology

BILLING CODE 5001–06–C

Transmittal No. 19-39

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser*: Government of Greece

(ii) *Total Estimated Value*:

Major Defense Equipment * ..	$300 million
Other	$300 million
Total	$600 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:*

Major Defense Equipment (MDE):

Seven (7) MH-60R Multi-Mission Helicopters, equipped with the following:

Ten (10) APS-l 53(V) Multi-Mode Radars (7 installed, 3 spares)

Eighteen (18) 1700 GE-401 C Engines (14 installed, 4 spares)

Seven (7) Airborne Low Frequency System (ALFS) (7 installed)

Ten (10) AN/AAS-44C(V) Multi-Spectral Targeting Systems (7 installed, 3 spares)

Eighteen (18) Embedded Global Positioning System/Inertial

Navigation Systems with Selective Availability/Anti-Spoofing Module (SAASM) (14 installed, 4 spares)
One-thousand (1,000) AN/SSQ-36/53/62 Sonobuoys
Two (2) AGM-114 M36-E9 Captive Air Training Missiles (CATM)
Four (4) AGM-l 14Q Hellfire Training Missiles
One Hundred (100) Advanced Precision Kill Weapons System (APKWS) Rockets Thirty (30) MK 54 Torpedoes
Twelve (12) M-240D Crew Served Guns
Twelve (12) GAU-21 Crew Served Guns

Non-MDE:

Also included are eighteen (18) AN/ARC-210 APX-1990A(C) Radios with COMSEC (14 installed and 4 spares); twenty-four (24) AN/AVS-9 Night Vision Devices; ten (10) AN/APX-123 Identification Friend or Foe (IFF) transponders (8 installed, 2 spares); spare engine containers; facilities study, design, and construction; spare and repair parts; support and test equipment; communication equipment; ferry support; publications and technical documentation; personnel training and training equipment; U.S. Government and contractor engineering, technical and logistics support services; and other related elements of logistical and program support.

(iv) *Military Department*: Navy (GR-P-SCK)

(v) *Prior Related Cases, if any*: None

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid*: None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold*: See Attached Annex (viii) *Date Report Delivered to Congress*: July 12, 2019

* As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Greece — MH-60R Multi-Mission Helicopters

The Government of Greece has requested to buy up to seven (7) MH-60R Multi-Mission Helicopters equipped with ten (10) APS-l 53(V) Multi-Mode Radars (7 installed, 3 spares); eighteen (18) T700 GE-401 C Engines (14 installed, 4 spares); seven (7) Airborne Low Frequency System (ALFS) (7 installed); ten (10) AN/ AAS-44C(V) Multi-Spectral Targeting Systems (7 installed, 3 spares); eighteen (18) Embedded Global Positioning System/Inertial Navigation Systems with Selective Availability/Anti-Spoofing Module (SAASM) (14 installed, 4 spares); one-thousand (1,000) AN/SSQ-36/53/62 Sonobuoys; two (2) AGM-114 M36-E9 Captive Air Training Missiles (CATM); four (4) AGM-114Q Hellfire Training Missiles; one Hundred (100) Advanced Precision Kill Weapons System (APKWS) Rockets; thirty (30) MK 54 Torpedoes; twelve (12) M-2400 Crew Served Guns; and twelve (12) GAU-21 Crew Served Guns. Also included are eighteen (18) AN/ARC-210 APX-1990A(C) Radios with COMSEC (14 installed and 4 spares); twenty-four (24) AN/AVS-9 Night Vision Devices; ten (10) AN/APX-123 Identification Friend or Foe (IFF) transponders (8 installed, 2 spares); spare engine containers; facilities study, design, and construction; spare and repair parts; support and test equipment; communication equipment; ferry support; publications and technical documentation; personnel training and training equipment; U.S. Government and contractor engineering, technical and logistics support services; and other related elements of logistical and program support. The estimated total case value is $600 million.

This proposed sale will support U.S. foreign policy and national security objectives by helping to improve the security of a NATO ally, which is an important partner for political stability and economic progress in Europe. The MH-60R helicopters will bolster the Hellenic Navy's ability to support NATO and remain interoperable with the U.S. and the NATO alliance.

The proposed sale will improve Greece's capability to meet current and future threats. The MH-60R Multi-Mission Helicopter will provide the capability to perform anti-surface and anti-submarine warfare missions along with the ability to perform secondary missions including vertical replenishment, search and rescue, and communications relay. Greece will have no difficulty absorbing these helicopters into its armed forces.

The proposed sale of this equipment will not alter the basic military balance in the region.

The principal contractor will be Lockheed Martin Rotary and Mission Systems in Owego, New York. There are no known offset agreements in connection with this potential sale.

Implementation of this proposed sale will require the assignment of five (5) additional U.S. Government personnel and five (5) contractor representatives to Greece.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vii

(vii) *Sensitivity of Technology*:

1. The MH-60R Multi-Mission Helicopter is employed primarily for anti-submarine and anti-surface warfare missions. The MH-60R carries several sensors and data links to enhance its ability to work in a network-centric battle group and as an extension of its home ship/main operating base. The mission systems consists of the following sensors and subsystems: an acoustics system consisting of a dipping sonar, sonobuoys, and acoustics processor; Multi-Mode Radar (MMR) with integrated Identification Friend or Foe (IFF) interrogator; Radios with COMSEC; Electronic Support Measures (ESM); Integrated Self-Defense (ISD); and Multi-Spectral Targeting System (MTS). Also, Night Vision Devices (AN/AVS-9) are included for CONOPS and interoperability with USN. It can carry AGM-l 14NB/K/N Hellfire missiles and Mk 46/54 lightweight torpedoes to engage surface and sub-surface targets. The Hellenic Navy MH-60R platform will include provisions for the Mk 54 lightweight torpedo. The MH-60R weapons system is classified up to SECRET. Unless otherwise noted below, MH-60R hardware and support equipment, test equipment and maintenance spares are unclassified except when electrical power is applied to hardware containing volatile data storage. Technical data and documentation for MH-60R weapons systems (to include sub-systems and weapons listed below) are classified up to SECRET. The sensitive technologies include:

a. The AGM-114 HELLFIRE missile is an air-to-surface missile with a multimission, multi-target, precision strike capability. The HELLLFIRE can be launched from multiple air platforms and is the primary precision weapon for the United States Army. The highest level for release of the AGM-114 HELLFIRE is SECRET, based upon the software. The highest level of classified information that could be disclosed by a proposed sale or by testing of the end item is SECRET; the highest level that must be disclosed for production, maintenance, or training is CONFIDENTIAL. Reverse engineering could reveal CONFIDENTIAL information. Vulnerability data, countermeasures, vulnerability/susceptibility analyses, and threat

definitions are classified SECRET or CONFIDENTIAL.

b. Advanced Precision Kill Weapon System (APKWS) laser guided rocket to counter the fast attack craft and fast inshore attack craft threat. APKWS hardware is UNCLASSIFIED.

c. The lightweight air launched torpedo (Mk54) is used for surface and subsurface targets. The acquisition of Mk54 will include ancillary equipment and publications.

d. Communications security (COMSEC) devices contain sensitive encryption algorithms and keying material. The purchasing country has previously been released and utilizes COMSEC devices in accordance with set procedures and without issue. COMSEC devices will be classified up to SECRET when keys are loaded.

e. Identification Friend or Foe (IFF) (KIV-78) contains embedded security devices containing sensitive encryption algorithms and keying material. The purchasing country will utilize COMSEC devices in accordance with set procedures. The AN/APX-123 is classified up to SECRET.

f. GPS/PPS/SAASM - Global Positioning System (OPS) provides a space-based Global Navigation Satellite System (GNSS) that has reliable location and time information in all weather and at all times and anywhere on or near the earth when and where there is an unobstructed line of sight to four or more OPS satellites. Selective Availability/Anti-Spoofing Module (SAASM) (AN/PSN-11) is used by military OPS receivers to allow decryption of precision OPS coordinates. In addition, the OPS Antenna System (GAS-I) provides protection from enemy manipulation of the OPS system. The OPS hardware is UNCLASSIFIED. When electrical power is applied, the system is classified up to SECRET.

g. Acoustics algorithms are used to process dipping sonar and sonobuoy data for target tracking and for the Acoustics Mission Planner (AMP), which is a tactical aid employed to optimize the deployment of sonobuoys and the dipping sonar. Acoustics hardware is UNCLASSIFIED. The acoustics system is classified up to SECRET when environmental and threat databases are loaded and/or the system is processing acoustic data.

h. The AN/APS-153 multi-mode radar with an integrated IFF and Inverse Synthetic Aperture (ISAR) provides target surveillance/detection capability. The AN/APS-153 hardware is UNCLASSIFIED. When electrical power is applied and mission data loaded, the AN/APS-153 is classified up to SECRET.

i. The AN/ALQ-210 (ESM) system identifies the location of an emitter. The ability of the system to identify specific emitters depends on the data provided by Hellenic Navy. The AN/ALQ-210 hardware is Unclassified. When electrical power is applied and mission data loaded, the AN/ALQ-210 system is classified up to SECRET.

j. The AN/AAS-44C(V) Multi-spectral Targeting System (MTS) operates in day/night and adverse weather conditions. Imagery is provided by a ForwardLooking Infrared (FLIR) sensor, a color/monochrome day television (DTV) camera, and a Low-Light TV (LLTV). The AN/AAS-44C(V) hardware is UNCLASSIFIED. When electrical power is applied, the AN/AAS-44C(V) is classified up to SECRET.

k. Ultra High Frequency/Very High Frequency (UHFNHF) Radios (ARC 210) contain embedded sensitive encryption algorithms and keying material. The purchasing country will utilize COMSEC devices in accordance with set procedures. The ARC-210 hardware is UNCLASSIFIED. When electrical power is applied and mission data loaded, the ARC-210 is classified up to SECRET.

l. Advanced Data Transfer System (ADTS) with Type 1 encryption for data at rest.

m. Satellite Communications Demand Assigned Multiple Access (SATCOM DAMA), which provides increased, interoperable communications capabilities with US forces. SATCOM DAMA hardware is UNCLASSIFIED. When electrical power is applied and mission data loaded these systems are classified up to SECRET.

2. All the mission data, including sensitive parameters, is loaded from an off board station before each flight and does not stay with the aircraft after electrical power has been removed. Sensitive technologies are protected as defined in the program protection and anti-tamper plans. The mission data and off board station are classified up to SECRET.

3. If a technologically advanced adversary were to obtain knowledge of the specific hardware and software elements, the information could be used to develop countermeasures or equivalent systems, which might reduce weapon system effectiveness or be used in the development of a system with similar or advanced capabilities.

4. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the enclosed Policy Justification. A determination has been made that Greece can provide the same degree of protection for the sensitive technology being released as the U.S. Government.

5. All defense articles and services listed in this transmittal have been authorized for release and export to Greece.

[FR Doc. 2019–20838 Filed 9–24–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 19–16]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Arms sales notice.

SUMMARY: The Department of Defense is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: Karma Job at *karma.d.job.civ@mail.mil* or (703) 697–8976.

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 19–16 with attached Policy Justification.

Dated: September 20, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

JUN 2 7 2019

The Honorable Nancy Pelosi
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

Dear Madam Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 19-16 concerning the Air Force's proposed Letter(s) of Offer and Acceptance to the Government of Morocco for defense articles and services estimated to cost $250.4 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

Charles W. Hooper
Lieutenant General, USA
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Regional Balance (Classified document provided under separate cover)

BILLING CODE 5001–06–C

Transmittal No. 19-16

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Kingdom of Morocco

(ii) *Total Estimated Value:*

Major Defense Equipment *	$ 0 million
Other	$250.4 million
Total	$250.4 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:*

Major Defense Equipment (MDE): None

Non-MDE:

F-16 support equipment, spares and repair parts; personnel training and training equipment; publications and technical documentation; munitions support equipment (for AMRAAM, CMBRE, JDAM, PAVEWAY), support and test equipment; integration and test; U.S. Government and contractor engineering, technical and logistical

support services; and other related elements of logistics and program support.

(iv) *Military Department:* Air Force (MO-D-QAK)

(v) *Prior Related Cases, if any:* MO-D-SAY

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* None

(viii) *Date Report Delivered to Congress:* June 27, 2019

* As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Morocco—Sustainment for F-16 Fleet

The Government of Morocco has requested a continuation of sustainment support to its current F-16 fleet to include the following non-MDE components: F-16 support equipment, spares and repair parts; personnel training and training equipment; publications and technical documentation; munitions support equipment (for AMRAAM, CMBRE, JDAM, PAVEWAY), support and test equipment; integration and test; U.S. Government and contractor engineering, technical and logistical support services; and other related elements of logistics and program support. The total estimated program cost is $250.4 million.

This proposed sale will support the foreign policy and national security of the United States by helping to improve the security of a major Non-NATO ally that is an important force for political stability and economic progress in North Africa.

The proposed sale will improve Morocco's self-defense capability. Additionally, the continuation of sustainment for their F-16 fleet strengthens the interoperability with the United States and other regional allies. Morocco already operates an F-16 fleet and this sustainment case will ensure that they can continue operating their fleet in the future. Morocco will have no difficulty absorbing this support into its armed forces.

The proposed sale will not alter the basic military balance in the region.

The principal contractor will be Lockheed Martin Corporation, Bethesda, Maryland. The purchaser typically requests offsets. Any offset agreement will be defined in negotiations between the purchaser and the contractor.

Implementation of this proposed sale will not require the assignment of additional U.S. Government and/or contractor representatives to Morocco.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

[FR Doc. 2019–20825 Filed 9–24–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 19–30]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Arms sales notice.

SUMMARY: The Department of Defense is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: Karma Job at *karma.d.job.civ@mail.mil* or (703) 697–8976.

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 19–30 with attached Policy Justification.

Dated: September 20, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

JUL 2 6 2019

The Honorable Nancy Pelosi
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

Dear Madam Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 19-30, concerning the Air Force's proposed Letter(s) of Offer and Acceptance to the Government of India for defense articles and services estimated to cost $670 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

Charles W. Hooper
Lieutenant General, USA
Director

Enclosures:
1. Transmittal
2. Policy Justification

Transmittal No. 19-30

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser*: Government of India

(ii) *Total Estimated Value*:

Major Defense Equipment* ..	$ 0 million
Other	$670 million
Total	$670 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:*

Major Defense Equipment (MDE): None

Non-MDE:

C-17 follow-on support includes spares and repair parts; support equipment; personnel training and training equipment; publications and technical documentation; support and test equipment; U.S. Government and contractor engineering, technical and logistical support services; and other related elements of logistics and program support.

(iv) *Military Department*: Air Force IN-D-QAC

(v) *Prior Related Cases, if any*: IN-D-SAC, IN-D-SAE

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid*: None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold*: None

(viii) *Date Report Delivered to Congress*: July 26, 2019

*As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

India – C-17 Sustainment Follow-On Support

The Government of India has requested to buy equipment for C-17 follow-on support, to include spares and repair parts; support equipment; personnel training and training equipment; publications and technical documentation; support and test equipment; U.S. Government and contractor engineering, technical and logistical support services; and other related elements of logistics and program support. The total estimated program cost is $670 million.

This proposed sale will support the foreign policy and national security of the United States by helping to strengthen the U.S.-Indian strategic relationship and to improve the mobility capabilities of a major defensive partner which continues to be an important force for political stability, peace, and economic progress in the Indo-Pacific and South Asia region.

India needs this follow-on support to maintain its operational readiness and ability to provide Humanitarian Assistance and Disaster Relief (HA/DR) assistance in the region. India will have no difficulty absorbing this support into its armed forces.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The prime contractor will be the Boeing Corporation, Chicago, Illinois. There are no known offset agreements proposed in connection with this potential sale, however, the purchaser typically requests offsets. Any offset agreement will be defined in negotiations between the purchaser and the prime contractor.

Implementation of this proposed sale will require the assignment of one U.S. Government representative and 23 contractor representatives to India.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

[FR Doc. 2019–20837 Filed 9–24–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 19–33]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Arms sales notice.

SUMMARY: The Department of Defense is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: Karma Job at *karma.d.job.civ@mail.mil* or (703) 697–8976.

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 19–33 with attached Policy Justification and Sensitivity of Technology.

Dated: September 20, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

JUL 2 6 2019

The Honorable Nancy Pelosi
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

Dear Madam Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 19-33 concerning the Army's proposed Letter(s) of Offer and Acceptance to the Government of Thailand for defense articles and services estimated to cost $175 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

Charles W. Hooper
Lieutenant General, USA
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology

BILLING CODE 5001–06–C

Transmittal No. 19-33

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser*: Government of Thailand

(ii) *Total Estimated Value*:

Major Defense Equipment *	$125 million
Other	$ 50 million
Total	$175 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase*:

Major Defense Equipment (MDE):
Sixty (60) Stryker Infantry Carrier Vehicles (ICV)
Sixty (60) M2 Flex .50 Cal Machine Guns

Non-MDE:
Also included are spare parts, Basic Issue Items (BII), Components of End Items (COEI), Additional Authorized List (AAL), Special Tools and Test Equipment (STTE), technical manuals, OCONUS Deprocessing Service, M6 smoke grenade launchers (4 per vehicle) and associated spares, AN/VAS-5 Driver's Vision Enhancer (DVE),

AN/VIC-3 vehicle intercommunications system, contractor provided training and Field Service Representatives (FSR), and other related elements of logistics and program support.

(iv) *Military Department*: Army (TH-B-WGX)

(v) *Prior Related Cases, if any*: None

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid*: None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold*: See Annex Attached

(viii) *Date Report Delivered to Congress*: July 26, 2019

*As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Thailand – Stryker Infantry Carrier Vehicles

The Government of Thailand has requested to buy sixty (60) Stryker Infantry Carrier Vehicles (ICV); and sixty (60) M2 Flex .50 cal machine guns. Also included are spare parts, Basic Issue Items (BII), Components of End Items (COEI), Additional Authorized List (AAL) (specific items for operations and maintenance), Special Tools and Test Equipment (STTE), technical manuals, OCONUS Deprocessing Service, M6 smoke grenade launchers (4 per vehicle) and associated spares, AN/VAS-5 Driver's Vision Enhancer (DVE), AN/VIC-3 vehicle intercommunications system, contractor provided training and Field Service Representatives (FSR), and other related elements of logistics and program support. The total estimated program cost is $175 million.

This proposed sale will support the foreign policy and national security objectives of the United States by helping to improve security of a Major Non-NATO ally in INDO-PACOM which is an important force for political stability and economic progress in the region.

The Stryker vehicles will increase Thailand's capability to defend its sovereign territory against traditional and non-traditional threats by filling the capability void between light infantry soldiers and heavy mechanized units. Thailand will have no difficulty absorbing this equipment into its armed forces.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The principal contractor for the Stryker vehicle is General Dynamics Land Systems, Sterling Heights, MI. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will not require the assignment of any permanent additional U.S. Government or Contractor representatives to Thailand.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 19-33

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vii

(vii) *Sensitivity of Technology:*

1. The M1126 Stryker is an infantry carrier vehicle transporting nine soldiers, their mission equipment and a crew of two consisting of a driver and vehicle commander. It is equipped with armor protection, M2 machine guns and M6 Smoke Grenade Launchers for self-protection. The Stryker is an eight-wheeled vehicle powered by a 350hp diesel engine. It incorporates a central tire inflation system, run-flat tires, and a vehicle height management system. The Stryker is capable of supporting a communications suite, a Global Positioning System (GPS), and a high frequency and near-term digital radio systems. The Stryker is deployable by C-130 aircraft and combat capable upon arrival. The Stryker is capable of self-deployment by highway and self-recovery. It has a low noise level that reduces crew fatigue and enhances survivability. It moves about the battlefield quickly and is optimized for close, complex, or urban terrain. The Stryker program leverages non-developmental items with common subsystems and components to quickly acquire and field these systems. Stryker is UNCLASSIFIED.

2. The AN/VAS-5 Driver's Vision Enhancer (DVE) is a compact thermal camera providing armored vehicle drivers with day or night time visual awareness in clear or reduced vision (fog, smoke, dust) situation. The system provides the driver a 180 degree viewing angle using a high resolution infrared sensor and image stabilization to reduce the effect of shock and vibration. The viewer and monitor are ruggedized for operation in tactical environments. The system is UNCLASSIFIED but considered SENSITIVE technology.

3. If a technologically advanced adversary were to obtain knowledge of the specific hardware and software elements, the information could be used to develop countermeasures that might reduce weapon system effectiveness or be used in the development of a system with similar or advanced capabilities.

4. A determination has been made that Thailand can provide substantially the same degree of protection for the technology being released as the U.S. Government. This sale supports the U.S. foreign policy and national security objectives as outlined in the Policy Justification.

5. All defense articles and services listed in this transmittal have been authorized for release and export to Thailand.

[FR Doc. 2019–20836 Filed 9–24–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2019–OS–0089]

Submission for OMB Review; Comment Request

AGENCY: Office of the Under Secretary of Defense for Intelligence, 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 October 25, 2019.

ADDRESSES: Comments and recommendations on the proposed information collection should be emailed to Ms. Jasmeet Seehra, DoD Desk Officer, at *oira_submission@omb.eop.gov.* Please identify the proposed information collection by DoD Desk Officer, Docket ID number, and title of the information collection.

FOR FURTHER INFORMATION CONTACT: Angela James, 571–372–7574, or *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Department of Defense Security Agreement; DD Form 441, DD Form 441–1, OMB Control Number 0704–0194.

Type of Request: Extension.

Number of Respondents: 4,021.

Responses per Respondent: 1.

Annual Responses: 4,021.

Average Burden per Response: 24 minutes.

Annual Burden Hours: 869.63.

Needs and Uses: This information collection requirement is necessary for inspecting and monitoring the contractors, licensees, and grantees who

require or will require access to, or who store or will store classified information; and for determining the eligibility for access to classified information of contractors, licensees, and grantees and their respective employees.

Affected Public: Individuals or households.

Frequency: On occasion.

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 James.

Requests for copies of the information collection proposal should be sent to Ms. James at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: September 20, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2019–20847 Filed 9–24–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 19–21]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Arms sales notice.

SUMMARY: The Department of Defense is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: Karma Job at *karma.d.job.civ@mail.mil* or (703) 697–8976.

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 19–21 with attached Policy Justification and Sensitivity of Technology.

Dated: September 20, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

JUL 0 8 2019

The Honorable Nancy Pelosi
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

Dear Madam Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 19-21 concerning the Army's proposed Letter(s) of Offer and Acceptance to the Taipei Economic and Cultural Representative Office in the United States (TECRO) for defense articles and services estimated to cost $223.56 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

Charles W. Hooper
Lieutenant General, USA
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology

Transmittal No. 19-21

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Taipei Economic and Cultural Representative Office in the United States (TECRO)

(ii) *Total Estimated Value:*

Major Defense Equipment *	$114.13 million
Other	$109.43 million
Total	$223.56 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:*

Major Defense Equipment (MDE):
Two hundred fifty (250) Block I -92F MANPAD Stinger Missiles
Four (4) Block I -92F MANPAD Stinger Fly-to-Buy Missiles

Non-MDE:

Also included is one (1) Captive Flight Trainer (CFT), twenty-three (23) Field Handling Trainers (FHTs), one hundred eight (108) Gripstock Control Groups, one hundred eight (108) Medium Thermal Weapon Sights (MTWS), seven (7) Tracking Head Trainers (THTs), two (2) Sierra Coolant Recharging Units (CRUs), one (1) Missile Go/No Go Test Set, one hundred eight (108) Identification Friend or Foe (IFF), IFF Development, one (1) Integrated Electronic Technical Manuals (IETMs), Government Furnished Equipment, spare and repair parts, telemeters, range and test support, contractor technical support, contractor training, contractor engineering services, contractor logistics services, consolidation, total package fielding, material fielding team, Field Service Representative (FSR), U.S. Government technical support, and other associated equipment and services and other related elements of logistics and program support.

(iv) *Military Department:* Army (TW-B-ZZZ)

(v) *Prior Related Cases, if any:* None

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* See Attached Annex

(viii) *Date Report Delivered to Congress:* July 8, 2019

* As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Taipei Economic and Cultural Representative Office in the United States (TECRO) – Block I -92F MANPAD Stinger Missiles and Related Equipment and Support

TECRO has requested to buy two hundred fifty (250) Block I -92F MANPAD Stinger missiles and four (4) Block I -92F MANPAD Stinger Fly-to-Buy missiles. Also included is one (1) Captive Flight Trainer (CFT), twenty-three (23) Field Handling Trainers (FHTs), one hundred eight (108) Gripstock Control Groups, one hundred eight (108) Medium Thermal Weapon Sights (MTWS), seven (7) Tracking Head Trainers (THTs), two (2) Sierra Coolant Recharging Units (CRUs), one(]) Missile Go/No Go Test Set, one hundred eight (108) Identification Friend or Foe (IFF), TFF Development, one(]) Integrated Electronic Technical Manuals (IETMs), Government Furnished Equipment, spare and repair parts, telemeters, range and test support, contractor technical support, contractor training, contractor engineering services, contractor logistics services, consolidation, total package fielding, material fielding team, Field Service Representative (FSR), U.S. Government technical support, and other associated equipment and services and other related elements of logistics and program support. The total estimated program cost is $223.56 million.

This proposed sale is consistent with U.S. law and policy as expressed in Public Law 96-8.

This proposed sale will support the foreign policy and national security of the United States by helping to improve the security and defensive capability of the recipient, an important force for political stability, military balance, and economic progress in the region.

The recipient intends to use these defense articles and services to modernize its armed forces and expand its existing air defense architecture to counter threats. This will contribute to the recipient military's goal to update its capability while further enhancing greater interoperability between the recipient, the U.S., and other allies. The recipient will have no difficulty absorbing this equipment into its armed forces.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The principal contractors will be Raytheon Missile Systems. There are no known offset agreements proposed. However, the purchaser typically requests offsets. Any offset agreement will be defined in negotiations between the purchaser and the contractor.

Implementation of this proposed sale will require 12 U.S. Government or contractor representatives to travel to the recipient for a period of 6 weeks (non-concurrent).

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 19-21

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vii

(vii) *Sensitivity of Technology:*

1. The highest classification of the Stinger 92F Reprogrammable MicroProcessor (RMP) Block I Missile and Stinger Man-Portable Air Defense System (MANPADS) hardware is CONFIDENTIAL, and the highest classification of data and information is SECRET.

The Stinger RMP Block I Missile, hardware, embedded software object code and operating documentation contain sensitive technology and are classified CONFIDENTIAL. The guidance section of the missile and tracking head trainer contain highly sensitive technology and are classified CONFIDENTIAL. Missile System hardware components contain sensitive critical technologies. Stinger Block I critical technology is primarily in the area of design and production know-how and not end-items. This sensitive/critical technology is inherent in the hybrid microcircuit assemblies; microprocessors; magnetic and amorphous metals; purification; firmware; printed circuit boards; laser roll rate sensor; dual detector assembly; detector filters; optical coatings; ultraviolet sensors; compounding and handling of electronic, electro-optic, and optical materials; test equipment operating instructions; energetic materials fabrication and loading technology; warhead components and seeker assembly. Information on countermeasures vulnerability to electronic countermeasures, system performance capabilities and effectiveness, simulation and test data and software source code are classified up to SECRET.

2. If a technologically advanced adversary were to obtain knowledge of the hardware and software elements, the information could be used to develop countermeasures or equivalent systems which might reduce system effectiveness or be used in the development of a system with similar or advanced capabilities.

3. A determination has been made that the recipient can provide substantially the same degree of protection for the sensitive technology being released as the U.S. Government. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the Policy Justification.

4. All defense articles and services listed in this transmittal have been authorized for release and export to the recipient.

[FR Doc. 2019–20830 Filed 9–24–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 19–42]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Arms sales notice.

SUMMARY: The Department of Defense is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: Karma Job at *karma.d.job.civ@mail.mil* or (703) 697–8976.

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 19–42 with attached Policy Justification and Sensitivity of Technology.

Dated: September 20, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, SUITE 101
ARLINGTON, VA 22202-5408

JUL 12 2019

The Honorable Nancy Pelosi
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

Dear Madam Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 19-42 concerning the Army's proposed Letter(s) of Offer and Acceptance to the Government of Germany for defense articles and services estimated to cost $401 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

for Charles W. Hooper
Lieutenant General, USA
Director

Enclosures:
1. Transmittal
1. Policy Justification
2. Sensitivity of Technology

BILLING CODE 5001–06–C

Transmittal No. 19-42

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser*: Government of Germany

(ii) *Total Estimated Value*:

Major Defense Equipment *	$229 million
Other	$172 million
Total	$401 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:*

Major Defense Equipment (MDE):

Fifty (50) Patriot Advanced Capability 3 (PAC-3) Missiles Segment Enhanced (MSE)

Non-MDE:

Also included are PAC-3 MSE launcher conversion kits; Missile Round Trainers (MRTs); Empty Round Trainers (ERTs); Launcher Stations (LS) heater controllers; PAC-3 ground support equipment; concurrent spare parts; documentation and publications; PAC-3 MSE shorting plugs; Quality Assurance Team; missile canister consumables; missile skid kits; PAC-3 MSE repair and return; missile Field Surveillance Program (FSP) for PAC-3 MSE; U.S. Government transportation; MSE launcher spare parts; PAC-3/MSE GMT kits; MSE DC motor kits; targets; Telemetry; U.S. Government range support; MSE flight test support; U.S. Government and contractor engineering; technical and logistics support services; and other related elements of logistical and program support.

(iv) *Military Department*: Army (GY-B-XAV)

(v) *Prior Related Cases, if any*: N/A

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid*: None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services*

Proposed to be Sold: See Attached Annex

(viii) *Date Report Delivered to Congress*: July 12, 2019

* As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Government of Germany – Patriot Advanced Capability 3 (PAC-3) Missiles Segment Enhanced

The Government of Germany has requested to buy fifty (50) Patriot Advanced Capability 3 (PAC-3) Missiles Segment Enhanced (MSE). Also included are PAC-3 MSE launcher conversion kits; Missile Round Trainers (MRTs); Empty Round Trainers (ERTs); Launcher Stations (LS) heater controllers; PAC-3 ground support equipment; concurrent spare parts; documentation and publications; PAC-3 MSE shorting plugs; Quality Assurance Team; missile canister consumables; missile skid kits; PAC-3 MSE repair and return; missile Field Surveillance Program (FSP) for PAC-3 MSE; U.S. Government transportation; MSE launcher spare parts; PAC-3/MSE GMT kits; MSE DC motor kits; targets; Telemetry; U.S. Government range support; MSE flight test support; U.S. Government and contractor engineering; technical and logistics support services; and other related elements of logistical and program support. The total estimated value is $401 million.

This proposed sale will support to the foreign policy and national security of the United States by helping to improve the security of a NATO ally, which is an important force for political and economic stability in Europe. It is vital to U.S. national interests to assist our German ally in developing and maintaining a strong and ready self-defense capability.

The proposed sale will enhance Germany's capability to maintain the largest air defense capacity in Europe. The purchase of these additional missiles will allow Germany to build a more robust air defense capability and increase its air lethality against air defense threats. This purchase also assist Germany with its NATO commitments. Germany will have no difficulty absorbing these additional missiles into its armed forces.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The prime contractor will be Lockheed Martin, Dallas, TX. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will require additional contractor representatives to travel to Germany. It is not expected additional U.S. Government personnel will be required in country for an extended period of time.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 19-42

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vii

(vii) *Sensitivity of Technology:*

1. The PATRIOT Air Defense System contains classified CONFIDENTIAL hardware components, SECRET tactical software and critical/sensitive technology. The Patriot Advanced Capability 3 (PAC-3) Missile Segment Enhancement (MSE) hardware is classified CONFIDENTIAL and the associated launcher hardware is UNCLASSIFIED. The PAC-3 MSE is a high velocity, hit-to-kill, surface-to-air missile that provides critical air and missile defense by intercepting and destroying Tactical Ballistic Missiles (TBM), Air-Breathing Threats (ABT), cruise missiles, and Unmanned Aerial Systems (UAS).

2. The PAC-3 MSE sensitive/critical technology is primarily in the area of design and production know-how and primarily inherent in the design, development and/or manufacturing data related to certain components. The list of components is classified CONFIDENTIAL.

3. Information on system performance capabilities, effectiveness, survivability, missile seeker capabilities, select software/software documentation and test data are classified up to and including SECRET.

4. If a technologically advanced adversary were to obtain knowledge of the hardware and software elements, the information could be used to develop countermeasures or equivalent systems, which might reduce system effectiveness or be used in the development of a system with similar or advanced capabilities.

5. A determination has been made that the recipient country can provide substantially the same degree of protection for the sensitive technology being released as the U.S. Government. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the Policy Justification.

6. All defense articles and services listed in this transmittal are authorized for release and export to the Government of Germany.

[FR Doc. 2019–20839 Filed 9–24–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 19–22]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Arms sales notice.

SUMMARY: The Department of Defense is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: Karma Job at *karma.d.job.civ@mail.mil* or (703) 697–8976.

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 19–22 with attached Policy Justification and Sensitivity of Technology.

Dated: September 20, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

JUL 0 8 2019

The Honorable Nancy Pelosi
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

Dear Madam Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 19-22 concerning the Army's proposed Letter(s) of Offer and Acceptance to the Taipei Economic and Cultural Representative Office in the United States (TECRO) for defense articles and services estimated to cost $2.0 billion. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

Charles W. Hooper
Lieutenant General, USA
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology

BILLING CODE 5001–06–C

Transmittal No. 19-22

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser*: Taipei Economic and Cultural Representative Office in the United States (TECRO)

(ii) *Total Estimated Value*:

Major Defense Equipment *	$1.450 billion
Other	$ .550 billion
Total	$2.000 billion

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:*

Major Defense Equipment (MDE):

One hundred eight (108) M1A2T Abrams Tanks
One hundred twenty-two (122) M2 Chrysler Mount Machine Guns
Two hundred sixteen (216) M240 Machine Guns
Fourteen (14) M88A2 HERCULES Vehicles
Sixteen (16) M1070A1 Heavy Equipment Transporters (HET)
Five hundred seventy-two (572) M1002 TPMP-T1 Rounds
Three hundred fifty-nine (359) M831A1 HEAT Rounds
Six hundred twenty-one (621) M865 TPCSPS-T2 Rounds
Eight hundred twenty-eight (828) CZ11 Advanced Multipurpose Rounds
Eight hundred twenty eight (828) M830Al HEAT Rounds

Non-MDE:

Also included are sixteen (16) M1000 Heavy Equipment Transporter (HET) Semi-Trailers; sixty four (64) Export Single Channel Ground and Airborne Radio System (SINCGARS); one hundred eight (108) AN/PSN-13A Defense Advanced Global Positioning System (GPS) Receiver (DAGR) with Selective-Availability/Anti-Spoofing Module (SAASM); one hundred thirty eight (138) AN/VAS-5B Driver Vision Enhancer (DVE-A) Kits; one hundred eight (108) M250 Smoke Grenade Launchers; fourteen (14) M239 Smoke Grenade Launchers; seven thousand eight hundred sixty-two (7,862) KEW-Al Rounds; one thousand nine hundred sixty six (1,966) CA38 - Cartridge, l20MM Canister Round; eight hundred sixty four (864) M76 (G826) or L8Al /L8A3 (G815) Smoke Grenade Rounds; eight hundred twenty eight (828) Insensitive Munitions High Explosive Tracer (IMHE-T) rounds; twenty two (22) sets Dummy CTG, 120mm ArmorPiercing, Fin-Stabilized, Discarding Sabot (CA64); twenty two (22) Dummy Cartridge 120mm Canister Ml028; twenty two (22) Dummy M865 TPCSPS-T (C785); FMS export armor; Hunter/Killer technology, Commander's Independent Thermal Viewer (CITV); Common Remotely Operated Weapon Station-Low Profile (CROWS-LP); spare parts; support equipment; AGT-1500 tank engines and X-1100 tank transmissions; depot level support; Government-Furnished Equipment (GFE); repair parts; communication support equipment; communication equipment integration; tools and test equipment; training; training simulators; repair and return program; U.S. Government and contractor engineering, technical, and logistics support services; Technical Assistance Field Team (TAFT); and other related elements of logistics and program support. Additionally, the following recommended basic load ammunition may be included upon request from customer: One hundred fifteen thousand four hundred (115,400) A576 Cartridge, .50 Caliber Linked 4 API/API-T F/M2; one thousand eighty (1,080) G8l5 - Grenade, Smoke Screening L8A1/A3; two million four hundred sixty two thousand four hundred (2,462,400) A131 - Cartridge 7.62MM 4 BALL 1 TRACER; one million two hundred thirty-one thousand two hundred (1,231,200) A111 - Cartridge, 7.62mm Blank M82 Linked; one thousand five hundred twelve (1,512) A541 - 50 Armor Piercing Incendiary, Tracer M20 F/M2; ninety one thousand eight hundred (91,800) A557 - Cartridge, .50 Caliber 4 Ball/1 Tracer Linked M33 F/M2; fifty four thousand (54,000) A598 - Cartridge, .50 Caliber Blank F/M2 (MILES); and four thousand nine hundred sixty eight (4,968) AA38 - Cartridge, .50 Caliber M962 (SLAP); and other related elements of logistics and program support.

(iv) *Military Department*: Army (TW-B-ZCT)

(v) *Prior Related Cases, if any*: None

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid*: None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold*: See Attached Annex

(viii) *Date Report Delivered to Congress*: July 8, 2019

* As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Taipei Economic and Cultural Representative Office in the United States (TECRO) – M1A2T Abrams Tanks and Related Equipment and Support

TECRO has requested to buy one hundred eight (108) M1A2T Abrams Tanks; one hundred twenty-two (122) M2 Chrysler Mount Machine Guns; two hundred sixteen (216) M240 Machine Guns; fourteen (14) M88A2 HERCULES Vehicles; sixteen (16) M1070A1 Heavy Equipment Transporters (HET); five hundred seventy-two (572) M1002 TPMP-T1 Rounds; three hundred fifty-nine (359) M831A1 HEAT Rounds; and six hundred twenty-one (621) M865 TPCSPS-T2 Rounds, and eight hundred twenty eight (828) M830Al HEAT Rounds. Also included are sixteen (16) M1000 Heavy Equipment Transporter (HET) Semi-Trailers; sixty four (64) Export Single Channel Ground and Airborne Radio; System (SINCGARS); one hundred eight (108) AN/PSN-13A Defense Advanced; Global Positioning System (GPS) Receiver (DAGR) with Selective-Availability/Anti-Spoofing Module (SAASM); one hundred thirty eight (138); AN/VAS-5B Driver Vision Enhancer (DVE-A) Kits; one hundred eight (108); M250 Smoke Grenade Launchers; fourteen (14) M239 Smoke Grenade Launchers; seven thousand eight hundred sixty-two (7,862) KEW-Al Rounds; one thousand nine hundred sixty six (1,966) CA38 - Cartridge, l20MM Canister Round; eight hundred sixty four (864) M76 (G826) or L8Al /L8A3 (G815) Smoke Grenade Rounds; eight hundred twenty eight (828) Insensitive Munitions High Explosive Tracer (IMHE-T) rounds; twenty two (22) sets Dummy CTG, 120mm ArmorPiercing, Fin-Stabilized, Discarding Sabot (CA64); twenty two (22) Dummy Cartridge 120mm Canister Ml028; twenty two (22) Dummy M865 TPCSPS-T (C785); FMS export armor; Hunter/Killer technology, Commander's Independent Thermal Viewer (CITV); Common Remotely Operated Weapon Station-Low Profile (CROWS-LP); spare parts; support equipment; AGT-1500 tank engines and X-1100 tank transmissions; depot level support; Government-Furnished Equipment (GFE); repair parts; communication support equipment; communication equipment integration; tools and test equipment; training; training simulators; repair and return program; U.S. Government and contractor engineering, technical, and logistics support services; Technical Assistance Field Team (TAFT); and other related elements of logistics and program support. Additionally, the following recommended basic load ammunition may be included upon request from customer: One hundred fifteen thousand four hundred (115,400) A576 Cartridge, .50 Caliber Linked 4 API/API-T F/M2; one thousand eighty (1,080) G8l5 - Grenade, Smoke Screening L8A1/A3; two million four hundred sixty two thousand four hundred (2,462,400) A131 - Cartridge 7.62MM 4 BALL 1 TRACER; one million two hundred thirty-one thousand two hundred (1,231,200) A111 - Cartridge, 7.62mm Blank M82 Linked; one thousand five hundred twelve (1,512) A541 - 50 Armor Piercing Incendiary, Tracer M20 F/M2; ninety one thousand eight hundred (91,800) A557 - Cartridge, .50

Caliber 4 Ball/1 Tracer Linked M33 F/M2; fifty four thousand (54,000) A598 - Cartridge, .50 Caliber Blank F/M2 (MILES); and four thousand nine hundred sixty eight (4,968) AA38 - Cartridge, .50 Caliber M962 (SLAP); and other related elements of logistics and program support. The total estimated program cost is $2.00 billion.

This proposed sale is consistent with U.S. law and policy as expressed in Public Law 96-8.

This proposed sale serves U.S. national, economic, and security interests by supporting the recipient's continuing efforts to modernize its armed forces and to maintain a credible defensive capability. The proposed sale will help improve the security of the recipient and assist in maintaining political stability, military balance, and economic progress in the region.

This proposed sale of MlA2 tanks will contribute to the modernization of the recipient's main battle tank fleet, enhancing its ability to meet current and future regional threats and to strengthen its homeland defense. These tanks will contribute to the recipient's goal of updating its military capability while further enhancing interoperability with the United States and other allies. The recipient will have no difficulty absorbing this equipment into its armed forces.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The MlA2T tank prime contractor will be General Dynamics Land Systems, Sterling Heights, Michigan. Production will be at Anniston Army Depot, Anniston, Alabama, and the Joint Systems Manufacturing Center, Lima, Ohio. The M88A2 recovery vehicle prime contractor will be BAE, York, Pennsylvania. The M1070Al Heavy Equipment Transporter (HET) prime contractor will be Oshkosh, Oshkosh, Wisconsin. There are no known offset agreements proposed. However, the purchaser typically requests offsets. Any offset agreement will be defined in negotiations between the purchaser and the contractor.

Implementation of this proposed sale will require annual trips to the recipient involving up to 30 U.S. Government and 15 contractor representatives for a period of up to six years to manage the fielding and training for the program.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 19-22

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vii

(vii) *Sensitivity of Technology*:

1. Thermal Imaging System (TIS). The TIS is a target acquisition system which, when operated with other tank systems, gives the tank crew a substantial advantage over the adversary. The TIS provides the gunner and commander with the ability to effectively aim and fire the tank main armament system under a broad range of adverse battlefield conditions. The Hunter/Killer technology provides the commander the ability to search for and acquire targets while the gunner engages priority targets. The hardware itself is UNCLASSIFIED. The engineering design and manufacturing data associated with the detector and infrared (IR) optics and coatings are considered sensitive. The technical data package is UNCLASSIFIED with the exception of the specifications for target acquisition range (CONFIDENTIAL), nuclear hardening (CONFIDENTIAL, restricted data) and laser hardening (SECRET).

2. Special Armor. Major components of special armor are fabricated in sealed modules and in serialized removable subassemblies. Special armor vulnerability data for both chemical and kinetic energy rounds are classified SECRET. Engineering design and manufacturing data related to special armor are also classified SECRET.

3. AGT 1500 Gas Turbine Propulsion System. The use of a gas turbine propulsion system in the MIA2T Abrams tank is a unique application of armored vehicle power pack technology. The AGT-1500 engine and X-1100 transmission are not classified. Manufacturing processes associated with the production of turbine blades, recuperator, bearings and shafts, and hydrostatic pump and motor, are proprietary and therefore are commercially competition sensitive.

4. Compartmentation. A major survivability feature of the Abrams Tank is the compartmentation of fuel and ammunition. Compartmentation is the positive separation of the crew and critical components from combustible materials so that in the event the fuel or ammunition ignites or is detonated by an incoming round, the crew is fully protected. As demonstrated during the Abram Live Fire tests, compartmentation significantly enhances crew survivability and substantially reduces the likelihood of the tank being immobilized by an ammunition explosion and fire. Sensitive information (SBU) includes the performance of the ammunition compartments as well as the compartment design parameters.

5. The CROWS-LP (M153A2El) is a commander's weapon station. It allows for under armor operation of weapons - M2HB, M2Al, M240B and M240. The CROWS-LP is an updated version of the M153A2 CROWS and is approximately 10 inches lower in height. The CROWS-LP increases crew visibility over the weapon station. The fire control system of the CROWS-LP allows an operator to fire on a target from either a stationary or moving platform. The CROWS-LP integrates a day camera (VIM-C), thermal camera (TIM 1500) and laser range finder (STORM/STORM-PI) is UNCLASSIFIED.

6. M76 Infra-Red (IR) Grenade. The M76 InfraRed (IR) grenade is UNCLASSIFIED but sensitive. The grenade uses a brass particle fill that is specifically designed, when shattered by a high explosive shock wave, to disperse in a cloud of specific sized particles. These particles obscure the visual through the far infrared portions of the electromagnetic spectrum. As a result, this grenade defeats night sights, thermal viewers, laser designators, laser rangefinders, and any other equipment that relies on visual or infrared active or passive technologies. The properties of the brass fill are easily reverse engineered, and therefore could be used to defeat U.S. imaging and targeting systems on the battlefield. The highest level of information that could be transferred with the sale of this round is UNCLASSIFIED.

7. 120mm Kinetic Energy-Tungsten (KE-W) ammunition. This is a commercially developed item and is not warranted by the US Government. All components of the cartridge, 120mm Kinetic Energy - Tungsten are UNCLASSIFIED. The capabilities of this cartridge, to include the terminal effects, target impact dispersion, and armor defeating capabilities, are classified CONFIDENTIAL, except for armor penetration test results against Special Armored Targets, which are classified SECRET, or the same level of classification as the target, whichever is greater. The tungsten processing and penetrator manufacturing methods are sensitive data. No technological information regarding the tungsten penetrator material will be supplied with the cartridges being considered for foreign military sales. The highest level of information that could be transferred

with the sale of this round is UNCLASSIFIED.

8. If a technologically advanced adversary were to obtain knowledge of the hardware and software elements, the information could be used to develop countermeasures or equivalent systems which might reduce system effectiveness or be used in the development of a system with similar or advanced capabilities.

9. A determination has been made that the recipient can provide substantially the same degree of protection for the sensitive technology being released as the U.S. Government. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the Policy Justification.

10. All defense articles and services listed in this transmittal have been authorized for release and export to the recipient.

[FR Doc. 2019–20831 Filed 9–24–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 19–0I]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Arms sales notice.

SUMMARY: The Department of Defense is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: Karma Job at *karma.d.job.civ@mail.mil* or (703) 697–8976.

SUPPLEMENTARY INFORMATION: This 36(b)(5)(C) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 19–0I with attached Policy Justification.

Dated: September 20, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

JUL 0 8 2019

The Honorable Nancy Pelosi
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

Dear Madam Speaker:

Pursuant to the reporting requirements of Section 36(b)(5)(C) of the Arms Export Control Act (AECA), as amended, we are forwarding Transmittal No. 19-0I. This report relates to enhancements or upgrades from the level of sensitivity of technology or capability described in the Section 36(b)(1) AECA certification 15-74 of December 16, 2015.

Sincerely,

Charles W. Hooper
Lieutenant General, USA
Director

Enclosures:
1. Transmittal

BILLING CODE 5001–06–C

Transmittal No. 19-0I

REPORT OF ENHANCEMENT OR UPGRADE OF SENSITIVITY OF TECHNOLOGY OR CAPABILITY (SEC. 36(B)(5)(C), AECA)

(i) *Purchaser*: Taipei Economic and Cultural Representative Office (TECRO)

(ii) *Sec. 36(b)(1), AECA Transmittal No.*: 15-74
Date: December 16, 2015
Military Department: Army

(iii) *Description*: On December 16, 2015, Congress was notified by Congressional certification transmittal number 15-74, of the possible sale under Section 36(b)(1) of the Arms Export Control Act of two-hundred and eight (208) Javelin Guided Missiles; U.S. Government and contractor technical assistance, above the line transportation costs, and other related elements of logistics and program support.. The estimated total cost was $57 million. Major Defense Equipment (MDE) constituted $50 million of this total.

This transmittal notifies the inclusion of the following MDE items: four hundred nine (409) FGM-148E Javelin Missiles; and forty-six (46) Javelin Command Launch Units (CLUs). Also included are Basic Skill Trainers (BST); U.S. Government and contractor technical assistance; training; support; transportation; and other related elements of logistics and program support. These inclusions will increase the MDE value by $105 million and the non-MDE value by $24 million, resulting in a new MDE cost of $155 million and new total case value of $186 million.

(iv) *Significance*: This notification will allow the recipient to improve its security and defensive capability.

(v) *Justification*: This proposed sale serves U.S. national, economic, and security interests by supporting the recipient's continuing efforts to modernize its armed forces and enhance its defensive capability. The proposed

sale will help improve the security of the recipient and assist in maintaining political stability, military balance, and economic progress in the region.

(vi) *Sensitivity of Technology*: The statement contained in the original AECA 36(b)(1) transmittal applies to the MDE items reported here.

(vii) *Date Report Delivered to Congress*: July 8, 2019

[FR Doc. 2019–20824 Filed 9–24–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Navy

[Docket ID: USN–2019–HQ–0020]

Proposed Collection; Comment Request

AGENCY: The Office of the Under Secretary of the Navy, DoD.

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Marine Corps 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 November 25, 2019.

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 Chief Management Officer, Directorate for Oversight and Compliance, 4800 Mark Center Drive, 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 Teresa Peck, Branch Head, Store Operations Services and Vending, Business and Support Services Division (MR), Headquarters, U.S. Marine Corps, 3044 Catlin Ave, Quantico, VA 22134–5009, or call 703–432–1973.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: NAF Retail Point of Sale System (RPOS), OMB Control Number 0703–XXXX.

Needs and Uses: This information system will provide a means to manage and administer a robust Marine Corps Community Services (MCCS) retail point of sales system to control sales and capture and process customer orders and transactions for the Marine Corps Exchanges, package stores, Marine Marts, and Uniform Shops. The information collection requirement is necessary to manage and administer special orders, rain checks, send sales, returns and exchanges, check cashing, tender by check, and recruit tenders. All information is collected verbally at the point-of-sale terminal and entered into the NAF RPOS by an MCCS employee.

Affected Public: Individuals or households.

Annual Burden Hours: 12,109.

Number of Respondents: 294,953.

Responses per Respondent: 1 to 2 (dependent on transaction type).

Annual Responses: 366,365.

Average Burden per Response: 1 to 10 minutes (dependent on transaction type).

Frequency: As required.

Respondents are individuals who patronize MCCS retail activities. Without this information collection, MCCS would not be able to provide individualized services upon request such as processing special orders or returning merchandise without a receipt. The intended results are managing and administering retail sales in an effective and efficient manner that streamlines service delivery; improves customer experience; and increases retention rates, utilization, and sales.

Dated: September 20, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2019–20800 Filed 9–24–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

Submission of Data by State Educational Agencies; Submission Dates for State Revenue and Expenditure Reports for Fiscal Year 2019, Revisions to Those Reports, and Revisions to Prior Fiscal Year Reports

AGENCY: National Center for Education Statistics, Institute of Education Sciences, Department of Education.

ACTION: Notice.

SUMMARY: The Secretary announces dates for State educational agencies (SEAs) to submit expenditure and revenue data and average daily attendance statistics on ED Form 2447 (the National Public Education Financial Survey (NPEFS)) for fiscal year (FY) 2019, revisions to those reports, and revisions to reports for previous fiscal years. The Secretary sets these dates to ensure that data are available to serve as the basis for timely distribution of Federal funds. The U.S. Census Bureau is the data collection agent for this request of the Department of Education's National Center for Education Statistics (NCES). The data will be published by NCES and will be used by the Secretary in the calculation of allocations for FY 2021 appropriated funds.

DATES: SEAs can begin submitting data on Thursday, January 30, 2020. SEAs are urged to submit accurate and complete data by Friday, March 27, 2020, to facilitate timely processing. The deadline for the final submission of all data, including any revisions to previously submitted data for FY 2018 and FY 2019, is Friday, August 14, 2020. Any resubmissions of FY 2018 or FY 2019 data by SEAs in response to requests for clarification or reconciliation or other inquiries by NCES or the Census Bureau must be completed as soon as possible, but no later than Tuesday, September 8, 2020. All outstanding data issues must be reconciled or resolved by the SEAs, NCES, and the Census Bureau as soon as possible, but no later than September 8, 2020.

ADDRESSES: Submission Information—SEAs may mail ED Form 2447 to: U.S. Census Bureau, ATTENTION: Economic Reimbursable Surveys Division, 4600 Silver Hill Road, Suitland, MD 20746.

If an SEA's submission is received by the Census Bureau after August 14, 2020, the SEA must show one of the following as proof that the submission was mailed on or before that date:

1. A legibly dated U.S. Postal Service postmark.
2. A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.
3. A dated shipping label, invoice, or receipt from a commercial carrier.
4. Any other proof of mailing acceptable to the Secretary.

If the SEA mails ED Form 2447 through the U.S. Postal Service, the Secretary does not accept either of the following as proof of mailing:

1. A private metered postmark.
2. A mail receipt that is not dated by the U.S. Postal Service.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, an SEA should check with its local post office.

SEAs may submit data online using the interactive survey form on the NPEFS data collection website at: *http://surveys.nces.ed.gov/ccdnpefs.* The NPEFS interactive survey includes a digital confirmation page where a personal identification number (PIN) may be entered. A successful entry of the PIN serves as a signature by the authorizing official. Alternatively, a certification form also may be printed from the website, signed by the authorizing official, and mailed to the Economic Reimbursable Surveys Division of the Census Bureau at the Washington, DC, address provided above, within five business days after submission of the NPEFS web interactive form.

Alternatively, SEAs may hand-deliver submissions by 4:00 p.m. Eastern Time on August 14, 2020, to: U.S. Census Bureau, Economic Reimbursable Surveys Division, 4600 Silver Hill Road, Suitland, MD 20746.

FOR FURTHER INFORMATION CONTACT: Stephen Q. Cornman, NPEFS Project Director, National Center for Education Statistics, Institute of Education Sciences, U.S. Department of Education. Telephone: (202) 245–7753. Email: *stephen.cornman@ed.gov.* You may also contact an NPEFS team member at the Census Bureau. Telephone: 1–800–437–4196 or (301) 763–1571. Email: *erd.npefs.list@census.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service, toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: Under section 153(a)(1)(I) of the Education Sciences Reform Act of 2002, 20 U.S.C. 9543(a)(1)(I), which authorizes NCES to gather data on the financing and management of education, NCES collects data annually from SEAs through ED Form 2447. The report from SEAs includes attendance, revenue, and expenditure data from which NCES determines a State's ''average per-pupil expenditure'' (SPPE) for elementary and secondary education, as defined in section 8101(2) of the Elementary and Secondary Education Act of 1965, as amended (ESEA) (20 U.S.C. 7801(2)).

In addition to using the SPPE data as general information on the financing of elementary and secondary education, the Secretary uses these data directly in calculating allocations for certain formula grant programs, including, but not limited to, title I, part A, of the ESEA, Impact Aid, and Indian Education programs. Other programs, such as the Education for Homeless Children and Youth program under title VII of the McKinney-Vento Homeless Assistance Act, and the Student Support and Academic Enrichment Grants under title IV, part A of the ESEA make use of SPPE data indirectly because their formulas are based, in whole or in part, on State title I, part A, allocations.

In January 2020, the Census Bureau, acting as the data collection agent for NCES, will email ED Form 2447 to SEAs, with instructions, and will request that SEAs commence submitting FY 2019 data to the Census Bureau on Thursday, January 30, 2020. SEAs are urged to submit accurate and complete data by Friday, March 27, 2020, to facilitate timely processing.

Submissions by SEAs to the Census Bureau will be analyzed for accuracy and returned to each SEA for verification. SEAs must submit all data, including any revisions to FY 2018 and FY 2019 data, to the Census Bureau no later than Friday, August 14, 2020. Any resubmissions of FY 2018 or FY 2019 data by SEAs in response to requests for clarification or reconciliation or other inquiries by NCES or the Census Bureau must be completed by Tuesday, September 8, 2020. Between August 14, 2020, and September 8, 2020, SEAs may also, on their own initiative, resubmit data to resolve issues not addressed in their final submission of NPEFS data by August 13, 2020. All outstanding data issues must be reconciled or resolved by the SEAs, NCES, and the Census Bureau as soon as possible, but no later than September 8, 2020.

In order to facilitate timely submission of data, the Census Bureau will send reminder notices to SEAs in June and July of 2020.

Having accurate, consistent, and timely information is critical to an efficient and fair Department of Education (Department) allocation process and to the NCES statistical process. To ensure timely distribution of Federal education funds based on the best, most accurate data available, the Department establishes, for program funding allocation purposes, Friday, August 14, 2020, as the final date by which the SEAs must submit data using either the interactive survey form on the NPEFS data collection website at: *http://surveys.nces.ed.gov/ccdnpefs* or ED Form 2447.

Any resubmissions of FY 2018 or FY 2019 data by SEAs in response to requests for clarification or reconciliation or other inquiries by NCES or the Census Bureau must be completed through the interactive survey form on the NPEFS data collection website or ED Form 2447 by Tuesday, September 8, 2020. If an SEA submits revised data after the final deadline that result in a lower SPPE figure, the SEA's allocations may be adjusted downward, or the Department may direct the SEA to return funds. SEAs should be aware that all of these data are subject to audit and that, if any inaccuracies are discovered in the audit process, the Department may seek recovery of overpayments for the applicable programs.

Note: The following are important dates in the data collection process for FY 2019 data and revisions to reports for previous fiscal years:

Date	Activity
January 30, 2020	SEAs can begin to submit accurate and complete data for FY 2019 and revisions to previously submitted data for FY 2018.
March 27, 2020	Date by which SEAs are urged to submit accurate and complete data for FY 2018 and FY 2019.
August 14, 2020	Mandatory final submission date for FY 2018 and FY 2019 data to be used for program funding allocation purposes.
September 8, 2020	Mandatory final deadline for responses by SEAs to requests for clarification or reconciliation or other inquiries by NCES or the Census Bureau. All data issues must be resolved.

Accessible Format: Individuals with disabilities may obtain this document in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Authority: 20 U.S.C. 9543.

Mark Schneider,

Director of the Institute of Education Sciences.

[FR Doc. 2019–20835 Filed 9–24–19; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2019–ICCD–0117]

Agency Information Collection Activities; Comment Request; Borrower Defenses Regulations

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a revision of an existing information collection.

DATES: Interested persons are invited to submit comments on or before November 25, 2019.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2019–ICCD–0117. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the regulations.gov site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 550 12th Street SW, PCP, Room 9086, Washington, DC 20202–0023.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger, 202–377–4018.

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: Borrower Defenses Regulations.

OMB Control Number: 1845–0142.

Type of Review: A revision of an existing information collection.

Respondents/Affected Public: Individuals or Households; Private Sector.

Total Estimated Number of Annual Responses: 11,487.

Total Estimated Number of Annual Burden Hours: 5,531.

Abstract: The Department of Education (the Department) requests a revision of the current information collection associated with OMB Control Number 1845–0142 due to an increase in the number of borrowers asserting a borrower defense to repayment claim. The only change to the collection is an update to increase the number of respondents, responses and burden hours.

The regulations in § 685.222 provide a framework for the borrower defense individual and group process that applies to loans first disbursed on or after July 1, 2017 and before July 1, 2020, including descriptions of the circumstances under which group borrower defense claims could be considered, and the process the Department will follow for borrower defenses for a group. The regulations establish a process for review and determination of a borrower defense for groups identified by the Secretary for which the borrower defense is made regarding a Direct Loans for attendance at a closed school that has not provided financial protection currently available to the Secretary from which to recover any losses based on borrower defense claims, and for which there is no appropriate entity from which the Secretary can otherwise practicably recover such losses. The regulations also establish the process for groups identified by the Secretary for which the borrower defense is asserted with respect to Direct Loans to attend an open school.

Dated: September 13, 2019.

Kate Mullan,

PRA Coordinator, Information Collection Clearance Program, Information Management Branch, Office of the Chief Information Officer.

[FR Doc. 2019–20209 Filed 9–24–19; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2019–ICCD–0075]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Profiles of Selected Practices of Charter Schools, Charter Management Organizations, and Charter School Authorizers

AGENCY: Office of Planning, Evaluation and Policy Development (OPEPD), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before October 25, 2019.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2019–ICCD–0075. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the regulations.gov site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 550 12th Street SW, PCP, Room 9089, Washington, DC 20202–0023.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Michael Fong, 202–401–7462.

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: Profiles of Selected Practices of Charter Schools, Charter Management Organizations, and Charter School Authorizers.

OMB Control Number: 1875–NEW.

Type of Review: A new information collection.

Respondents/Affected Public: Individuals or Households.

Total Estimated Number of Annual Responses: 240.

Total Estimated Number of Annual Burden Hours: 265.

Abstract: This project will support the development and dissemination of profiles of innovative practices to create learning resources that highlight how some in the charter sector have addressed persistent educational challenges, such as improving whole schools, supporting high-needs students, and building teacher and leader capacity. The profiles will be disseminated to educators, policymakers, parents, and other stakeholders to help them learn from and potentially replicate innovative practices that will give more students and families more public school options that take their unique needs and preferences into account.

Dated: September 20, 2019.

Stephanie Valentine,

PRA Coordinator, Information Collection Clearance Program, Information Management Branch, Office of the Chief Information Officer.

[FR Doc. 2019–20789 Filed 9–24–19; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Notice of Request for Information (RFI) on Identifying Wells of Opportunity for Critical Geothermal Field Research Applications

AGENCY: Office of Energy Efficiency and Renewable Energy (EERE), Department of Energy (DOE).

ACTION: Request for information (RFI).

SUMMARY: The U.S. Department of Energy (DOE) invites public comment on its Request for Information (RFI) regarding the identification of wells of opportunity for critical geothermal field research application. DOE is seeking information from the geothermal community about underutilized wells in known geothermal resource areas in the United States. The goal is to obtain feedback on industry willingness to partner with DOE's Geothermal Technologies Office (GTO) to test downhole tools, technologies, and methodologies that can improve the probability of successful geothermal commercialization.

DATES: Responses to the RFI must be received by October 25, 2019.

ADDRESSES: Interested parties are to submit comments electronically to *GeothermalRFI@ee.doe.gov.* Include Wells of Opportunity in the subject of the title. The complete RFI document is located at *https://eere-exchange.energy.gov/.*

FOR FURTHER INFORMATION CONTACT: Questions may be addressed to *GeothermalRFI@ee.doe.gov,* or Lauren Boyd, 202–287–1854. Further instruction can be found in the RFI document posted on EERE Exchange.

SUPPLEMENTARY INFORMATION: The purpose of this RFI is to solicit feedback from industry, academia, research laboratories, government agencies, and other stakeholders on existing Wells of Opportunity (underutilized wells in known geothermal resources) that DOE and partners can use for downhole testing of tools, technologies, and methodologies. EERE is specifically interested in information from stakeholders with available well infrastructure on their willingness to participate and allow research and testing for downhole tools, technologies, and methods in their well. Additionally, EERE is interested in stakeholder feedback on their well asset acquisition experiences for technology testing, development, or other purposes, particularly on what incentives were important towards obtaining the necessary infrastructure. The RFI is available at: *https://eere-exchange.energy.gov/.*

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.

Factors of interest to DOE when evaluating requests to treat submitted information as confidential include: (1) A description of the items; (2) whether and why such items are customarily treated as confidential within the industry; (3) whether the information is generally known by or available from other sources; (4) whether the information has previously been made available to others without obligation concerning its confidentiality; (5) an explanation of the competitive injury to the submitting person that would result from public disclosure; (6) when such information might lose its confidential character due to the passage of time; and (7) why disclosure of the information would be contrary to the public interest.

Signed in Washington, DC, on September 12, 2019.

Susan Hamm,

Director Geothermal Technologies Office.

[FR Doc. 2019–20809 Filed 9–24–19; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP19–1574–000.
Applicants: Natural Gas Pipeline Company of America.
Description: § 4(d) Rate Filing: Amendment to a Negotiated Rate Agreement—Peoples Gas Light and Coke to be effective 9/18/2019.
Filed Date: 9/18/19.
Accession Number: 20190918–5000.
Comments Due: 5 p.m. ET 9/30/19.

Docket Numbers: RP19–1575–000.
Applicants: Iroquois Gas Transmission System, L.P.
Description: § 4(d) Rate Filing: 091819 Negotiated Rates—Macquarie Energy LLC R–4090–19 to be effective 11/1/2019.
Filed Date: 9/18/19.
Accession Number: 20190918–5021.
Comments Due: 5 p.m. ET 9/30/19.

Docket Numbers: RP19–1576–000.
Applicants: Iroquois Gas Transmission System, L.P.
Description: § 4(d) Rate Filing: 091819 Negotiated Rates—Sequent Energy Management, L.P. R–3075–11 to be effective 11/1/2019.
Filed Date: 9/18/19.
Accession Number: 20190918–5024.
Comments Due: 5 p.m. ET 9/30/19.

Docket Numbers: RP19–1577–000.
Applicants: Iroquois Gas Transmission System, L.P.
Description: § 4(d) Rate Filing: 091819 Negotiated Rates—Sequent Energy Management, L.P. R–3075–12 to be effective 11/1/2019.
Filed Date: 9/18/19.
Accession Number: 20190918–5027.
Comments Due: 5 p.m. ET 9/30/19.

Docket Numbers: RP19–1578–000.
Applicants: Iroquois Gas Transmission System, L.P.
Description: § 4(d) Rate Filing: 091819 Negotiated Rates—Shell Energy North America (US) L.P. R–2170–12 to be effective 11/1/2019.
Filed Date: 9/18/19.
Accession Number: 20190918–5028.
Comments Due: 5 p.m. ET 9/30/19.

Docket Numbers: RP19–1579–000.
Applicants: Iroquois Gas Transmission System, L.P.
Description: § 4(d) Rate Filing: 091819 Negotiated Rates—Shell Energy North America (US) L.P. R–2170–13 to be effective 11/1/2019.
Filed Date: 9/18/19.
Accession Number: 20190918–5031.
Comments Due: 5 p.m. ET 9/30/19.

The filings are accessible in the Commission's eLibrary system by clicking on the links or 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: September 19, 2019.

Nathaniel J. Davis Sr.,

Deputy Secretary.

[FR Doc. 2019–20792 Filed 9–24–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL19–87–000]

Idaho Power Company; Notice of Institution of Section 206 Proceeding and Refund Effective Date

On September 19, 2019, the Commission issued an order in Docket No. EL19–87–000, pursuant to section 206 of the Federal Power Act (FPA), 16 U.S.C. 824e (2018), instituting an investigation into whether Idaho Power's market-based rate authority in the Idaho Power balancing authority area remains just and reasonable. *Idaho Power Company,* 168 FERC ¶ 61,156 (2019).

The refund effective date in Docket No. EL19–87–000, established pursuant to section 206(b) of the FPA, will be the date of publication of this notice in the **Federal Register.**

Any interested person desiring to be heard in Docket No. EL19–87–000 must file a notice of intervention or motion to intervene, as appropriate, with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rule 214 of the Commission's Rules of Practice and Procedure, 18 CFR 385.214 (2019), within 21 days of the date of issuance of the order.

Dated: September 19, 2019.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2019–20793 Filed 9–24–19; 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: EG19–186–000.
Applicants: 224WB 8me LLC.
Description: Notice of Self-Certification of Exempt Wholesale Generator Status of 224WB 8me LLC.
Filed Date: 9/19/19.
Accession Number: 20190919–5053.
Comments Due: 5 p.m. ET 10/10/19.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER12–2310–008.
Applicants: Zephyr Wind, LLC.
Description: Notice of Non Material Change in Status of Zephyr Wind, LLC.

Filed Date: 9/19/19.
Accession Number: 20190919–5098.
Comments Due: 5 p.m. ET 10/10/19.

Docket Numbers: ER18–1266–003.
Applicants: Moxie Freedom LLC.
Description: Compliance filing: Settlement Compliance Filing to be effective 5/1/2018.
Filed Date: 9/18/19.
Accession Number: 20190918–5115.
Comments Due: 5 p.m. ET 10/9/19.

Docket Numbers: ER19–592–001.
Applicants: Valentine Solar, LLC.
Description: Notice of Change in Status of Valentine Solar, LLC.
Filed Date: 9/18/19.
Accession Number: 20190918–5156.
Comments Due: 5 p.m. ET 10/9/19.

Docket Numbers: ER19–2830–000.
Applicants: Midcontinent Independent System Operator, Inc., ALLETE, Inc.
Description: § 205(d) Rate Filing: 2019–09–18 SA 2700 Minnesota Power-Manitoba-Minnesota Power 1st Rev MPFCA (GNTL) to be effective 9/19/2019.
Filed Date: 9/18/19.
Accession Number: 20190918–5153.
Comments Due: 5 p.m. ET 10/9/19.

Docket Numbers: ER19–2831–000.
Applicants: Southwest Power Pool, Inc.
Description: Notice of cancellation of Point-To-Point Transmission Service Agreement of Southwest Power Pool, Inc.
Filed Date: 9/18/19.
Accession Number: 20190918–5163.
Comments Due: 5 p.m. ET 10/9/19.

Docket Numbers: ER19–2832–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Orginal WMPA SA No. 5488; Queue No. AE2–006 to be effective 9/12/2019.
Filed Date: 9/19/19.
Accession Number: 20190919–5069.
Comments Due: 5 p.m. ET 10/10/19.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES19–58–000.
Applicants: Michigan Electric Transmission Company, LLC.
Description: Application under Section 204 of the Federal Power Act for Authorization to Extend Maturity of Revolving Credit Facility of Michigan Electric Transmission Company, LLC.
Filed Date: 9/18/19.
Accession Number: 20190918–5127.
Comments Due: 5 p.m. ET 10/9/19.

Take notice that the Commission received the following qualifying facility filings:

Docket Numbers: QF18–452–000.
Applicants: North American Natural Resources, Inc.
Description: Refund Report of North American Natural Resources, Inc.
Filed Date: 9/19/19.
Accession Number: 20190919–5091.
Comments Due: 5 p.m. ET 10/10/19.

The filings are accessible in the Commission's eLibrary system by clicking on the links or 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: September 19, 2019.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2019–20791 Filed 9–24–19; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2004–0077; FRL 10000–44–OAR]

Proposed Information Collection Request; Comment Request; Significant New Alternatives Policy (SNAP) Program (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is planning to submit an information collection request (ICR), ''Significant New Alternatives Policy (SNAP) Program (Renewal)'' (EPA ICR No. 1596.10, OMB Control No. 2060–0226) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. Before doing so, EPA is soliciting public comments on specific aspects of the proposed information collection as described below. This is a proposed extension of the ICR, which is currently approved through May 31, 2020. An Agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Comments must be submitted on or before November 25, 2019.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–OAR–2004–0077, online using *www.regulations.gov* (our preferred method), by email to *a-and-r-docket@epa.gov* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Christina Thompson, Stratospheric Protection Division, Office of Atmospheric Programs, (Mail Code 6205T), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564–0983; fax number: (202) 343–2362; email address: *thompson.christina@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Pursuant to section 3506(c)(2)(A) of the PRA, EPA is soliciting comments and information to enable it to: (i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (ii) evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology,

e.g., permitting electronic submission of responses. EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, EPA will issue another **Federal Register** notice to announce the submission of the ICR to OMB.

Abstract: Information collected under this rulemaking is necessary to implement the requirements of the Significant New Alternatives Policy (SNAP) program for evaluating and regulating substitutes for ozone-depleting substances (ODS) being phased out under the stratospheric ozone protection provisions of the Clean Air Act (CAA) and globally under the *Montreal Protocol on Substances that Deplete the Ozone Layer.* Under CAA Section 612, EPA is authorized to identify and restrict the use of substitutes for class I and class II ODS (listed in 40 CFR part 82, subpart A, appendices A and B) where EPA determines other alternatives are available or potentially available that reduce overall risk to human health and the environment. Any producer of a new substitute must submit a notice of intent to introduce a substitute into interstate commerce 90 days prior to such introduction. The producer must also provide EPA with information covering a wide range of health and environmental factors. The SNAP program, based on information collected from the manufacturers, formulators, and/or sellers of such substitutes, identifies acceptable substitutes. Responses to the collection of information are mandatory under Section 612 for anyone who sells or, in certain cases, uses substitutes for an ODS after April 18, 1994, the effective date of the final rule. Measures to protect confidentiality of information collected under the SNAP program are based on EPA's confidentiality regulations (40 CFR 2.201 *et seq.,* or Subpart B). Submitters may designate all or portions of their forms or petitions as confidential. EPA requires the submitters to substantiate their claim of confidentiality. Under CAA Section 114(c), emissions information may not be claimed as confidential.

To develop the lists of acceptable and unacceptable substitutes, the Agency must assess and compare ''overall risks to human health and the environment'' posed by use of substitutes in the context of particular applications. EPA requires submission of information covering a wide range of health and environmental factors. These include intrinsic properties such as physical and chemical information, atmospheric effects including ozone depleting potential and global warming potential, toxicity, and flammability, and use-specific data such as substitute applications, process description, environmental release data, exposure data during use of a substitute, environmental fate and transport, and cost information of the substitute. Once a completed submission has been received, the SNAP program will commence its review. Any substitute which is a new chemical must also be submitted to the Agency under the Premanufacture Notice program under the Toxic Substances Control Act (TSCA). Alternatives that will be used as sterilants must be filed jointly with EPA's Office of Pesticide Programs and with SNAP.

Form Numbers: 1265–14.

Respondents/affected entities: Manufacturers, importers, formulators and processors of substitutes for ODS.

Respondent's obligation to respond: Mandatory (40 CFR 82.176).

Estimated number of respondents: 180 (per year).

Frequency of response: Annual.

Total estimated burden: 5,557 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $471,714, which includes $22,938 annualized capital or O&M costs.

Changes in Estimates: There is a decrease of 814 hours in the total estimated respondent burden compared with the ICR currently approved by OMB. The Agency anticipates the number of submissions to the SNAP program to remain the same as the previous ICR during the next 3 years. Many of the recent SNAP submissions, and those anticipated over the next three years, are for chemicals previously found acceptable for other SNAP applications or for blends of alternatives already found acceptable. For the expected submissions, the burden of developing supporting information for the majority of these submissions is expected to decrease because it is easier to find and review information for substitutes that have been reviewed previously. EPA estimates a reduction in the number of respondents responsible for recordkeeping for substitutes acceptable subject to use conditions and narrowed use limits. The increased availability of alternatives reduces the need for industry to use alternatives previously listed as acceptable subject to narrowed use limits.

Dated: September 13, 2019.

Cynthia A. Newberg,

Director, Stratospheric Protection Division.

[FR Doc. 2019–20862 Filed 9–24–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2019–0027; FRL–9995–19–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Information Collection Request for the Greenhouse Gas Reporting Program (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Greenhouse Gas Reporting Program (EPA ICR No. 2300.18, OMB Control No. 2060–0629) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through September 30, 2019. Public comments were previously requested via the **Federal Register** on February 26, 2019 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before October 25, 2019.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OAR–2019–0027, to (1) EPA online using *www.regulations.gov* (our preferred method), or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460, and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential

Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Rachel Schmeltz, Climate Change Division, Office of Atmospheric Programs (MC–6207A), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 343–9124; fax number: (202) 343–2342; email address: *GHGReporting@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Abstract: In response to the FY2008 Consolidated Appropriations Act (H.R. 2764; Pub. L. 110–161) and under authority of the Clean Air Act, the EPA finalized the Mandatory Reporting of Greenhouse Gases Rule (GHG Reporting Rule) (74 FR 56260; October 30, 2009). The GHG Reporting Rule, which became effective on December 29, 2009, establishes reporting requirements for certain large facilities and suppliers. It does not require control of greenhouse gases. Instead, it requires that sources emitting above certain threshold levels of carbon dioxide equivalent (CO_2e) monitor and report emissions.

Subsequent rules have promulgated requirements for additional facilities and suppliers; provided clarification and corrections to existing requirements; finalized confidentiality business information (CBI) determinations, amended recordkeeping requirements, and implemented an alternative verification approach. Collectively, the GHG Reporting Rule and its associated rulemakings are referred to as the Greenhouse Gas Reporting Program (GHGRP).

The purpose for this ICR is to renew and revise the GHG Reporting Rule ICR to update the burden and cost imposed by the current ICR under the GHGRP.

Form Numbers: None.

Respondents/affected entities: The respondents in this information collection include owners and operators of facilities that must report their GHG emissions and other data to EPA to comply with the rulemaking. To facilitate the analysis, EPA has divided respondents into groups that align with the source categories identified in the rule.

Reporting facilities include, but are not limited to, those operating one or more units that exceed the CO_2e threshold for the industry sectors listed in Table A–4 of 40 CFR 98.2(a)(2) or those in the categories in which all must report, such as petroleum refining facilities and all other large emitters listed in Table A–3 of 40 CFR 98.2(a)(1). Additionally, the GHGRP requires reporting of GHGs from certain suppliers as listed in Table A–5 of 40 CFR 98.2(a)(4).

Respondent's obligation to respond: Mandatory (Section 114 of the Clean Air Act provides EPA authority to require the information mandated by the Greenhouse Gas Reporting Program because such data will inform and are relevant to future policy decisions).

Estimated number of respondents: 13,180 (total).

Frequency of response: Annual.

Total estimated burden: 740,012 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $87,945,711 (per year), includes $29,526,397 annualized capital or operation & maintenance costs for respondents, labor cost of $58,419,314 for respondents.

Changes in the Estimates: There is an increase of 825 hours in the total estimated respondent burden compared with the ICR currently approved by OMB. This increase reflects an adjustment in the number of respondents from the previous ICR, an adjustment of capital costs to reflect 2017 dollars and changes to the tax law, a new methodology to determine the numbers of responses and responses per respondent, and a complete and comprehensive re-evaluation of the activities and costs associated with all subparts of the GHGRP. Finally, there is a large decrease in annual cost burden (represented by combined Capital and O&M costs) as compared with the ICR currently approved by OMB due to a data entry error. The amount entered for the previous ICR should have been $30,621,791 instead of $58,815,798.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2019–20787 Filed 9–24–19; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL DEPOSIT INSURANCE CORPORATION

FDIC Advisory Committee on Community Banking; Notice of Meeting

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice of open meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, notice is hereby given of a meeting of the FDIC Advisory Committee on Community Banking, which will be held in Washington, DC The Advisory Committee will provide advice and recommendations on a broad range of policy issues that have particular impact on small community banks throughout the United States and the local communities they serve, with a focus on rural areas.

DATES: Thursday, October 10, 2019, from 9:00 a.m. to 3:00 p.m.

ADDRESSES: The meeting will be held in the FDIC Board Room on the sixth floor of the FDIC Building located at 550 17th Street NW, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Requests for further information concerning the meeting may be directed to Mr. Robert E. Feldman, Committee Management Officer of the FDIC, at (202) 898–7043.

SUPPLEMENTARY INFORMATION:

Agenda: The agenda will include a discussion of current issues affecting community banking. The agenda is subject to change. Any changes to the agenda will be announced at the beginning of the meeting.

Type of Meeting: The meeting will be open to the public, limited only by the space available on a first-come, first-served basis. For security reasons, members of the public will be subject to security screening procedures and must present a valid photo identification to enter the building. The FDIC will provide attendees with auxiliary aids (*e.g.,* sign language interpretation) required for this meeting. Those attendees needing such assistance should call (703) 562–6067 (Voice or TTY) at least two days before the meeting to make necessary arrangements. Written statements may be filed with the committee before or after the meeting. This meeting of the Advisory Committee on Community Banking will be Webcast live via the internet *http://fdic.windrosemedia.com.* Questions or troubleshooting help can be found at the same link. For optimal viewing, a high-speed internet connection is recommended. Further, a video of the meeting will be available on-demand approximately two weeks after the event.

Federal Deposit Insurance Corporation.

Dated at Washington, DC, on September 20, 2019.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2019–20762 Filed 9–24–19; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th and Constitution Avenue NW, Washington DC 20551–0001, not later than October 25, 2019.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street Chicago, Illinois 60690–1414:

1. *Northstar Financial Group, Inc., Bad Axe, Michigan;* to acquire 100 percent of the voting shares of West Michigan Community Bank, Hudsonville, Michigan.

Board of Governors of the Federal Reserve System, September 19, 2019.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2019–20739 Filed 9–24–19; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th and Constitution Avenue NW, Washington DC 20551–0001, not later than October 9, 2019.

A. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. *Michael S. Wright, individually and as trustee of the E&N–AMG National Trust Bank Irrevocable Trust; and the NSW–AMG National Trust Bank Irrevocable Trust, all in Castle Pines, Colorado;* to retain voting shares of AMG National Corp., Greenwood Village, Colorado, parent of AMG National Trust Bank, Boulder, Colorado; and to become members of the Wright Family Group which controls AMG National Corp.

2. *Theodore L. Starr, Hiawatha, Kansas; and Randolph W. Starr, Loveland, Colorado;* to retain voting shares of Crossdale, Inc., and thereby indirectly acquire shares of Citizens State Bank & Trust Company, both in Hiawatha, Kansas.

Board of Governors of the Federal Reserve System, September 19, 2019.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2019–20737 Filed 9–24–19; 8:45 am]

BILLING CODE P

OFFICE OF GOVERNMENT ETHICS

Agency Information Collection Activities; Proposed Collection; Comment Request for Modified Qualified Trust Model Certificates and Model Trust Documents

AGENCY: Office of Government Ethics (OGE).

ACTION: Notice of request for agency and public comments.

SUMMARY: After this first round notice and public comment period, the U.S. Office of Government Ethics (OGE) intends to submit modified versions of the 12 OGE model certificates and model documents for qualified trusts to the Office of Management and Budget (OMB) for review and approval under the Paperwork Reduction Act of 1995.

DATES: Written comments by the public and the agencies on this proposed extension are invited and must be received on or before November 25, 2019.

ADDRESSES: Comments may be submitted to OGE by any of the following methods:

Email: usoge@oge.gov (Include reference to ''OGE qualified trust model certificates and model trust documents paperwork comment'' in the subject line of the message.)

Fax: 202–482–9237, Attn: Jennifer Matis.

Mail, Hand Delivery/Courier: Office of Government Ethics, 1201 New York Avenue NW, Suite 500, Attention: Jennifer Matis, Associate Counsel, Washington, DC 20005–3917.

Instructions: Comments may be posted on OGE's website, *www.oge.gov.* Sensitive personal information, such as account numbers or Social Security numbers, should not be included. Comments generally will not be edited to remove any identifying or contact information.

FOR FURTHER INFORMATION CONTACT: Jennifer Matis at the U.S. Office of Government Ethics; telephone: 202–482–9216; TTY: 800–877–8339; FAX: 202–482–9237; Email: *jmatis@oge.gov.* Copies of the model documents as currently approved are available on OGE's website, *www.oge.gov.* Electronic copies of these documents may also be obtained, without charge, by contacting Ms. Matis.

SUPPLEMENTARY INFORMATION:

Title: Executive Branch Qualified Trust Documents.

OMB Control Number: 3209–0007.

Type of Information Collection: Revision of a currently approved collection.

Type of Review Request: Regular.

Respondents: Any current or prospective executive branch officials who seek to establish or have established a qualified blind or diversified trust under the Ethics in Government Act of 1978 as a means to avoid conflicts of interest while in office.

Estimated Average Annual Number of Respondents: 2.

Total Estimated Time per Response: 20 minutes to 100 hours (see table below for detailed explanation).

Estimated Average Total Annual Burden: 120 hours.

Abstract: OGE is the supervising ethics office for the executive branch of the Federal Government under the Ethics in Government Act of 1978 (EIGA). Accordingly, OGE administers the qualified trust program for the executive branch. Presidential nominees to executive branch positions subject to Senate confirmation and any other executive branch officials may seek OGE approval for EIGA-qualified blind or diversified trusts as one means to be used to avoid conflicts of interest. The requirements for EIGA-qualified blind and diversified trusts are set forth in section 102(f) of the Ethics in Government Act, 5 U.S.C. app. § 102(f), and OGE's implementing financial disclosure regulations at subpart D of 5 CFR part 2634.

In order to ensure that all applicable requirements are met, OGE is the sponsoring agency for 12 model certificates and model trust documents for qualified blind and diversified trusts. See 5 CFR 2634.402(e)(3), 2634.402(f)(3), 2634.404(e)–(g), 2634.405(d)(2), 2634.407(a); 2634.408(b)(1)–(3), 2634.408(d)(4), 2634.409, and 2634.414. The various model certificates and model trust documents are utilized by settlors, trustees, and other fiduciaries in establishing and administering these qualified trusts. OGE plans to submit these model certificates and model trust documents (described in detail in the table below) to OMB for renewed approval pursuant to the Paperwork Reduction Act of 1995, 44 U.S.C. chapter 35.

The 12 model documents, along with their burden estimates, are as follows:

Model qualified trust documents	Estimated burden
(A) Blind Trust Communications (Expedited Procedure for Securing Approval of Proposed Communications).	20 minutes per communication.
(B) Model Qualified Blind Trust Provisions.	100 hours per model.
(C) Model Qualified Diversified Trust Provisions.	100 hours per model.
(D) Model Qualified Diversified Trust Provisions (For Use in the Case of Multiple Fiduciaries).	100 hours per model.
(E) Model Qualified Blind Trust Provisions (For Use in the Case of an Irrevocable Pre-Existing Trust).	100 hours per model.
(F) Hybrid Version of the Model Qualified Diversified Trust Provisions.	100 hours per model.
(G) Model Qualified Blind Trust Provisions (For Use in the Case of Multiple Fiduciaries).	100 hours per model.
(H) Model Qualified Diversified Trust Provisions (For Use in the Case of an Irrevocable Pre-Existing Trust).	100 hours per model.
(I) Model Confidentiality Agreement Provisions (For Use in the Case of a Privately Owned Business).	2 hours per agreement.
(J) Model Confidentiality Agreement Provisions (For Use in the Case of Investment Management Activities).	2 hours per agreement.

Model trust certificates	Estimated burden
(K) Certificate of Independence.	20 minutes per certificate.
(L) Certificate of Compliance	20 minutes per certificate.

These estimates are based on the amount of time imposed on professional trust administrators or private representatives. OGE notes that only one set of the various model trust provisions (items (B) through (H)) will be prepared for a single qualified trust, and only prior to the establishment of that qualified trust. Likewise, other model documents listed above are used in connection with establishing the qualified trust (items (I), (J), and (K)). The remaining model documents are used after the trust's creation (items (A) and (L)). Accordingly, OGE notes that the majority of the time burden for any given trust is imposed during the creation of the trust.

At the present time, there are no active qualified trusts in the executive branch. However, OGE anticipates possible limited use of these model documents during the forthcoming three-year period. OGE estimates that there may be an average of one individual per year who initiates a qualified trust using these model documents during calendar years 2020 through 2022. OGE has accordingly estimated the average annual number of respondents to be two, which represents one respondent establishing a qualified trust and one respondent maintaining a previously established qualified trust. Based on the above, OGE estimates an average annual time burden during the next three years of 120 hours. Using an estimated rate of $300 per hour for the services of a professional trust administrator or private representative, the estimated annual cost burden is $36,000.

Under OMB's implementing regulations for the Paperwork Reduction Act, any recordkeeping, reporting, or disclosure requirement contained in a rule of general applicability is deemed to involve ten or more persons. See 5 CFR 1320.3(c)(4)(i). Therefore, OGE intends to submit, after this first round notice and comment period, all 12 qualified trust model certificates and model documents described above (all of which are included under OMB paperwork control number 3209–0007) for a three-year extension of approval. At that time, OGE will publish a second notice in the **Federal Register** to inform the public and the agencies.

OGE is committed to making ethics records publicly available to the extent possible. The communications documents and the confidentiality agreements (items (A), (I) and (J) on the table above), once completed, will not be available to the public because they contain sensitive, confidential information. The other completed certificates and documents (except for any trust provisions that relate to the testamentary disposition of trust assets) are retained and made publicly available based upon a proper request under section 105 of the EIGA until the periods for retention of all other reports (usually the OGE Form 278 Public Financial Disclosure Reports) of the individual establishing the trust have lapsed (generally six years after the filing of the last report). See 5 U.S.C. app. 105; 5 CFR 2634.603(g)(2). The information collected with these model trust certificates and model trust documents is part of the OGE/GOVT–1 Governmentwide Privacy Act system of records.

In seeking an extension of approval, OGE is proposing several nonsubstantive changes to the 12

qualified trust certificates and model documents.

First, OGE proposes removing all references to Appendices A and B of 5 CFR part 2634 because these references are no longer applicable. The appendices, which contained the model Certificate of Independence and model Certificate of Compliance (items (K) and (L), respectively, on the table above), were eliminated as part of recent changes made by OGE to the Executive Branch Financial Disclosure, Qualified Trusts, and Certificates of Divestiture regulation at 5 CFR part 2634. The changes went into effect on January 1, 2019. The information previously found in Appendix B is available on *www.oge.gov.*

Second, OGE proposes removing all references to facsimile as the best means of communication and replacing it with email.

Third, with regard to the model communications (item (A) in the table above), OGE proposes to update the dates in the sample documents to make them more contemporary.

Fourth, OGE proposes to add one sentence to the Privacy Act statements to better notify users of the consequences of not providing the requested information.

Fifth, OGE proposes to make a few minor formatting corrections and to fix a typographical error in the Privacy Act statements.

Request for Comments: Agency and public comment is invited specifically on the need for and practical utility of this information collection, the accuracy of OGE's burden estimate, the enhancement of quality, utility, and clarity of the information collected, and the minimization of burden (including the use of information technology). Comments received in response to this notice will be summarized for, and may be included with, the OGE request for extension of OMB approval. The comments will also become a matter of public record.

Approved: September 20, 2019.

Emory Rounds,

Director, Office of Government Ethics.

[FR Doc. 2019–20774 Filed 9–24–19; 8:45 am]

BILLING CODE 6345–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–FY–1163; Docket No. CDC–2019–0084]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled *CDC Fellowship Programs Assessments* (OMB Control No. 0920–1163) This data collection is being submitted to assist CDC with quality improvement of CDC fellowship programs.

DATES: CDC must receive written comments on or before November 25, 2019.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2019–0084 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Lead, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov.*

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.
5. Assess information collection costs.

Proposed Project

Data Collection for CDC Fellowship Programs—Extension—Division of Scientific Education and Professional Development (DSEPD), Center for Surveillance, Epidemiology, and Laboratory Services (CSELS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC's mission is to protect America from health, safety, and security threats, both foreign, and in the U.S. To ensure a competent, sustainable, and empowered public health workforce prepared to meet these challenges, CDC plays a key role in developing, implementing, and managing a number of fellowship programs. A fellowship is defined as a training or work experience lasting at least one month and consisting of primarily experiential (*i.e.,*

on-the-job) learning, in which the trainee has a designated mentor or supervisor. CDC fellowships are intended to develop public health professionals, enhance the public health workforce, and strengthen collaborations with partners in public health and healthcare organizations, academia, and other stakeholders in governmental and non-governmental organizations. Assessing fellowship activities is essential to ensure that the public health workforce is equipped to promote and protect the public's health.

CDC requests a three-year extension of a generic clearance to collect data about its fellowship programs, as they relate to public health workforce development. Data collections will allow for ongoing, collaborative, and actionable communications between CDC fellowship programs and stakeholders (*e.g.,* fellows, supervisors/mentors, alumni). These collections might include short surveys, interviews, and focus groups. Intended use of the resulting information is to:

- Inform planning, implementation, and continuous quality improvement of fellowship activities and services;
- improve efficiencies in the delivery of fellowship activities and services; and
- determine to what extent fellowship activities and services are achieving established goals.

Collection and use of information about CDC fellowship activities will help ensure effective, efficient, and satisfying experiences among fellowship program participants and stakeholders.

CDC estimates that annually, a given fellowship program will conduct one query each with one of the three respondent groups: Fellowship applicants or fellows; mentors, supervisors, or employers; and alumni. The total annualized burden hours are estimated to be 2,957. OMB approval is requested for three years. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Applicants or fellows	Fellowship Data Collection Instrument.	1,848	1	30/60	924
Mentors, supervisors, or employers	Fellowship Data Collection Instrument.	370	1	30/60	185
Alumni	Fellowship Data Collection Instrument.	3,696	1	30/60	1,848
Total					2,957

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–20705 Filed 9–24–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–19–19BQB; Docket No. CDC–2019–0081]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Public Health Accreditation Board (PHAB): Assessment of Processes and Outcomes. This proposed collection aims to learn about program processes and the accreditation/reaccreditation standards to improve the program's quality, and to document program outcomes to demonstrate impact and inform decision making about future program direction.

DATES: CDC must receive written comments on or before November 25, 2019.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2019–0081 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov.*

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.
5. Assess information collection costs.

Proposed Project

Public Health Accreditation Board (PHAB): Assessment of Processes and Outcomes—New—Center for State, Tribal, Local and Territorial Support (CSTLTS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC) works to protect America from health, safety and security threats, both foreign, and in the U.S. CDC strives to fulfill this mission, in part, by supporting state, tribal, local, and territorial (STLT) health departments. One mechanism for supporting STLT health departments is through CDC's support of a national, voluntary accreditation program.

CDC supports the Public Health Accreditation Board (PHAB), a non-profit organization that serves as the independent accrediting body. PHAB, with considerable input from national, state, tribal, and local public health professionals, developed a consensus set of standards to assess the capacity of state, tribal, local, and territorial health departments. The first health departments were accredited by PHAB in early 2013; as of August 2019, a total of 268 health departments (36 state, three Tribal and 229 local), as well as one statewide integrated local public health department system have been accredited. Accreditation is granted for a five-year period and the first several health departments have successfully completed the reaccreditation process. Formal efforts to assess the outcomes of the accreditation program began in late 2012, and continue to date. Priorities focus on gathering feedback for program improvement and documenting program outcomes to demonstrate impact and inform decision making about future program direction. Starting in 2012 and running through December 2019, the Robert Wood Johnson Foundation (RWJF) and the social science organization NORC at the University of Chicago, led evaluation efforts. CDC will assume support of the evaluation starting in 2020 and as a result, OMB approval for data collection is being sought.

The purpose of this ICR is to support the collection of information from participating health departments through a series of five surveys. The surveys seek to collect longitudinal data on each health department throughout their accreditation process.

The respondent universe will include STLT health department directors or designees. All surveys will be administered electronically; a link to the survey website will be provided in the email invitation. The surveys will be administered on a quarterly basis and sent to all health departments that reach each milestone in the accreditation process (application, recently accredited, accredited for one year, approaching reaccreditation, and reaccreditation). Each health department will be invited to participate in each survey once (for a total of five surveys max per health department). The total annualized estimated burden is 100 hours. There are no costs to respondents except their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
STLT HD Directors or Designee	Survey 1: Applicants	60	1	20/60	20
STLT HD Directors or Designee	Survey 2: Recently Accredited HDs	60	1	20/60	20
STLT HD Directors or Designee	Survey 3: HDs Accredited One Year	60	1	20/60	20
STLT HD Directors or Designee	Survey 4: HDs Approaching Re-accreditation.	60	1	20/60	20
STLT HD Directors or Designee	Survey 5: Reaccredited HDs	60	1	20/60	20
Total					100

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–20704 Filed 9–24–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10062, CMS–10344 and CMS–588]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our

burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by November 25, 2019.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10062 Collection of Diagnostic Data in the Abbreviated RAPS Format from Medicare Advantage Organizations for Risk Adjusted Payments

CMS–10344 Elimination of Cost-Sharing for full benefit dual-eligible Individuals Receiving Home and Community-Based Services

CMS–588 Electronic Funds Transfer Authorization Agreement

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Collection of Diagnostic Data in the Abbreviated RAPS Format from Medicare Advantage Organizations for Risk Adjusted Payments; *Use:* The 1997 BBA and later legislation required CMS to adjust per-beneficiary payments with a risk adjustment methodology using diagnoses to measure relative risk due to health status instead of just demographic characteristics such as age, sex, and Medicaid eligibility. The purpose of risk adjustment is to pay plan sponsors accurately based on the health status and diagnoses of their Medicare enrollees. Risk adjustment using diagnoses provides more accurate payments for Medicare Advantage Organizations (MAO), with higher payments for enrollees at risk for being sicker, and lower payments for enrollees predicted to be healthier.

The BBA constituted the first legislative mandate for health status risk adjustment. Section 1853 (a)(3) of the Social Security Act as enacted by Section 4001 of Subtitle A of the BBA required the Secretary to implement a risk adjustment methodology that accounted for variations in per capita costs based on health status and other demographic factors for payment to Medicare+Choice (now MA) organizations. The new methodology was to be effective no later than January 1, 2000. The BBA also required that M+C organizations submit data for use in developing risk adjusted payments.

Risk adjustment allows CMS to pay plans for the health risk of the beneficiaries they enroll, instead of paying an identical an average amount for each enrollee Medicare beneficiaries. By risk adjusting plan payments, CMS is able to make appropriate and accurate payments for enrollees with differences in expected costs. Risk adjustment is used to adjust bidding and payment based on the health status and demographic characteristics of an enrollee. Risk scores measure individual beneficiaries' relative risk and the risk scores are used to adjust payments for each beneficiary's expected expenditures. By risk adjusting plan bids, CMS is able to also use standardized bids as base payments to plans.

CMS' fundamental goal for the abbreviate format RAPS data is to require collection of the minimum data necessary for accurate risk-adjusted payment. We believe that diagnostic data provide the most reliable approach to measuring health status, as required by statute. In the absence of these data, we would not be able to accurately determine the beneficiary's health (risk) status. *Form Number:* CMS–10062 (OMB control number: 0938–0878); *Frequency:* Quarterly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 761; *Total Annual Responses:* 46,610,448; *Total Annual Hours:* 33,484. (For policy questions regarding this collection contact Michael P. Massimini at 410–786–1566.)

2. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Elimination of Cost-Sharing for full benefit dual-eligible Individuals Receiving Home and Community-Based Services; *Use:* Each month CMS deems individuals automatically eligible for the full subsidy, based on data from State Medicaid Agencies and the Social Security Administration (SSA). The SSA sends a monthly file of Supplementary Security Income-eligible beneficiaries to CMS. Similarly, the State Medicaid agencies submit Medicare Modernization Act files to CMS that identify full subsidy beneficiaries. CMS deems the beneficiaries as having full subsidy and auto-assigns these beneficiaries to bench mark Part D plans. Part D plans receive premium amounts based on the monthly assessments.

State MMA Phase Down (SPD) exchange enables CMS to implement the Medicare Prescription Drug, Improvement, and Modernization Act, also called the Medicare Modernization Act (MMA), which was enacted into law in 2003. This data exchange allows the State Medicaid Agency (SMA) to identify Medicare beneficiaries with coverage under the Medicaid program. The SMAs also identify other low-income Medicare beneficiaries who have applied for the Part D Low-Income Subsidy (LIS). As a result of the identification of these two groups of beneficiaries, CMS auto-assigns and/or facilitates enrollment of the appropriate beneficiaries into Part D plans.

Section 1860 D–14 of the Social Security Act sets forth requirements for premium and cost-sharing subsidies for low-income beneficiaries enrolled in Medicare Part D. Based on this statute, 42 CFR 423.771, provides guidance concerning limitations for payments made by and on behalf of low-income Medicare beneficiaries who enroll in Part D plans. 42 CFR 423.771 (b) establishes requirements for determining a beneficiary's eligibility for full subsidy under the Part D program. Regulations set forth in 423.780 and 423.782 outline premium and cost sharing subsidies to which full subsidy eligible are entitled under the Part D program. *Form Number:* CMS–10344 (OMB control number: 0938–1127); *Frequency:* Monthly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 51; *Total Annual Responses:* 612; *Total Annual Hours:* 612. (For policy questions regarding this collection contact Roland Horrea at 410–786–0668.)

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Electronic Funds Transfer Authorization Agreement; *Use:* Section 1815(a) of the Social Security Act provides the authority for the Secretary of Health and Human Services to pay providers/suppliers of Medicare services at such time or times as the Secretary determines appropriate (but no less frequently than monthly). Under Medicare, CMS, acting for the Secretary, contracts with Fiscal Intermediaries and Carriers to pay claims submitted by providers/suppliers who furnish services to Medicare beneficiaries. Under CMS' payment policy, Medicare providers/suppliers have the option of receiving payments electronically. *Form Number:* CMS–588 (OMB control number: 0938–0626); *Frequency:* On occasion; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 100,000; *Total Annual Responses:* 100,000; *Total Annual Hours:* 100,000. For questions regarding this collection contact Kim McPhillips at 410–786–5374.

Dated: September 20, 2019.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2019–20858 Filed 9–24–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10595]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by October 25, 2019.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–5806 *OR* Email: *OIRA_submission@omb.eop.gov.*

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

1. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

2. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. Type of Information Collection Request: Extension without change of a currently approved collection; *Title of Information Collection:* QHP Issuers Data Collection for Notices for Plan or Display Errors Special Enrollment Periods; *Use:* The Patient Protection and Affordable Care Act (Pub. L. 111–148) and Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), collectively referred to as the PPACA, established new competitive private health insurance markets called Marketplaces, or Exchanges, which gave millions of Americans and small businesses access to qualified health plans (QHPs), including stand-alone dental plans (SADPs)— private health

and dental insurance plans that have been certified as meeting certain standards.

In the final rule, the Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017 (CMS–9937–F), we finalized 45 CFR 156.1256, which requires QHP issuers, in the case of a material plan or benefit display error included in 45 CFR 155.420(d)(12), to notify their enrollees of the error and the enrollees' eligibility for a special enrollment period (SEP) within 30 calendar days after the issuer is informed by an Federally-facilitated Exchange (FFE) that the error is corrected, if directed to do so by the FFE. This requirement provides notification to QHP enrollees of errors that may have impacted their QHP selection and enrollment and any associated monthly or annual costs, as well as the availability of an SEP under § 155.420(d)(12) for the enrollee to select a different QHP, if desired. The Centers for Medicare and Medicaid Services (CMS) is renewing this information collection request (ICR) in connection with standards regarding Plan or Display Errors SEPs. The title of the package has been changed to better reflect its subject matter. The burden estimate for the ICR included in this package reflects the time and effort for QHP issuers to provide notifications to enrollees on the ICRs regarding Plan or Display Errors SEPs. *Form Number:* CMS–10595 (OMB control number: 0938–1301); *Frequency:* Yearly; *Affected Public:* Private Sector (business or other for-profits, not-for-profit institutions); *Number of Respondents:* 505; *Total Annual Responses:* 3,400; *Total Annual Hours:* 1,700. (For questions regarding this collection contact Deborah Hunter at 202–309–1098).

Dated: September 20, 2019.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2019–20856 Filed 9–24–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–3614]

Recommendations for Sponsors of Medically Important Antimicrobial Drugs Approved for Use in Animals to Voluntarily Bring Under Veterinary Oversight All Products That Continue To Be Available Over-the-Counter; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, we, or Agency) is announcing the availability of a draft guidance for industry (GFI) #263 entitled ''Recommendations for Sponsors of Medically Important Antimicrobial Drugs Approved for Use in Animals to Voluntarily Bring Under Veterinary Oversight All Products That Continue to be Available Over-the-Counter.'' This draft guidance document, when finalized, will provide information to sponsors of medically important antimicrobial new animal drug products who are interested in changing the approved marketing status of these products from over-the-counter (OTC) to by veterinary prescription (Rx) consistent with FDA's recommendation that the use of such drugs in animals be limited to uses that include veterinary oversight to mitigate development of antimicrobial resistance. It also will recommend timeframes for stakeholders wishing to comply voluntarily with this guidance.

DATES: Submit either electronic or written comments on the draft guidance by December 24, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

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

Written/Paper Submissions

Submit written/paper submissions as follows:

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

Instructions: All submissions received must include the Docket No. FDA–2019–D–3614 for ''Recommendations for Sponsors of Medically Important Antimicrobial Drugs Approved for Use in Animals to Voluntarily Bring Under Veterinary Oversight All Products That Continue to be Available Over-the-Counter.'' 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.

- 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.gpo.gov/fdsys/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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Cindy Burnsteel, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0817, email: *cindy.burnsteel@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft GFI #263 entitled ''Recommendations for Sponsors of Medically Important Antimicrobial Drugs Approved for Use in Animals to Voluntarily Bring Under Veterinary Oversight All Products That Continue to be Available Over-the-Counter.'' This draft guidance, when finalized, will provide information to sponsors of certain new animal drug products who are interested in changing the approved marketing status of these products from OTC to Rx consistent with FDA's recommendation that the use of such drugs in animals be limited to uses that include veterinary oversight in order to mitigate development of antimicrobial resistance and thereby preserve the effectiveness of these drugs for use as therapies to treat infections in humans and animals. The draft guidance, when finalized, also will recommend timeframes for stakeholders wishing to comply voluntarily with this guidance.

In 2016, in response to recommendations made by FDA as part of a strategy to address antimicrobial resistance associated with the use of antimicrobial drugs in animal agriculture, sponsors of all medically important antimicrobial drugs approved for use in or on the feed or drinking water of food-producing animals worked with FDA to voluntarily withdraw approval of indications that were not considered necessary for assuring animal health (production indications), and voluntarily change all remaining approved uses of such new animal drugs from OTC to either Veterinary Feed Directive or Rx marketing status, as applicable.[1]

Although all medically important antimicrobials used in feed or water for food-producing animals are currently under veterinary oversight, some other dosage form products (*e.g.,* injectable, tablet, intramammary infusion) intended for use in food-producing and non-food-producing animals remain available OTC. This draft guidance, when finalized, will provide sponsors with specific recommendations on how to facilitate voluntary changes to the approved conditions of use of these drugs to prescription marketing status. The voluntary process outlined in this draft guidance will help to ensure new animal drugs containing antimicrobials of human medical importance are administered only under veterinary oversight and only for therapeutic uses.

II. Significance of Guidance

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on veterinary oversight of medically important antimicrobial drugs administered to animals. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This draft guidance is not subject to Executive Order 12866.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in section 512(n)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(n)(1)) have been approved under OMB control number 0910–0669. The collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0032.

IV. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *https://www.regulations.gov*.

Dated: September 18, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–20688 Filed 9–23–19; 11:15 am]

BILLING CODE 4164–01–P

[1] See GFI #213, ''New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209'' (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-213-new-animal-drugs-and-new-animal-drug-combination-products-administered-or-medicated-feed*)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Assistant Secretary for Administration; Delegation of Authority

Notice is hereby given that I have delegated to the Assistant Secretary for Preparedness and Response (ASPR); the Director, Centers for Disease Control and Prevention (CDC); the Administrator, Health Resources and Services Administration (HRSA); the Director, National Institutes for Health (NIH); the Director, Office of Global Affairs (OGA); and the Administrator, Substance Abuse and Mental Health Services Administration (SAMHSA) the authority vested in the Secretary by section 212(l) of the Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019 (FY 19 HHS Appropriations Act) Public Law 115–245, division B, title II, (September 28, 2018), or substantially similar authorities vested in me in the future by Congress, in order to carry out international health activities, including HIV/AIDS and other infectious disease, chronic and environmental disease, and other health activities abroad. Section 212(l) of the FY19 HHS Appropriations

Act permits the Secretary of HHS to exercise authority equivalent to that available to the Secretary of State under 22 U.S.C. 2669(c) to award personal services contracts for work performed in foreign countries.

The authority delegated herein includes the authority to determine the necessity of negotiating, executing, and performing such contracts without regard to statutory provisions as relate to the negotiation, making, and performance of contracts and performance of work in the United States. This authority is immediately revoked in the event that any subsequent fiscal year HHS appropriations act does not contain the provision currently in section 212(1) or substantially similar authority.

The Director, CDC may redelegate this authority to the Chief Operating Officer, CDC for a period of one (1) year from the effective date of this delegation to respond to the current Ebola outbreak. This authority may not be further redelegated except as noted above.

The delegatees shall consult with the Secretary of State and relevant Chief of Mission to ensure that this authority is exercised in a manner consistent with section 207 of the Foreign Service Act of 1980 and other applicable statutes administered by the Department of State.

This delegation became effective upon date of signature. In addition, I hereby affirm and ratify any actions taken by the delegatees or their subordinates which involved the exercise of the authorities delegated herein, or substantially similar authorities vested in me by prior annual HHS appropriations acts, prior to the effective date of the delegation.

Dated: September 19, 2019.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2019–20840 Filed 9–24–19; 8:45 am]

BILLING CODE 4151–17–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Presidential Advisory Council on HIV/AIDS

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Service is hereby giving notice that the Presidential Advisory Council on HIV/AIDS (PACHA or the Council) will be holding the 65th full Council meeting in Miami, Florida. Miami-Dade County is one of the counties indicated in *Ending the HIV Epidemic: A Plan for America.* Agenda items will include an update on HIV and the Latinx Community, Ending the HIV Epidemic in Florida and Puerto Rico, addressing the unique needs in Florida and Puerto Rico, a federal panel to discuss federal efforts and mechanisms to ensure continued community engagement, and a presentation on performance indicators for tracking the Initiative. The meeting will be open to the public; a public comment session will be held during the meeting. Pre-registration is encouraged for members of the public who wish to attend the meeting and who wish to participate in the public comment session. Individuals who wish to attend the meeting and/or send in their public comment via email should send an email to Caroline Talev, MPA, at *Caroline.Talev@hhs.gov.* Pre-Registration must be complete by Tuesday, October 15, 2019.

DATES: The Council meeting is scheduled to convene on Monday, October 21, 2019 from approximately 1:30 p.m. to 5:30 p.m. ET and Tuesday, October 22, 2019 from approximately 9:00 a.m. to 5:00 p.m. ET (times are tentative and subject to change). The meeting agenda will be posted on the PACHA web page at *https://www.hiv.gov/federal-response/pacha/about-pacha.* Public attendance is limited to available space.

ADDRESSES: Miami Marriott Biscayne Bay, 1633 N Bayshore Drive, Miami, Florida 33132.

FOR FURTHER INFORMATION CONTACT: Ms. Caroline Talev, MPA, Public Health Analyst, Presidential Advisory Council on HIV/AIDS, 330 C Street SW, Room L106B, Washington, DC 20024; (202) 795–7622 or *Caroline.Talev@hhs.gov.* Additional information can be obtained by accessing the Council's page on the *HIV.gov* site at *www.hiv.gov/pacha.*

SUPPLEMENTARY INFORMATION: PACHA was established by Executive Order 12963, dated June 14, 1995, as amended by Executive Order 13009, dated June 14, 1996 and is currently operating under the authority given in Executive Order 13811, dated September 29, 2017. The Council was established to provide advice, information, and recommendations to the Secretary regarding programs and policies intended to promote effective prevention and care of HIV infection and AIDS. The functions of the Council are solely advisory in nature.

The Council consists of not more than 25 members. Council members are selected from prominent community leaders with particular expertise in, or knowledge of, matters concerning HIV and AIDS, public health, global health, philanthropy, marketing or business, as well as other national leaders held in high esteem from other sectors of society. Council members are appointed by the Secretary or designee, in consultation with the White House. The agenda for will be posted on HIV.gov at *https://www.hiv.gov/federal-response/pacha/about-pacha.*

Public attendance at the meeting is limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify Caroline Talev at *Caroline.Talev@hhs.gov.* Due to space constraints, pre-registration for public attendance is advisable and can be accomplished by contacting Caroline Talev at *Caroline.Talev@hhs.gov* by close of business Tuesday, October 15, 2019. Members of the public will have the opportunity to provide comments during the meeting. Comments will be limited to no more than three minutes per speaker. Any individual who wishes to participate in the public comment session must register with Caroline Talev at *Caroline.Talev@hhs.gov* by close of business Tuesday, October 15, 2019; registration for public comment will not be accepted by telephone. Individuals are encouraged to provide a written statement of any public comment(s) for accurate minute taking purposes. Any members of the public who wish to have printed material distributed to PACHA members at the meeting are asked to submit, at a minimum, 1 copy of the material(s) to Caroline Talev, no later than close of business on Tuesday, October 15, 2019.

Dated: September 16, 2019.

B. Kaye Hayes,

Principal Deputy Director, Office of Infectious Disease and HIV/AIDS Policy, Executive Director, Presidential Advisory Council on HIV/AIDS, Office of the Assistant Secretary for Health, Department of Health and Human Services.

[FR Doc. 2019–20783 Filed 9–24–19; 8:45 am]

BILLING CODE 4150–43–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 October 21, 2019 meeting, the Advisory Council will welcome six new members, and discuss ways to increase access to long-term services and supports that support people with dementia and their caregivers in their homes and the community including innovative state programs. Federal workgroups will also provide updates on work completed in the last quarter, as well as an overview of the 2019 Update to the National Plan to Address Alzheimer's Disease.

DATES: The meeting will be held on October 21, 2019 from 9:00 am to 4:30 pm EST.

ADDRESSES: The meeting will be held in Room 800 in the Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201.

Comments: Time is allocated on the agenda to hear public comments. The time for oral comments will be limited to two (2) minutes per individual. In lieu of oral comments, formal written comments may be submitted for the record 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: Seating may be limited. Those wishing to attend the meeting must send an email to *napa@hhs.gov* and put ''October 21 Meeting Attendance'' in the subject line by Friday, October 11 so that their names may be put on a list of expected attendees and forwarded to the security officers at the Department of Health and Human Services. Any interested member of the public who is a non-U.S. citizen should include this information at the time of registration to ensure that the appropriate security procedure to gain entry to the building is carried out. Although the meeting is open to the public, procedures governing security and the entrance to Federal buildings may change without notice. If you wish to make a public comment, you must note that within your email.

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: The Advisory Council will welcome six new members, and discuss ways to increase access to long-term services and supports that support people with dementia and their caregivers in their homes and the community including innovative state programs. Federal workgroups will also provide updates on work completed in the last quarter, as well as an overview of the 2019 Update to the National Plan to Address Alzheimer's Disease.

Procedure and Agenda: This meeting is open to the public. Please allow 30 minutes to go through security and walk to the meeting room. The meeting will also be webcast at *www.hhs.gov/live.*

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: September 17, 2019.

Brenda Destro

Deputy Assistant Secretary for Planning and Evaluation, Office of Human Services Policy.

[FR Doc. 2019–20784 Filed 9–24–19; 8:45 am]

BILLING CODE 4150–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel Fellowships: Cell Biology, Developmental Biology and Bioengineering.

Date: October 24–25, 2019.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Raj K Krishnaraju, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6190, Bethesda, MD 20892, 301–435–1047, *kkrishna@csr.nih.gov.*

Name of Committee: Digestive, Kidney and Urological Systems Integrated Review Group Systemic Injury by Environmental Exposure.

Date: October 24–25, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Sir Francis Drake Hotel, 450 Powell Street at Sutter, San Francisco, CA 94102.

Contact Person: Meenakshisundar Ananthanarayanan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4200, Bethesda, MD 20817, 301–435–1234, *ananth.ananthanarayanan@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel Fellowships: Biophysical, Physiological, Pharmacological and Bioengineering Neuroscience.

Date: October 24–25, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Wyndham Grand Chicago Riverfront, 71 E. Wacker Drive, Chicago, IL 60601.

Contact Person: Sussan Paydar, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, RM 5222, Bethesda, MD 20817, (301) 827–4994, *sussan.paydar@nih.gov.*

Name of Committee: Population Sciences and Epidemiology Integrated Review Group Cancer, Heart, and Sleep Epidemiology A Study Section.

Date: October 24–25, 2019.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Marriott Wardman Park Washington DC Hotel, 2660 Woodley Road NW, Washington, DC 20008.

Contact Person: Denise Wiesch, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3138, MSC 7770, Bethesda, MD 20892, (301) 437–3478, *wieschd@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel Member Conflict: Biological Chemistry and Macromolecular Biophysics.

Date: October 24–25, 2019.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Sergei Ruvinov, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4158, MSC 7806, Bethesda, MD 20892, 301–435–1180, *ruvinser@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel Mechanisms of Emotion, Stress and Health.

Date: October 24, 2019.

Time: 4:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, Montgomery County Conference Center Facility, 5701 Marinelli Road, North Bethesda, MD 20852.

Contact Person: Maribeth Champoux, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3182, MSC 7759, Bethesda, MD 20892, 301–594–3163, *champoum@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel Interventions to Prevent and Treat Addictions (IPTA).

Date: October 25, 2019.

Time: 8:00 a.m. to 9:00 a.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Palomar, 2121 P Street NW, Washington, DC 20037.

Contact Person: Lee S Mann, Ph.D, JD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3224, MSC 7808, Bethesda, MD 20892, (301) 435–0677, *mannl@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel PAR Panel: Genomics and Animal/Biological Resource Facilities.

Date: October 25, 2019.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Luis Dettin, Ph.D, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2208, Bethesda, MD 20892, 301 451 1327, *dettinle@csr.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: September 19, 2019.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–20752 Filed 9–24–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Pediatric Trauma and Injury Prevention.

Date: November 18, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Kimberly Lynette Houston, M.D., Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6710B Rockledge Drive, Rm. 2127B, Bethesda, MD 20892–7510, 301–827–4902, *kimberly.houston@nih.gov*.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; The Role of Stem/Progenitor Cells in the Pathogenesis and Treatment of Gynecologic Disorders (R21).

Date: December 9, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Peter Zelazowski, Ph.D., Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6710B Rockledge Drive, Rm. 2125D, Bethesda, MD 20892–7510, 301–435–6902, *peter.zelazowski@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: September 19, 2019.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–20759 Filed 9–24–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; Application and Impact of Clinical Research Training on Healthcare Professionals in Academia and Clinical Research (Office of the Director)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: Desk Officer for NIH.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Anne Zajicek, Deputy Director, Office of Clinical Research, OD, NIH, Building 1, Room 208A, 1 Center Drive, Bethesda, MD 20892, or call non-toll-free number (301) 480–9913 or Email your request, including your address to: *zajiceka@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** on Friday, July 12, 2019, Volume 84, pages 33270–33272 (64 FR 15367) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

The Office of Clinical Research, Office of the Director, National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed Collection: Application and Impact of Clinical Research Training on Healthcare Professionals in Academia and Clinical Research, Office of Clinical Research (OCR), National Institutes of Health (NIH), Office of the Director (OD).

Need and Use of Information Collection: The purpose of this survey is to assess the long-term impact and outcomes of clinical research training programs provided by the Office of Clinical Research located in the NIH Office of the Director (OD) over a ten-year follow-up period. The information received from respondents will provide insight on the following: Impact of the courses on (a) promotion of professional competence, (b) research productivity and independence, and (c) future career development within clinical, translational and academic research settings. These surveys will provide preliminary data and guidance in (1) developing recommendations for collecting outcomes to assess the effectiveness of the training courses, and (2) tracking the impact of the curriculum on participants' ability to perform successfully in academic, non-academic, research, and non-research settings.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 1,589.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondents	Estimated number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hours
OCR Learning Portal Registration (Attachment 1)	Healthcare Professionals.	2000	1	10/60	333
	Students	1000	1	10/60	167
	General Public	500	1	10/60	83
IPPCR Lecture Evaluation (Attachment 2)	Healthcare Professionals.	750	1	10/60	125
	Students	500	1	10/60	83
	General Public	250	1	10/60	42
IPPCR Final Course Evaluation (Attachment 4)	Healthcare Professionals.	750	1	10/60	125
	Students	500	1	10/60	83
	General Public	250	1	10/60	42
PCP Lecture Evaluation (Attachment 3)	Healthcare Professionals.	750	1	10/60	125
	Students	500	1	10/60	83
	General Public	250	1	10/60	42
PCP Final Course Evaluation (Attachment 5)	Healthcare Professionals.	750	1	10/60	125
	Students	500	1	10/60	83
	General Public	250	1	10/60	42
NIH Summer Course in Clinical and Translational Research Course Evaluation (Attachment 6).	Healthcare Professionals.	20	1	10/60	3
Sabbatical in Clinical Research Management Course Evaluation (Attachment 7).	Healthcare Professionals.	20	1	10/60	3
Total			9,540		1,589

Dated: September 18, 2019.

Lawrence A. Tabak,

Principal Deputy Director, National Institutes of Health.

[FR Doc. 2019–20747 Filed 9–24–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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: Heart, Lung, and Blood Initial Review Group Single-Site and Pilot Clinical Trials Review Committee NHLBI Single-Site Clinical Trials & Pilot Studies.

Date: October 30–31, 2019.

Time: 8:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites—Chevy Chase Pavilion, Tenley Town Ballroom, 4300 Military Road NW, Washington, DC 20015.

Contact Person: Carol (Chang-Sook) Kim, Ph.D., Scientific Review Administrator, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7188, Bethesda, MD 20892, 301–827–7940, *carolko@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: September 19, 2019.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–20753 Filed 9–24–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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: Heart, Lung, and Blood Initial Review Group; NHLBI Mentored Patient-Oriented Research.

Date: October 24–25, 2019.

Time: 8:30 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The William F. Bolger Center, 9600 Newbridge Drive, Potomac, MD 20854.

Contact Person: Stephanie Johnson Webb, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7196, Bethesda, MD 20892, 301–827–7992, *stephanie.webb@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: September 19, 2019.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–20757 Filed 9–24–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, NIA.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual grant applications conducted by the NATIONAL INSTITUTE ON AGING, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, NIA.

Date: October 13–15, 2020.

Closed: October 13, 2020, 8:00 a.m. to 8:20 a.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Place: National Institute on Aging, Biomedical Research Center, 3rd Floor Conference Room 03C227, 251 Bayview Boulevard, Baltimore, MD 21224.

Open: October 13, 2020, 8:20 a.m. to 11:50 a.m.

Agenda: Committee discussion, individual presentations, laboratory overview.

Place: National Institute on Aging, Biomedical Research Center, 3rd Floor Conference Room 03C227, 251 Bayview Boulevard, Baltimore, MD 21224.

Closed: October 13, 2020, 11:50 a.m. to 1:05 p.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Place: National Institute on Aging, Biomedical Research Center, 3rd Floor Conference Room 03C227, 251 Bayview Boulevard, Baltimore, MD 21224.

Open: October 13, 2020, 1:05 p.m. to 4:05 p.m.

Agenda: Committee discussion, individual presentations, laboratory overview.

Place: National Institute on Aging, Biomedical Research Center, 3rd Floor Conference Room 03C227, 251 Bayview Boulevard, Baltimore, MD 21224.

Closed: October 13, 2020, 4:05 p.m. to 5:45 p.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Place: National Institute on Aging, Biomedical Research Center, 3rd Floor Conference Room 03C227, 251 Bayview Boulevard, Baltimore, MD 21224.

Closed: October 14, 2020, 8:00 a.m. to 8:20 a.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Place: National Institute on Aging, Biomedical Research Center, 3rd Floor Conference Room 03C227, 251 Bayview Boulevard, Baltimore, MD 21224.

Open: October 14, 2020, 8:20 a.m. to 11:50 a.m.

Agenda: Committee discussion, individual presentations, laboratory overview.

Place: National Institute on Aging, Biomedical Research Center, 3rd Floor Conference Room 03C227, 251 Bayview Boulevard, Baltimore, MD 21224.

Closed: October 14, 2020, 11:50 a.m. to 1:05 p.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Place: National Institute on Aging, Biomedical Research Center, 3rd Floor Conference Room 03C227, 251 Bayview Boulevard, Baltimore, MD 21224.

Open: October 14, 2020, 1:05 p.m. to 3:05 p.m.

Agenda: Committee discussion, individual presentations, laboratory overview.

Place: National Institute on Aging, Biomedical Research Center, 3rd Floor Conference Room 03C227, 251 Bayview Boulevard, Baltimore, MD 21224.

Closed: October 14, 2020, 3:05 p.m. to 3:55 p.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Place: National Institute on Aging, Biomedical Research Center, 3rd Floor Conference Room 03C227, 251 Bayview Boulevard, Baltimore, MD 21224.

Open: October 14, 2020, 3:55 p.m. to 4:55 p.m.

Agenda: Committee discussion, individual presentations, laboratory overview.

Place: National Institute on Aging, Biomedical Research Center, 3rd Floor Conference Room 03C227, 251 Bayview Boulevard, Baltimore, MD 21224.

Closed: October 14, 2020, 4:55 p.m. to 5:55 p.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Place: National Institute on Aging, Biomedical Research Center, 3rd Floor Conference Room 03C227, 251 Bayview Boulevard, Baltimore, MD 21224.

Closed: October 15, 2020, 8:00 a.m. to 8:20 a.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Place: National Institute on Aging, Biomedical Research Center, 3rd Floor Conference Room 03C227, 251 Bayview Boulevard, Baltimore, MD 21224.

Open: October 15, 2020, 8:20 a.m. to 11:50 a.m.

Agenda: Committee discussion, individual presentations, laboratory overview.

Place: National Institute on Aging, Biomedical Research Center, 3rd Floor Conference Room 03C227, 251 Bayview Boulevard, Baltimore, MD 21224.

Closed: October 15, 2020, 11:50 a.m. to 12:50 p.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Place: National Institute on Aging, Biomedical Research Center, 3rd Floor Conference Room 03C227, 251 Bayview Boulevard, Baltimore, MD 21224.

Contact Person: Luigi Ferrucci, MD, Ph.D., Scientific Director, National Institute on Aging, 251 Bayview Boulevard, Suite 100, Room 4C225, Baltimore, MD 21224, (410) 558–8110, *lf27z@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: September 19, 2019.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–20754 Filed 9–24–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Immunology Integrated Review Group Immunity and Host Defense Study Section.

Date: October 24–25, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The William F. Bolger Center, 9600 Newbridge Drive, Potomac, MD 20854.

Contact Person: Scott Jakes, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4198, MSC 7812, Bethesda, MD 20892 (301) 435–1506 *jakesse@mail.nih.gov*

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group Molecular Neuropharmacology and Signaling Study Section.

Date: October 24–25, 2019.

Time: 8:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Wyndham Grand Chicago Riverfront, 71 E Wacker Drive, Chicago, IL 60601.

Contact Person: Vanessa S Boyce, Ph.D., Scientific Review Officer Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rm. 4016F, MSC 7812, Bethesda, MD 20892, (301) 435–0908, *boycevs@csr.nih.gov*.

Name of Committee: Oncology 1-Basic Translational Integrated Review Group Cancer Genetics Study Section.

Date: October 24–25, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Zoe Fisherman's Wharf, 425 North Point Street, San Francisco, CA 94133.

Contact Person: Juraj Bies, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4158, MSC 7806, Bethesda, MD 20892 (301)435–1256 *biesj@mail.nih.gov*.

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group Biobehavioral Mechanisms of Emotion, Stress and Health Study Section.

Date: October 24–25, 2019.

Time: 8:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel Conference Center, Montgomery County Conference Center Facility, 5701 Marinelli Road, North Bethesda, MD 20852.

Contact Person: Benjamin Greenberg Shapero, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3182, Bethesda, MD 20892, (301) 402–4786, *shaperobg@mail.nih.gov*.

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group Emerging Imaging Technologies and Applications Study Section.

Date: October 24–25, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Ritz-Carlton Hotel, 1700 Tysons Boulevard, McLean, VA 22102.

Contact Person: Songtao Liu, MD Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5118, Bethesda, MD 20817, (301) 827–6828, *songtao.liu@nih.gov*.

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group Drug Discovery for the Nervous System Study Section.

Date: October 24–25, 2019.

Time: 8:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Radisson Plaza Lord Baltimore, 20 West Baltimore Street, Baltimore, MD 21201.

Contact Person: Mary Custer, Ph.D. Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4148, MSC 7850 Bethesda, MD 20892, (301) 435–1164, *custerm@csr.nih.gov*.

Name of Committee: Bioengineering Sciences & Technologies Integrated Review Group Modeling and Analysis of Biological Systems Study Section.

Date: October 24–25, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The William F. Bolger Center, 9600 Newbridge Drive, Potomac, MD 20854.

Contact Person: Craig Giroux, Ph.D., Scientific Review Officer, BST IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5150, Bethesda, MD 20892, (301) 435–2204, *girouxcn@csr.nih.gov*.

Name of Committee: Oncology 2—Translational Clinical Integrated Review Group Cancer Prevention Study Section.

Date: October 24–25, 2019.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Marriott Courtyard Gaithersburg Washingtonian Ctr, 204 Boardwalk Place, Gaithersburg, MD 20878.

Contact Person: Svetlana Kotliarova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214, Bethesda, MD 20892, (301) 594–7945, *kotliars@mail.nih.gov*.

Name of Committee: Digestive, Kidney and Urological Systems Integrated Review Group Gastrointestinal Mucosal Pathobiology Study Section.

Date: October 24–25, 2019.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: American Inn of Bethesda, 8130 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Aiping Zhao, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2188, Bethesda, MD 20892–7818, (301)435–0682, *zhaoa2@csr.nih.gov*.

Name of Committee: Oncology 1-Basic Translational Integrated Review Group Cancer Etiology Study Section.

Date: October 24–25, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Ola Mae Zack Howard, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Dr., Room 4192, MSC 7806, Bethesda, MD 20892, (301) 451–4467 *howardz@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS).

Dated: September 19, 2019.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–20756 Filed 9–24–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Vascular and Hematology Integrated Review Group Hemostasis and Thrombosis Study Section.

Date: October 21, 2019.

Time: 8:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Ai-Ping Zou, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118, MSC 7814, Bethesda, MD 20892, 301–408–9497, *zouai@csr.nih.gov*.

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review Group Cardiac Contractility, Hypertrophy, and Failure Study Section.

Date: October 23–24, 2019.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Ritz-Carlton Hotel at Pentagon City, 1250 South Hayes Street, Arlington, VA 22202.

Contact Person: Abdelouahab Aitouche, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4222, MSC 7814, Bethesda, MD 20892, 301–435–2365, *aitouchea@csr.nih.gov*.

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review Group Myocardial Ischemia and Metabolism Study Section.

Date: October 24–25, 2019.

Time: 8:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Melrose Hotel, 2430 Pennsylvania Avenue NW, Washington, DC 20037.

Contact Person: Kimm Hamann, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118A, MSC 7814, Bethesda, MD 20892, 301–435–5575, *hamannkj@csr.nih.gov*.

Name of Committee: Risk, Prevention and Health Behavior Integrated Review Group Interventions to Prevent and Treat Addictions Study Section.

Date: October 24–25, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Palomar, 2121 P Street NW, Washington, DC 20037.

Contact Person: Miriam Mintzer, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive Room 3108, Bethesda, MD 20892, (301) 523–0646, *mintzermz@csr.nih.gov*.

Name of Committee: Infectious Diseases and Microbiology Integrated Review Group Virology—A Study Section.

Date: October 24–25, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Hotel and Suites, Alexandria-Old Towne, 625 First Street, Alexandria, VA 22314.

Contact Person: Kenneth M Izumi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3204, MSC 7808, Bethesda, MD 20892, 301–496–6980, *izumikm@csr.nih.gov*.

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group Imaging Guided Interventions and Surgery Study Section.

Date: October 24–25, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Liaison Washington Capitol Hill, 415 New Jersey Avenue NW, Washington, DC 20001.

Contact Person: Ileana Hancu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5116, Bethesda, MD 20817, 3014023911, *ileana.hancu@nih.gov*.

Name of Committee: Infectious Diseases and Microbiology Integrated Review Group Bacterial Pathogenesis Study Section.

Date: October 24, 2019.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Marines' Memorial Club & Hotel, 609 Sutter Street, San Francisco, CA 94102.

Contact Person: Marci Scidmore, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3192, MSC 7808, Bethesda, MD 20892, 301–435–1149, *marci.scidmore@nih.gov*.

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group Integrative and Clinical Endocrinology and Reproduction Study Section.

Date: October 24, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Double Tree by Hilton-Silver Spring, 8727 Colesville Road, Silver Spring, MD 20910.

Contact Person: Dianne Hardy, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6175, MSC 7892, Bethesda, MD 20892, 301–435–1154, *dianne.hardy@nih.gov*.

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group Oral, Dental and Craniofacial Sciences Study Section.

Date: October 24–25, 2019.

Time: 8:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Garden Inn Washington DC/Georgetown, 2201 M. Street NW, Washington, DC 20037.

Contact Person: Yi-Hsin Liu, Ph.D. Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7814, Bethesda, MD 20892, 301–435–1781, *liuyh@csr.nih.gov*.

Name of Committee: Immunology Integrated Review Group Vaccines Against Microbial Diseases Study Section.

Date: October 24–25, 2019.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Jian Wang, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4218, MSC 7812, Bethesda, MD 20892, (301) 435–2778, *wangjia@csr.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS).

Dated: September 19, 2019.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–20758 Filed 9–24–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–6180–N–01]

Statutorily Mandated Designation of Difficult Development Areas and Qualified Census Tracts for 2020

AGENCY: Office of the Assistant Secretary for Policy Development and Research, HUD.

ACTION: Notice.

SUMMARY: This document designates ''Difficult Development Areas'' (DDAs) and ''Qualified Census Tracts'' (QCTs) for purposes of the Low-Income Housing Tax Credit (LIHTC) under Internal Revenue Code (IRC) Section 42, as enacted by the Tax Reform Act of 1986. The United States Department of Housing and Urban Development (HUD) makes new DDA and QCT designations annually.

FOR FURTHER INFORMATION CONTACT: For questions on how areas are designated and on geographic definitions, contact Michael K. Hollar, Senior Economist, Public Finance and Regulatory Analysis Division, Office of Policy Development and Research, Department of Housing and Urban Development, 451 Seventh Street SW, Room 8216, Washington, DC 20410–6000; telephone number 202–402–5878, or send an email to *Michael.K.Hollar@hud.gov.* For specific legal questions pertaining to Section 42, contact Branch 5, Office of the Associate Chief Counsel, Passthroughs and Special Industries, Internal Revenue Service, 1111 Constitution Avenue NW, Washington, DC 20224; telephone number 202–317–4137, fax number 202–317–6731. For questions about the ''HUBZone'' program, contact Bruce Purdy, Deputy Director, HUBZone Program, Office of Government Contracting and Business Development, U.S. Small Business Administration, 409 Third Street SW, Suite 8800, Washington, DC 20416; telephone number 202–205–7554, or send an email to *hubzone@sba.gov.* (These are not toll-free telephone numbers.) A text telephone is available for persons with hearing or speech impairments at 800–877–8339. Additional copies of this notice are available through HUD User at 800–245–2691 for a small fee to cover duplication and mailing costs.

Copies Available Electronically: This notice and additional information about DDAs and QCTs including the lists of DDAs and QCTs are available electronically on the internet at *http://www.huduser.org/datasets/qct.html.*

SUPPLEMENTARY INFORMATION:

I. This Notice

Under 26 U.S.C. 42(d)(5)(B)(iii)(I), for purposes of the LIHTC, the Secretary of HUD must designate DDAs, which are areas with high construction, land, and utility costs relative to area median gross income (AMGI). This notice designates DDAs for each of the 50 states, the District of Columbia, Puerto Rico, American Samoa, Guam, the Northern Mariana Islands, and the U.S. Virgin Islands. The designations of DDAs in this notice are based on modified Fiscal Year (FY) 2019 Small Area Fair Market Rents (Small Area FMRs), FY 2019 nonmetropolitan county FMRs, FY 2019 income limits, and 2010 Census population counts, as explained below.

Similarly, under 26 U.S.C. 42(d)(5)(B)(ii)(I), the Secretary of HUD must designate QCTs, which are areas where either 50 percent or more of the households have an income less than 60 percent of the AMGI for such year or have a poverty rate of at least 25 percent. This notice designates QCTs based on new income and poverty data released in the American Community Survey (ACS). Specifically, HUD relies on the most recent three sets of ACS data to ensure that anomalous estimates, due to sampling, do not affect the QCT status of tracts.

II. Data Used To Designate DDAs

Data from the 2010 Census on total population of metropolitan areas, metropolitan ZIP Code Tabulation Areas (ZCTAs), and nonmetropolitan areas are used in the designation of DDAs. The Office of Management and Budget (OMB) published updated metropolitan areas in OMB Bulletin No. 15–01 on July 15, 2015. FY 2019 FMRs and FY 2019 income limits used to designate DDAs are based on these metropolitan statistical area (MSA) definitions, with modifications to account for substantial differences in rental housing markets (and, in some cases, median income levels) within MSAs. Small Area FMRs are calculated for the ZCTAs, or portions of ZCTAs within the metropolitan areas defined by OMB Bulletin No. 15–01.

III. Data Used To Designate QCTs

Data from the 2010 Census on total population of census tracts, metropolitan areas, and the nonmetropolitan parts of states are used in the designation of QCTs. The FY 2019 income limits used to designate QCTs are based on these MSA definitions with modifications to account for substantial differences in rental housing markets (and in some cases median income levels) within MSAs. This QCT designation uses the OMB metropolitan area definitions published in OMB Bulletin No. 15–01 on July 15, 2015, without modification for purposes of evaluating how many census tracts can be designated under the population cap but uses the HUD-modified definitions and their associated area median incomes for determining QCT eligibility.

Because the 2010 Decennial Census did not include questions on respondent household income, HUD uses ACS data to designate QCTs. The ACS tabulates data collected over 5 years to provide estimates of socioeconomic variables for small areas containing fewer than 65,000 persons, such as census tracts. Due to sample-related anomalies in estimates from year to year, HUD utilizes three sets of ACS tabulations to ensure that anomalous estimates do not affect QCT status.

IV. Background

The U.S. Department of the Treasury (Treasury) and its Internal Revenue Service (IRS) are authorized to interpret and enforce the provisions of the LIHTC found at IRC Section 42. In order to assist in understanding HUD's mandated designation of DDAs and QCTs for use in administering IRC Section 42, a summary of the section is provided below. The following summary does not purport to bind Treasury or the IRS in any way, nor does it purport to bind HUD, since HUD has authority to interpret or administer the IRC only in instances where it receives explicit statutory delegation.

V. Summary of the Low-Income Housing Tax Credit

A. Determining Eligibility

The LIHTC is a tax incentive intended to increase the availability of low-income rental housing. IRC Section 42 provides an income tax credit to certain owners of newly constructed or substantially rehabilitated low-income rental housing projects. The dollar amount of the LIHTC available for allocation by each state (credit ceiling) is limited by each state's population. Each state is allowed a credit ceiling based on a statutory formula indicated at IRC Section 42(h)(3)(C). According to IRC Section 42(h)(3)(D)(ii), states may carry forward unallocated credits derived from the credit ceiling for one year; however, to the extent such unallocated credits are not used by then, the credits go into a national pool to be redistributed to states as additional credit. State and local housing agencies allocate the state's credit ceiling among

low-income housing buildings whose owners have applied for the credit. Besides IRC Section 42 credits derived from the credit ceiling, under IRC Section 42(h)(4), the LIHTCs may also be available to owners of buildings based on the percentage of certain building costs financed by tax-exempt bond proceeds. Credits available under the tax-exempt bond ''volume cap'' do not reduce the credits available from the credit ceiling.

The credits allocated to a building are based on the cost of units placed in service as low-income units under particular minimum occupancy and maximum rent criteria. Prior to the enactment of the Consolidated Appropriations Act of 2018 (Act), under IRC Section 42(g)(1), a building was required to meet one of two tests to be eligible for the LIHTC; either: (1) 20 percent of the units must be rent-restricted and occupied by tenants with incomes no higher than 50 percent of the area median gross income (AMGI), or (2) 40 percent of the units must be rent-restricted and occupied by tenants with incomes no higher than 60 percent of AMGI. A unit is ''rent-restricted'' if the gross rent, including an allowance for tenant-paid utilities, does not exceed 30 percent of the imputed income limitation (*i.e.,* 50 percent or 60 percent of AMGI) applicable to that unit. The rent and occupancy thresholds remain in effect for at least 15 years, and building owners are required to enter into agreements to maintain the low-income character of the building for at least an additional 15 years.

The Act added a third test, the average income test. See § 42(g)(1)(C), as added by section 103(a)(1), Division T, of the Act. A building meets the minimum requirements of the average income test if 40 percent or more (25 percent or more in the case of a project located in a high cost housing area as described in IRS Section 142(d)(6)) of the residential units in such project are both rent-restricted and occupied by individuals whose income does not exceed the imputed income limitation designated by the taxpayer with respect to the respective unit. The taxpayer designates the imputed income limitation for each unit. The designated imputed income limitation of any unit is determined in 10-percentage-point increments, and may be designated as 20, 30, 40, 50, 60, 70, or 80 percent of AMGI. The average of the imputed income limitations designated must not exceed 60 percent of AMGI. See § 42(g)(1)(C), as added by section 103(a)(2), Division T, of the Act.

B. Calculating the LIHTC

The LIHTC reduces income tax liability dollar-for-dollar. It is taken annually for a term of 10 years and is intended to yield a present value of either: (1) 70 percent of the ''qualified basis'' for new construction or substantial rehabilitation expenditures that are not federally subsidized (as defined in IRC Section 42(i)(2)), or (2) 30 percent of the qualified basis for the cost of acquiring certain existing buildings or projects that are federally subsidized. The tax credit rates are determined monthly under procedures specified in IRC Section 42 and cannot be less than 9 percent for new buildings that are not federally subsidized. Individuals can use the credits up to a deduction equivalent of $25,000 (the actual maximum amount of credit that an individual can claim depends on the individual's marginal tax rate). For buildings placed in service after December 31, 2007, individuals can use the credits against the alternative minimum tax. Corporations, other than S or personal service corporations, can use the credits against ordinary income tax. These corporations also can deduct losses from the project.

The qualified basis represents the product of the building's ''applicable fraction'' and its ''eligible basis.'' The applicable fraction is based on the number of low-income units in the building as a percentage of the total number of units, or based on the floor space of low-income units as a percentage of the total floor space of residential units in the building. The eligible basis is the adjusted basis attributable to acquisition, rehabilitation, or new construction costs (depending on the type of LIHTC involved). These costs include amounts chargeable to a capital account that are incurred prior to the end of the first taxable year in which the qualified low-income building is placed in service or, at the election of the taxpayer, the end of the succeeding taxable year. In the case of buildings located in designated DDAs or designated QCTs, or buildings designated by the state agency, eligible basis can be increased up to 130 percent from what it would otherwise be. This means that the available credits also can be increased by up to 30 percent. For example, if a 70 percent credit is available, it effectively could be increased to as much as 91 percent (70 percent x 130 percent).

C. Defining Difficult Development Areas (DDAs) and Qualified Census Tracts (QCTs)

As stated above, IRC Section 42(d)(5)(B)(iii) defines a DDA as an area designated by the Secretary of HUD that has high construction, land, and utility costs relative to the AMGI. All designated DDAs in metropolitan areas (taken together) may not contain more than 20 percent of the aggregate population of all metropolitan areas, and all designated areas not in metropolitan areas may not contain more than 20 percent of the aggregate population of all nonmetropolitan areas.

Similarly, IRC Section 42(d)(5)(B)(ii) defines a QCT as an area designated by the Secretary of HUD where, for the most recent year for which census data are available on household income in such tract, either 50 percent or more of the households in the tract have an income which is less than 60 percent of the AMGI or the tract's poverty rate is at least 25 percent. All designated QCTs in a single metropolitan area or nonmetropolitan area (taken together) may not contain more than 20 percent of the population of that metropolitan or nonmetropolitan area. Thus, unlike the restriction on DDA designations, QCTs are restricted by the total population of each individual area as opposed to the aggregate population across all metropolitan areas and nonmetropolitan areas.

IRC Section 42(d)(5)(B)(v) allows states to award an increase in basis up to 30 percent to buildings located outside of federally designated DDAs and QCTs if the increase is necessary to make the building financially feasible. This state discretion applies only to buildings allocated credits under the state housing credit ceiling and is not permitted for buildings receiving credits entirely in connection with tax-exempt bonds. Rules for such designations shall be set forth in the LIHTC-allocating agencies' qualified allocation plans (QAPs). *See* 26 U.S.C. 42(m).

VI. Explanation of HUD Designation Method

A. 2020 Difficult Development Areas

In developing the 2020 list of DDAs, as required by 26 U.S.C. 42(d)(5)(B)(iii), HUD compared housing costs with incomes. HUD used 2010 Census population for ZCTAs, and nonmetropolitan areas, and the MSA definitions, as published in OMB Bulletin 15–01 on July 15, 2015, with modifications, as described below. In keeping with past practice of basing the coming year's DDA designations on data from the preceding year, the basis for

these comparisons is the FY 2019 HUD income limits for very low-income households (very low-income limits, or VLILs), which are based on 50 percent of AMGI, and modified FMRs based on the FY 2019 FMRs used for the Housing Choice Voucher (HCV) program. For metropolitan DDAs, HUD used Small Area FMRs based on three annual releases of ACS data, to compensate for statistical anomalies which affect estimates for some ZCTAs. For non-metropolitan DDAs, HUD used the FY 2019 FMRs published on August 31, 2018 (83 FR 44644) as updated through March 14, 2019 (84 FR 9371).

In formulating the FY 2019 FMRs and VLILs, HUD modified the current OMB definitions of MSAs to account for differences in rents among areas within each current MSA that were in different FMR areas under definitions used in prior years. HUD formed these ''HUD Metro FMR Areas'' (HMFAs) in cases where one or more of the parts of newly defined MSAs were previously in separate FMR areas. All counties added to metropolitan areas are treated as HMFAs with rents and incomes based on their own county data, where available. HUD no longer requires recent-mover rents to differ by five percent or more in order to form a new HMFA. All HMFAs are contained entirely within MSAs. All nonmetropolitan counties are outside of MSAs and are not broken up by HUD for purposes of setting FMRs and VLILs. (Complete details on HUD's process for determining FY 2019 FMR areas and FMRs are available at *https://www.huduser.gov/portal/datasets/fmr.html#2019.* Complete details on HUD's process for determining FY 2019 income limits are available at *https://www.huduser.gov/portal/datasets/il.html#2019.*)

HUD's unit of analysis for designating metropolitan DDAs consists of ZCTAs, whose Small Area FMRs are compared to metropolitan VLILs. For purposes of computing VLILs in metropolitan areas, HUD considers entire MSAs in cases where these were not broken up into HMFAs for purposes of computing VLILs; and HMFAs within the MSAs that were broken up for such purposes. Hereafter in this notice, the unit of analysis for designating metropolitan DDAs will be called the ZCTA, and the unit of analysis for nonmetropolitan DDAs will be the nonmetropolitan county or county equivalent area. The procedure used in making the DDA designations follows:

1. *Calculate FMR-to-Income Ratios.* For each metropolitan ZCTA and each nonmetropolitan county, HUD calculated a ratio of housing costs to income. HUD used a modified FY 2019 two-bedroom Small Area FMR for ZCTAs, the FY 2019 two-bedroom FMR as published for non-metropolitan counties, and the FY 2019 four-person VLIL for this calculation.

The modified FY 2019 two-bedroom Small Area FMRs for ZCTAs differ from the FY 2019 Small Area FMRs in four ways. First, HUD did not limit the Small Area FMR to 150 percent of its metropolitan area FMR. Second, HUD did not limit annual decreases in Small Area FMRs to ten percent, which was first applied in the FY 2019 FMR calculations. Third, HUD adjusted the Small Area FMRs in New York City using the New York City Housing and Vacancy Survey, which is conducted by the U.S. Census Bureau, to adjust for the effect of local rent control and stabilization regulations. No other jurisdictions have provided HUD with data that could be used to adjust Small Area FMRs for rent control or stabilization regulations.[1] Finally, the Small Area FMRs are not limited to the State non-metropolitan minimum FMR.

The numerator of the ratio, representing the development cost of housing, was the area's FY 2019 FMR, or Small Area FMR in metropolitan areas. In general, the FMR is based on the 40th-percentile gross rent paid by recent movers to live in a two-bedroom rental unit.

The denominator of the ratio, representing the maximum income of eligible tenants, was the monthly LIHTC income-based rent limit, which was calculated as 1/12 of 30 percent of 120 percent of the area's VLIL (where the VLIL was rounded to the nearest $50 and not allowed to exceed 80 percent of the AMGI in areas where the VLIL is adjusted upward from its 50 percent-of-AMGI base).

2. *Sort Areas by Ratio and Exclude Unsuitable Areas.* The ratios of the FMR, or Small Area FMR, to the LIHTC income-based rent limit were arrayed in descending order, separately, for ZCTAs and for nonmetropolitan counties. ZCTAs with populations less than 100 were excluded in order to avoid designating areas unsuitable for residential development, such as ZCTAs containing airports.

3. *Select Areas with Highest Ratios and Exclude QCTs.* The DDAs are those areas with the highest ratios that cumulatively comprise 20 percent of the 2010 population of all metropolitan areas and all nonmetropolitan areas. For purposes of applying this population cap, HUD excluded the population in areas designated as 2020 QCTs. Thus, an area can be designated as a QCT or DDA, but not both.

B. Application of Population Caps to DDA Determinations

In identifying DDAs, HUD applied caps, or limitations, as noted above. The cumulative population of metropolitan DDAs cannot exceed 20 percent of the cumulative population of all metropolitan areas, and the cumulative population of nonmetropolitan DDAs cannot exceed 20 percent of the cumulative population of all nonmetropolitan areas.

In applying these caps, HUD established procedures to deal with how to treat small overruns of the caps. The remainder of this section explains those procedures. In general, HUD stops selecting areas when it is impossible to choose another area without exceeding the applicable cap. The only exceptions to this policy are when the next eligible excluded area contains either a large absolute population or a large percentage of the total population, or the next excluded area's ranking ratio, as described above, was identical (to four decimal places) to the last area selected, and its inclusion resulted in only a minor overrun of the cap. Thus, for both the designated metropolitan and nonmetropolitan DDAs, there may be minimal overruns of the cap. HUD believes the designation of additional areas in the above examples of minimal overruns is consistent with the intent of the IRC. As long as the apparent excess is small due to measurement errors, some latitude is justifiable, because it is impossible to determine whether the 20 percent cap has been exceeded. Despite the care and effort involved in a Decennial Census, the Census Bureau and all users of the data recognize that the population counts for a given area and for the entire country are not precise. Therefore, the extent of the measurement error is unknown. There can be errors in both the numerator and denominator of the ratio of populations used in applying a 20 percent cap. In circumstances where a strict application of a 20 percent cap results in an anomalous situation, recognition of the unavoidable imprecision in the census data justifies accepting small variances above the 20 percent limit.

C. Qualified Census Tracts

In developing the list of QCTs, HUD used 2010 Census 100-percent count data on total population, total households, and population in households; the median household

[1] HUD encourages other jurisdictions with rent control laws that affect rents paid by recent movers into existing units to contact HUD about what data might be provided or collected to adjust Small Area FMRs in those jurisdictions.

income and poverty rate as estimated in the 2011–2015, 2012–2016 and 2013–2017, ACS tabulations; the FY 2019 Very Low-Income Limits (VLILs) computed at the HUD Metropolitan FMR Area (HMFA) level to determine tract eligibility; and the MSA definitions published in OMB Bulletin No. 15–01 on July 15, 2015, for determining how many eligible tracts can be designated under the statutory 20 percent population cap.

HUD uses the HMFA-level AMGIs to determine QCT eligibility because the statute, specifically IRC Section 42(d)(5)(B)(iv)(II), refers to the same section of the IRC that defines income for purposes of tenant eligibility and unit maximum rent, specifically IRC Section 42(g)(4). By rule, the IRS sets these income limits according to HUD's VLILs, which, starting in FY 2006 and thereafter, are established at the HMFA level. HUD uses the entire MSA to determine how many eligible tracts can be designated under the 20 percent population cap as required by the statute (IRC Section 42(d)(5)(B)(ii)(III)), which states that MSAs should be treated as singular areas.

The QCTs were determined as follows:

1. *Calculate 60 percent AMGI.* To be eligible to be designated a QCT, a census tract must have 50 percent of its households with incomes below 60 percent of the AMGI or have a poverty rate of 25 percent or more. Due to potential statistical anomalies in the ACS 5-year estimates, one of these conditions must be met in at least 2 of the 3 ACS 5-year tabulations for a tract to be considered eligible for QCT designation. HUD calculates 60 percent of AMGI by multiplying by a factor of 1.2 the HMFA or nonmetropolitan county FY 2019 VLIL adjusted for inflation to match the ACS estimates, which are adjusted to the value of the dollar in the last year of the 5-year group.

2. *Determine Whether Census Tracts Have Less than 50 percent of Households Below 60 percent AMGI.* For each census tract, whether or not 50 percent of households have incomes below the 60 percent income standard (income criterion) was determined by: (a) calculating the average household size of the census tract, (b) adjusting the income standard to match the average household size, and (c) comparing the average-household-size-adjusted income standard to the median household income for the tract reported in each of the three years of ACS tabulations (2011–2015, 2012–2016 and 2013–2017). HUD did not consider estimates of median household income to be statistically reliable unless the margin of error was less than half of the estimate (or a Margin of Error Ratio, MoER, of 50 percent or less). If at least two of the three estimates were not statistically reliable by this measure, HUD determined the tract to be ineligible under the income criterion due to lack of consistently reliable median income statistics across the three ACS tabulations. Since 50 percent of households in a tract have incomes above and below the tract median household income, if the tract median household income is less than the average-household-size-adjusted income standard for the tract, then more than 50 percent of households have incomes below the standard.

3. *Estimate Poverty Rate.* For each census tract, the poverty rate was determined in each of the three releases of ACS tabulations (2011–2015, 2012–2016 and 2013–2017) by dividing the population with incomes below the poverty line by the population for whom poverty status has been determined. As with the evaluation of tracts under the income criterion, HUD applies a data quality standard for evaluating ACS poverty rate data in designating the 2020 QCTs. HUD did not consider estimates of the poverty rate to be statistically reliable unless both the population for whom poverty status has been determined and the number of persons below poverty had MoERs of less than 50 percent of the respective estimates. If at least two of the three poverty rate estimates were not statistically reliable, HUD determined the tract to be ineligible under the poverty rate criterion due to lack of reliable poverty statistics across the ACS tabulations.

4. *Designate QCTs Where 20 percent or Less of Population Resides in Eligible Census Tracts.* QCTs are those census tracts in which 50 percent or more of the households meet the income criterion in at least two of the three years evaluated, or 25 percent or more of the population is in poverty in at least two of the three years evaluated, such that the population of all census tracts that satisfy either one or both of these criteria does not exceed 20 percent of the total population of the respective area.

5. *Designate QCTs Where More than 20 percent of Population Resides in Eligible Census Tracts.* In areas where more than 20 percent of the population resides in eligible census tracts, census tracts are designated as QCTs in accordance with the following procedure:

a. The statistically reliable income and poverty criteria are each averaged over the three ACS tabulations (2011–2015, 2012–2016 and 2013–2017). Statistically reliable values that did not exceed the income and poverty rate thresholds were included in the average.

b. Eligible tracts are placed in one of two groups based on the averaged values of the income and poverty criteria. The first group includes tracts that satisfy both the income and poverty criteria for QCTs for at least two of the three evaluation years; a different pair of years may be used to meet each criterion. The second group includes tracts that satisfy either the income criterion in at least two of the three years, or the poverty criterion in at least two of three years, but not both. A tract must qualify by at least one of the criteria in at least two of the three evaluation years to be eligible.

c. Tracts in the first group are ranked from highest to lowest by the average of the ratios of the tract average-household-size-adjusted income limit to the median household income. Then, tracts in the first group are ranked from highest to lowest by the average of the poverty rates. The two ranks are averaged to yield a combined rank. The tracts are then sorted on the combined rank, with the census tract with the highest combined rank being placed at the top of the sorted list. In the event of a tie, more populous tracts are ranked above less populous ones.

d. Tracts in the second group are ranked from highest to lowest by the average of the ratios of the tract average-household-size-adjusted income limit to the median household income. Then, tracts in the second group are ranked from highest to lowest by the average of the poverty rates. The two ranks are then averaged to yield a combined rank. The tracts are then sorted on the combined rank, with the census tract with the highest combined rank being placed at the top of the sorted list. In the event of a tie, more populous tracts are ranked above less populous ones.

e. The ranked first group is stacked on top of the ranked second group to yield a single, concatenated, ranked list of eligible census tracts.

f. Working down the single, concatenated, ranked list of eligible tracts, census tracts are identified as designated until the designation of an additional tract would cause the 20 percent limit to be exceeded. If a census tract is not designated because doing so would raise the percentage above 20 percent, subsequent eligible census tracts are then considered to determine if one or more eligible census tract(s) with smaller population(s) could be designated without exceeding the 20 percent limit.

D. Exceptions to OMB Definitions of MSAs and Other Geographic Matters

As stated in OMB Bulletin 15–01, defining metropolitan areas:

''OMB establishes and maintains the delineations of Metropolitan Statistical Areas, . . . solely for statistical purposes. . . . OMB does not take into account or attempt to anticipate any non-statistical uses that may be made of the delineations, [.] In cases where . . . an agency elects to use the Metropolitan . . . Area definitions in nonstatistical programs, it is the sponsoring agency's responsibility to ensure that the delineations are appropriate for such use. An agency using the statistical delineations in a nonstatistical program may modify the delineations, but only for the purposes of that program. In such cases, any modifications should be clearly identified as delineations from the OMB statistical area delineations in order to avoid confusion with OMB's official definitions of Metropolitan . . . Statistical Areas.''

Following OMB guidance, the estimation procedure for the FMRs and income limits incorporates the current OMB definitions of metropolitan Core-Based Statistical Areas (CBSAs) based on the CBSA standards, as implemented with 2010 Census data, but makes adjustments to the definitions, in order to separate subparts of these areas in cases where counties were added to an existing or newly defined metropolitan area. In CBSAs where subareas are established, it is HUD's view that the geographic extent of the housing markets are not the same as the geographic extent of the CBSAs.

In the New England states (Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont), HMFAs are defined according to county subdivisions or minor civil divisions (MCDs), rather than county boundaries. However, since no part of an HMFA is outside an OMB-defined, county-based MSA, all New England nonmetropolitan counties are kept intact for purposes of designating Nonmetropolitan DDAs.

Future Designations

DDAs are designated annually as updated HUD income limit and FMR data are made public. QCTs are designated annually as new income and poverty rate data are released.

Effective Date

The 2020 lists of QCTs and DDAs are effective:

(1) For allocations of credit after December 31, 2019; or

(2) for purposes of IRC Section 42(h)(4), if the bonds are issued and the building is placed in service after December 31, 2019.

If an area is not on a subsequent list of QCTs or DDAs, the 2020 lists are effective for the area if:

(1) The allocation of credit to an applicant is made no later than the end of the 730-day period after the applicant submits a complete application to the LIHTC-allocating agency, and the submission is made before the effective date of the subsequent lists; or

(2) for purposes of IRC Section 42(h)(4), if:

(a) The bonds are issued or the building is placed in service no later than the end of the 730-day period after the applicant submits a complete application to the bond-issuing agency, and

(b) the submission is made before the effective date of the subsequent lists, provided that both the issuance of the bonds and the placement in service of the building occur after the application is submitted.

An application is deemed to be submitted on the date it is filed if the application is determined to be complete by the credit-allocating or bond-issuing agency. A ''complete application'' means that no more than de minimis clarification of the application is required for the agency to make a decision about the allocation of tax credits or issuance of bonds requested in the application.

In the case of a ''multiphase project,'' the DDA or QCT status of the site of the project that applies for all phases of the project is that which applied when the project received its first allocation of LIHTC. For purposes of IRC Section 42(h)(4), the DDA or QCT status of the site of the project that applies for all phases of the project is that which applied when the first of the following occurred: (a) The building(s) in the first phase were placed in service, or (b) the bonds were issued.

For purposes of this notice, a ''multiphase project'' is defined as a set of buildings to be constructed or rehabilitated under the rules of the LIHTC and meeting the following criteria:

(1) The multiphase composition of the project (*i.e.,* total number of buildings and phases in project, with a description of how many buildings are to be built in each phase and when each phase is to be completed, and any other information required by the agency) is made known by the applicant in the first application of credit for any building in the project, and that applicant identifies the buildings in the project for which credit is (or will be) sought;

(2) the aggregate amount of LIHTC applied for on behalf of, or that would eventually be allocated to, the buildings on the site exceeds the one-year limitation on credits per applicant, as defined in the Qualified Allocation Plan (QAP) of the LIHTC-allocating agency, or the annual per-capita credit authority of the LIHTC allocating agency, and is the reason the applicant must request multiple allocations over 2 or more years; and

(3) all applications for LIHTC for buildings on the site are made in immediately consecutive years.

Members of the public are hereby reminded that the Secretary of Housing and Urban Development, or the Secretary's designee, has legal authority to designate DDAs and QCTs, by publishing lists of geographic entities as defined by, in the case of DDAs, the Census Bureau, the several states and the governments of the insular areas of the United States and, in the case of QCTs, by the Census Bureau; and to establish the effective dates of such lists. The Secretary of the Treasury, through the IRS thereof, has sole legal authority to interpret, and to determine and enforce compliance with the IRC and associated regulations, including **Federal Register** notices published by HUD for purposes of designating DDAs and QCTs. Representations made by any other entity as to the content of HUD notices designating DDAs and QCTs that do not precisely match the language published by HUD should not be relied upon by taxpayers in determining what actions are necessary to comply with HUD notices.

Interpretive Examples of Effective Date

For the convenience of readers of this notice, interpretive examples are provided below to illustrate the consequences of the effective date in areas that gain or lose QCT or DDA status. The examples covering DDAs are equally applicable to QCT designations.

(Case A) Project A is located in a 2020 DDA that is NOT a designated DDA in 2021 or 2022. A complete application for tax credits for Project A is filed with the allocating agency on November 15, 2020. Credits are allocated to Project A on October 30, 2022. Project A is eligible for the increase in basis accorded a project in a 2020 DDA because the application was filed BEFORE January 1, 2021 (the assumed effective date for the 2021 DDA lists), and because tax credits were allocated no later than the end of the 730-day period after the filing of the complete application for an allocation of tax credits.

(Case B) Project B is located in a 2020 DDA that is NOT a designated DDA in 2021 or 2022. A complete application for tax credits for Project B is filed with the allocating agency on December 1, 2020. Credits are allocated to Project B on March 30, 2023. Project B is NOT eligible for the increase in basis accorded a project in a 2020 DDA because, although the application for an allocation of tax credits was filed BEFORE January 1, 2021 (the assumed effective date of the 2021 DDA lists), the tax credits were allocated later than the end of the 730-day period after the filing of the complete application.

(Case C) Project C is located in a 2020 DDA that was not a DDA in 2019. Project C was placed in service on November 15, 2019. A complete application for tax-exempt bond financing for Project C is filed with the bond-issuing agency on January 15, 2020. The bonds that will support the permanent financing of Project C are issued on September 30, 2020. Project C is NOT eligible for the increase in basis otherwise accorded a project in a 2020 DDA, because the project was placed in service BEFORE January 1, 2020.

(Case D) Project D is located in an area that is a DDA in 2020 but is NOT a DDA in 2021 or 2022. A complete application for tax-exempt bond financing for Project D is filed with the bond-issuing agency on October 30, 2020. Bonds are issued for Project D on April 30, 2022, but Project D is not placed in service until January 30, 2023. Project D is eligible for the increase in basis available to projects located in 2020 DDAs because: (1) One of the two events necessary for triggering the effective date for buildings described in Section 42(h)(4)(B) of the IRC (the two events being bonds issued and buildings placed in service) took place on April 30, 2022, within the 730-day period after a complete application for tax-exempt bond financing was filed, (2) the application was filed during a time when the location of Project D was in a DDA, and (3) both the issuance of the bonds and placement in service of Project D occurred after the application was submitted.

(Case E) Project E is a multiphase project located in a 2020 DDA that is NOT a designated DDA or QCT in 2021. The first phase of Project E received an allocation of credits in 2020, pursuant to an application filed March 15, 2020, which describes the multiphase composition of the project. An application for tax credits for the second phase of Project E is filed with the allocating agency by the same entity on March 15, 2021. The second phase of Project E is located on a contiguous site. Credits are allocated to the second phase of Project E on October 30, 2021. The aggregate amount of credits allocated to the two phases of Project E exceeds the amount of credits that may be allocated to an applicant in one year under the allocating agency's QAP and is the reason that applications were made in multiple phases. The second phase of Project E is, therefore, eligible for the increase in basis accorded a project in a 2020 DDA, because it meets all of the conditions to be a part of a multiphase project.

(Case F) Project F is a multiphase project located in a 2020 DDA that is NOT a designated DDA in 2021 or 2022. The first phase of Project F received an allocation of credits in 2020, pursuant to an application filed March 15, 2020, which does not describe the multiphase composition of the project. An application for tax credits for the second phase of Project F is filed with the allocating agency by the same entity on March 15, 2022. Credits are allocated to the second phase of Project F on October 30, 2022. The aggregate amount of credits allocated to the two phases of Project F exceeds the amount of credits that may be allocated to an applicant in one year under the allocating agency's QAP. The second phase of Project F is, therefore, NOT eligible for the increase in basis accorded a project in a 2020 DDA, since it does not meet all of the conditions for a multiphase project, as defined in this notice. The original application for credits for the first phase did not describe the multiphase composition of the project. Also, the application for credits for the second phase of Project F was not made in the year immediately following the first phase application year.

Findings and Certifications

Environmental Impact

This notice involves the establishment of fiscal requirements or procedures that are related to rate and cost determinations and do not constitute a development decision affecting the physical condition of specific project areas or building sites. Accordingly, under 40 CFR 1508.4 of the regulations of the Council on Environmental Quality and 24 CFR 50.19(c)(6) of HUD's regulations, this notice is categorically excluded from environmental review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321).

Federalism Impact

Executive Order 13132 (entitled ''Federalism'') prohibits an agency from publishing any policy document that has federalism implications if the document either imposes substantial direct compliance costs on state and local governments and is not required by statute, or the document preempts state law, unless the agency meets the consultation and funding requirements of section 6 of the executive order. This notice merely designates DDAs and QCTs as required under IRC Section 42, as amended, for the use by political subdivisions of the states in allocating the LIHTC. This notice also details the technical methods used in making such designations. As a result, this notice is not subject to review under the order.

Dated: September 19, 2019.

Seth D. Appleton,

Assistant Secretary for Policy Development and Research.

[FR Doc. 2019–20833 Filed 9–24–19; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R4–ES–2019–N129; FXES11130400000EA–123–FF04EF1000]

Receipt of Incidental Take Permit Application and Proposed Habitat Conservation Plan for the Alabama Beach Mouse, Baldwin County, AL; Categorical Exclusion

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comment and information.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce receipt of an application from Creek Holdings, LLC (applicant), for an incidental take permit (ITP) under the Endangered Species Act. The applicant requests the ITP to take the federally listed Alabama beach mouse incidental to construction in Baldwin County, Alabama. We request public comment on the application, which includes the applicant's proposed habitat conservation plan (HCP), and the Service's preliminary determination that this HCP qualifies as ''low effect,'' categorically excluded, under the National Environmental Policy Act. To make this determination, we used our environmental action statement and low-effect screening form, both of which are also available for public review.

DATES: We must receive your written comments on or before October 25, 2019.

ADDRESSES: *Obtaining Documents:* Documents are available for public inspection by appointment during

regular business hours at either of the following locations:

• Atlanta Regional Office, Ecological Services, U.S. Fish and Wildlife Service, 1875 Century Boulevard, Atlanta, GA 30345.

• Alabama Ecological Services Office, U.S. Fish and Wildlife Service, 1208 Main Street, Daphne, Alabama.

Submitting Comments: If you wish to submit comments on any of the documents, you may do so by one of the following methods. Please reference TE33502D–0 in all comments. For additional guidance on submitting comments, please see Public Comments under **SUPPLEMENTARY INFORMATION**.

• *U.S. mail:* You may mail comments to the Service's Atlanta Regional Office.

• *Hand-delivery:* You may hand-deliver comments to the Atlanta or Alabama Offices.

• *Email:* You may email comments to *david_dell@fws.gov.* Please include your name and email address in your email message. If you do not receive an email confirmation from us that we have received your email message, contact us directly at either telephone number in **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT: Mr. David Dell, Regional HCP Coordinator, at the Atlanta Regional Office (see **ADDRESSES**) or Mr. William Lynn, Project Manager, at the Alabama Ecological Services Office (see **ADDRESSES**) or by telephone at 251–441–5868. If you use a telecommunications device for the deaf (TDD), please call the Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION: We, the U.S. Fish and Wildlife Service (Service), announce receipt of an application from Creek Holdings, LLC (applicant), for an incidental take permit (ITP) under the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.).* The applicant requests the ITP to take the federally listed Alabama beach mouse *(Peromyscus polionotus ammobates)* incidental to the construction of seven single family homes and amenities development (project) in Baldwin County, Alabama. We request public comment on the application, which includes the applicant's proposed habitat conservation plan (HCP) and the Service's preliminary determination that this HCP qualifies as ''low effect,'' categorically excluded, under the National Environmental Policy Act (NEPA; 42 U.S.C. 4231 *et seq.).* To make this determination, we used our environmental action statement and low-effect screening form, both of which also are available for public review.

Project

The applicant requests a 50-year ITP to take Alabama beach mice incidental to the conversion of approximately 0.63 acres of occupied Alabama beach mouse habitat for the construction of seven single family homes with amenities on a 2.83-acre parcel in Baldwin County, Alabama. The applicant proposes to implement standard minimization and mitigation measures to mitigate for take of the species. The standard mitigation and minimization measures include reducing the construction footprint on each of the seven lots by 0.10 acres or less and shifting the development south to increase habitat continuity for the species. The applicant will also install fully shielded exterior lighting and tinted windows within the development, landscape with native vegetation, construct driveways with materials that will not disperse in a storm surge, and implement refuse control measures during construction as well as require that future residents utilize such measures and restore species' habitat after tropical storms. The use of exterior rodenticide and ownership of free-roaming cats will be prohibited within the development. Monitoring of the onsite Alabama beach mouse population will occur via fall and spring trapping surveys conducted twice a year for 50 years. The Service would require the applicant to ensure the availability of funding for this HCP is available prior to engaging in activities associated with the project on the parcel.

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, be aware that your entire comment—including your personal identifying information—may be made available to the public. While you may request that we withhold your personal identifying information, we cannot guarantee that we will be able to do so.

Our Preliminary Determination

The Service has made a preliminary determination that the applicant's project, including land clearing, infrastructure building, landscaping, and the proposed minimization and mitigation measures, would individually and cumulatively have a minor or negligible effect on the Alabama beach mouse and the environment. Therefore, we have preliminarily concluded that the ITP for this project would qualify for categorical exclusion and the HCP is low effect under our NEPA regulations at 43 CFR 46.205 and 46.210. A low-effect HCP is one that would result in (1) minor or negligible effects on federally listed, proposed, and candidate species and their habitats; (2) minor or negligible effects on other environmental values or resources; and (3) impacts that, when considered together with the impacts of other past, present, and reasonably foreseeable similarly situated projects, would not over time result in significant cumulative effects to environmental values or resources.

Next Steps

The Service will evaluate the application and the comments received to determine whether to issue the requested permit. We will also conduct an intra-Service consultation pursuant to section 7 of the ESA to evaluate the effects of the proposed take. After considering the above findings, we will determine whether the permit issuance criteria of section 10(a)(l)(B) of the ESA have been met. If met, the Service will issue ITP number TE33502D–0 to Creek Holdings, LLC.

Authority

The Service provides this notice under section 10(c) (16 U.S.C. 1539(c)) of the ESA and NEPA regulation 40 CFR 1506.6.

William J. Pearson,

Field Supervisor, Alabama Field Office, Southeast Region.

[FR Doc. 2019–20729 Filed 9–24–19; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R3–ES–2019–N117; FXES11130300000–190–FF03E00000]

Endangered and Threatened Species; Receipt of Recovery Permit Application

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit application; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, have received an application for a permit to conduct activities intended to enhance the propagation or survival of endangered and threatened species under the Endangered Species Act. We invite the public and local, State, Tribal, and Federal agencies to comment on this application. Before issuing the requested permit, we will take into consideration any information that we

receive during the public comment period.

DATES: We must receive your written comments on or before October 25, 2019.

ADDRESSES: *Document availability and comment submission:* Submit requests for copies of the application and related documents, as well as any comments, by one of the following methods. All requests and comments should specify the applicant's name and application number (TE49715D):

- *Email: permitsR3ES@fws.gov.* Please refer to the respective application number TE49715D, in the subject line of your email message.
- *U.S. Mail:* Regional Director, Attn: Carlita Payne, U.S. Fish and Wildlife Service, Ecological Services, 5600 American Blvd. West, Suite 990, Bloomington, MN 55437–1458.

FOR FURTHER INFORMATION CONTACT: Carlita Payne, 612–713–5343 (phone); *permitsR3ES@fws.gov* (email). Individuals who are hearing or speech impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance.

SUPPLEMENTARY INFORMATION:

Background

The Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), prohibits certain activities with endangered and threatened species unless authorized by a Federal permit. The ESA and our implementing regulations in part 17 of title 50 of the Code of Federal Regulations (CFR) provide for the issuance of such permits and require that we invite public comment before issuing permits for activities involving endangered species.

A recovery permit issued by us under section 10(a)(1)(A) of the ESA authorizes the permittee to conduct activities with endangered species for scientific purposes that promote recovery or for enhancement of propagation or survival of the species. Our regulations implementing section 10(a)(1)(A) for these permits are found at 50 CFR 17.22 for endangered wildlife species, 50 CFR 17.32 for threatened wildlife species, 50 CFR 17.62 for endangered plant species, and 50 CFR 17.72 for threatened plant species.

Permit Applications Available for Review and Comment

We invite local, State, and Federal agencies, Tribes, and the public to comment on the following application.

Application No.	Applicant	Species	Location	Activity	Type of take	Permit action
TE49715D	Jared I. Varner, Bridgeport, WV.	Gray bat (*Myotis grisescens*), Indiana bat (*M. sodalis*), northern long-eared bat (*M. septentrionalis*), Virginia big-eared bat (*Corynorhinus* (=*Plecotus*) *townsendii virginianus*).	CT, FL, GA, IL, IN, KY, MA, ME, NC, NH, NY, OH, PA, SC, VA, WV.	Conduct presence/absence surveys, document habitat use, conduct population monitoring, evaluate impacts.	Capture, handle, mist-net, radio-tag, band, release.	New

Public Availability of Comments

Written comments we receive become part of the administrative record associated with this action. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can request in your comment that we withhold your personal identifying information from public review, 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.

Next Steps

If we decide to issue a permit to the applicant listed in this notice, we will publish a notice in the **Federal Register**.

Authority

We publish this notice under section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Lori Nordstrom,

Assistant Regional Director, Ecological Services, Region 3.

[FR Doc. 2019–20795 Filed 9–24–19; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[18X.LLAK930000 L131000.DP0000]

Notice of Availability of the Final Environmental Impact Statement for the Coastal Plain Oil and Gas Leasing Program, Alaska

AGENCY: Bureau of Land Management, Interior

ACTION: Notice of availability.

SUMMARY: The Bureau of Land Management (BLM), Alaska State Office, is issuing the Final Environmental Impact Statement (EIS) for the Coastal Plain Oil and Gas Leasing Program in accordance with the Tax Cuts and Jobs Act of 2017, and the National Environmental Policy Act of 1969, as amended (NEPA), and in a manner similar to the administration of lease sales under the Naval Petroleum Reserves Production Act of 1976, as amended.

DATES: The Final EIS is available to the public. After 30 days, the BLM can issue a Record of Decision (ROD).

ADDRESSES: Requests for information regarding the Final EIS may be mailed to: Coastal Plain Oil and Gas Leasing Program EIS, Attn: Nicole Hayes, 222 West 7th Avenue, #13 Anchorage, AK 99513–7504. The Final EIS is available on the BLM Alaska website at *https://www.blm.gov/alaska/Coastal-Plain-EIS* or at the BLM Alaska State Office, BLM Alaska Public Information Center, 222 West 7th Avenue, Anchorage, Alaska 99513.

FOR FURTHER INFORMATION CONTACT: Nicole Hayes, BLM Alaska State Office, telephone: 907–271–4354; email: *blm_ak_coastalplain_EIS@blm.gov;* or by mail: Bureau of Land Management, 222

West 7th Avenue, #13, Anchorage, Alaska 99513–7599. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact Ms. Hayes during normal business hours. FRS is available 24 hours a day, 7 days a week, to leave a message or question. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The Coastal Plain Oil and Gas Leasing Final Leasing Program EIS analyzes implementing an oil and gas leasing program in accordance with Section 20001 of the Tax Cuts and Jobs Act of 2017, Public Law 115–97 (Dec. 22, 2017) (Pub. L. 115–97), and the National Environmental Policy Act of 1969, as amended, and in a manner similar to the administration of lease sales under the Naval Petroleum Reserves Production Act of 1976, as amended. The Leasing EIS analyzes the potential environmental impacts of various leasing alternatives, including the areas to offer for sale, and the terms and conditions (*i.e.,* lease stipulations and required operating procedures) to be applied to leases and associated potential future oil and gas activities, to properly balance oil and gas development with existing uses and protection of surface resources. The lands comprising the Coastal Plain include approximately 1.6 million acres within the approximately 19.3 million-acre Arctic National Wildlife Refuge. The Final EIS will result in a ROD that will approve an oil and gas leasing program in the Coastal Plain of the Arctic National Wildlife Refuge, consistent with the direction provided in PL 115–97. The Draft EIS, published in December 2018, did not identify a Preferred Alternative, because the BLM did not have one at that time. The Final EIS identifies Alternative B as the BLM's Preferred Alternative.

In developing the preferred alternative, the BLM worked with interested parties to identify the management decisions best suited to local, regional, and national needs and concerns, in developing the preferred alternative consistent with the following criteria:

- Under Public Law 115–97, hold not fewer than two lease sales, each to include not fewer than 400,000 acres area-wide, prioritizing the areas with the highest potential for hydrocarbons;
- Consider all available Federal lands and waters within the Coastal Plain;
- Consider all five purposes of the Arctic National Wildlife Refuge;
- Address oil and gas leasing issues identified during scoping;
- Consider subsistence resources and users, as well as potential actions to minimize adverse impacts to subsistence in accordance with section 810 of the Alaska National Interest Lands Conservation Act (ANILCA); and
- Consider current surface management of the Coastal Plain.

Upon completion of a Final EIS and ROD, the BLM intends to conduct lease sales in accordance with Public Law 115–97.

Future on-the-ground actions requiring BLM approval, including proposed seismic and exploration plans or development proposals, would require further NEPA analysis based on specific and detailed information about where and what kind of activity is proposed. Additional site-specific terms and conditions may be required by the Authorized Officer prior to authorizing any oil and gas activity.

Chad B. Padgett,

State Director, Alaska.

[FR Doc. 2019–20832 Filed 9–24–19; 8:45 am]

BILLING CODE 4310–JA–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

[RR04093000, XXXR4081G3, RX.05940913.FY19310]

Glen Canyon Dam Adaptive Management Work Group Charter Renewal

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of charter renewal.

SUMMARY: Following consultation with the General Services Administration, notice is hereby given that the Secretary of the Interior (Secretary) is renewing the charter for the Glen Canyon Dam Adaptive Management Work Group. The purpose of the Adaptive Management Work Group is to provide advice and recommendations to the Secretary concerning the operation of Glen Canyon Dam and the exercise of other authorities pursuant to applicable Federal law.

FOR FURTHER INFORMATION CONTACT: Ms. Lee Traynham, (801) 524–3752, *ltraynham@usbr.gov.*

SUPPLEMENTARY INFORMATION: This notice is published in accordance with Section 9(a)(2) of the Federal Advisory Committee Act of 1972 (Pub. L. 92–463, as amended). The certification of renewal is published below.

Certification

I hereby certify that Charter renewal of the Glen Canyon Dam Adaptive Management Work Group is in the public interest in connection with the performance of duties imposed on the Department of the Interior.

David L. Bernhardt,

Secretary of the Interior.

[FR Doc. 2019–20801 Filed 9–24–19; 8:45 am]

BILLING CODE 4332–90–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–455 and 731–TA–1149 (Second Review)]

Circular Welded Carbon Quality Steel Line Pipe From China

Determinations

On the basis of the record [1] developed in these subject five-year reviews, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that revocation of the countervailing and antidumping duty orders on circular welded carbon quality steel line pipe from China would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.[2]

Background

The Commission, pursuant to section 751(c) of the Act (19 U.S.C. 1675(c)), instituted these reviews on April 1, 2019 (84 FR 12285) and determined on July 5, 2019 that it would conduct expedited reviews (84 FR 39861, August 12, 2019).

The Commission made these determinations pursuant to section 751(c) of the Act (19 U.S.C. 1675(c)). It completed and filed its determinations in these reviews on September 19, 2019. The views of the Commission are contained in USITC Publication 4955 (September 2019), entitled *Circular Welded Carbon Quality Steel Line Pipe from China: Investigation Nos. 701–TA–455 and 731–TA–1149 (Second Review).*

By order of the Commission.

Issued: September 20, 2019.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2019–20782 Filed 9–24–19; 8:45 am]

BILLING CODE 7020–02–P

[1] The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

[2] Commissioners Randolph J. Stayin and Amy A. Karpel did not participate.

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–417 and 731–TA–953, 957–959, and 961 (Third Review)]

Carbon and Certain Alloy Steel Wire Rod From Brazil, Indonesia, Mexico, Moldova, and Trinidad and Tobago; Notice of Commission Determinations To Conduct Full Five-Year Reviews

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice that it will proceed with full reviews pursuant to the Tariff Act of 1930 to determine whether revocation of the countervailing duty order on carbon and certain alloy steel wire rod (''wire rod'') from Brazil and the antidumping duty orders on wire rod from Brazil, Indonesia, Mexico, Moldova, and Trinidad and Tobago would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time. A schedule for the reviews will be established and announced at a later date.

DATES: September 6, 2019.

FOR FURTHER INFORMATION CONTACT: Jordan Harriman (202–205–2610), 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.* 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 through E (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

SUPPLEMENTARY INFORMATION: On September 6, 2019, the Commission determined that it should proceed to full reviews in the subject five-year reviews pursuant to section 751(c) of the Tariff Act of 1930 (19 U.S.C. 1675(c)).[1] The Commission found that the domestic interested party group response to its notice of institution (84 FR 25564, June 3, 2019) was adequate. The Commission also found that the respondent interested party group response concerning the antidumping duty order on wire rod from Mexico was adequate and, therefore, determined to proceed with a full review of that order. The Commission found that the respondent interested party group responses concerning the countervailing duty and antidumping duty orders on wire rod from Brazil and the antidumping duty orders on wire rod from Indonesia, Moldova, and Trinidad and Tobago were inadequate but determined to conduct full reviews of these orders in order to promote administrative efficiency in light of the determination to conduct a full review of the antidumping duty order on wire rod from Mexico. A record of the Commissioners' votes, the Commission's statement on adequacy, and any individual Commissioner's statements will be available from the Office of the Secretary and at the Commission's website.

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: September 20, 2019.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2019–20799 Filed 9–24–19; 8:45 am]

BILLING CODE 7020–02–P

[1] Commissioner Jason E. Kearns did not participate in these determinations.

DEPARTMENT OF LABOR

Employment and Training Administration

Labor Surplus Area Classification

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice.

SUMMARY: The purpose of this notice is to announce the annual Labor Surplus Area (LSA) list for Fiscal Year (FY) 2020.

DATES: The annual LSA list is effective October 1, 2019, for all states, the District of Columbia, and Puerto Rico.

FOR FURTHER INFORMATION CONTACT: Samuel Wright, Office of Workforce Investment, Employment and Training Administration, 200 Constitution Avenue NW, Room C–4514, Washington, DC 20210. Telephone: (202) 693–2870 (This is not a toll-free number) or email *wright.samuel.e@dol.gov.*

SUPPLEMENTARY INFORMATION: The Department of Labor's regulations implementing Executive Orders 12073 and 10582 are set forth at 20 CFR part 654, subpart A. These regulations require the Employment and Training Administration (ETA) to classify jurisdictions as LSAs pursuant to the criteria specified in the regulations, and to publish annually a list of LSAs. Pursuant to those regulations, ETA is hereby publishing the annual LSA list.

In addition, the regulations provide exceptional circumstance criteria for classifying LSAs when catastrophic events, such as natural disasters, plant closings, and contract cancellations are expected to have a long-term impact on labor market area conditions, discounting temporary or seasonal factors.

Eligible Labor Surplus Areas

A LSA is a civil jurisdiction that has a civilian average annual unemployment rate during the previous two calendar years of 20 percent or more above the average annual civilian unemployment rate for all states during the same 24-month reference period. ETA uses only official unemployment estimates provided by the Bureau of Labor Statistics in making these classifications. The average unemployment rate for all states includes data for the Commonwealth of Puerto Rico. The LSA classification criteria stipulate a civil jurisdiction must have a ''floor unemployment rate'' of 6 percent or higher to be classified a LSA. Any civil jurisdiction that has a ''ceiling unemployment rate'' of 10 percent or higher is classified a LSA.

Civil jurisdictions are defined as follows:

1. A city of at least 25,000 population on the basis of the most recently available estimates from the Bureau of the Census; or

2. A town or township in the States of Michigan, New Jersey, New York, or Pennsylvania of 25,000 or more population and which possess powers and functions similar to those of cities; or

3. All counties, except for those counties which contain any type of civil jurisdictions defined in ''1'' or ''2'' above; or

4. A ''balance of county'' consisting of a county less any component cities and townships identified in ''1'' or ''2'' above; or

5. A county equivalent which is a town in the States of Connecticut, Massachusetts, and Rhode Island, or a

municipio in the Commonwealth of Puerto Rico.

Procedures for Classifying Labor Surplus Areas

The Department of Labor (DOL) issues the LSA list on a fiscal year basis. The list becomes effective each October 1, and remains in effect through the following September 30. The reference period used in preparing the current list was January 2017 through December 2018. The national average unemployment rate (including Puerto Rico) during this period is rounded to 4.34 percent. Twenty percent higher than the national unemployment rate during this period is rounded to 5.21 percent. Since the calculated unemployment rate plus 20 percent (5.21 percent) is below the ''floor'' LSA unemployment rate of 6 percent, a civil jurisdiction must have a two-year unemployment rate of 6 percent or higher in order to be classified a LSA. To ensure that all areas classified as labor surplus meet the requirements, when a city is part of a county and meets the unemployment qualifier as a LSA, that city is identified in the LSA list, the balance of county, not the entire county, will be identified as a LSA if the balance of county also meets the LSA unemployment criteria. The FY 2019 LSA list, statistical data on the current and previous years' LSAs are available at *http://www.doleta.gov/programs/lsa.cfm.*

Petition for Exceptional Circumstance Consideration

The classification procedures also provide criteria for the designation of LSAs under exceptional circumstances criteria. These procedures permit the regular classification criteria to be waived when an area experiences a significant increase in unemployment which is not temporary or seasonal and which was not reflected in the data for the 2-year reference period. Under the program's exceptional circumstance procedures, LSA classifications can be made for civil jurisdictions, Metropolitan Statistical Areas or Combined Statistical Areas, as defined by the U.S. Office of Management and Budget. In order for an area to be classified as a LSA under the exceptional circumstance criteria, the state workforce agency must submit a petition requesting such classification to the Department of Labor's ETA. The current criteria for an exceptional circumstance classification are:

1. An area's unemployment rate is at least 6% percent for each of the three most recent months;

2. A projected unemployment rate of at least 6% percent for each of the next 12 months because of an event; and

3. Documentation that the exceptional circumstance event has occurred. The state workforce agency may file petitions on behalf of civil jurisdictions, Metropolitan Statistical Areas, or Micropolitan Statistical Areas.

State Workforce Agencies may submit petitions in electronic format to *wright.samuel.e@dol.gov,* or in hard copy to the U.S. Department of Labor, Employment and Training Administration, Office of Workforce Investment, 200 Constitution Avenue NW, Room C–4514, Washington, DC 20210, Attention Samuel Wright. Data collection for the petition is approved under OMB 1205–0207, expiration date July 31, 2020.

Signed at Washington, DC.

John Pallasch,

Assistant Secretary for Employment and Training Administration.

[FR Doc. 2019–20849 Filed 9–24–19; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Agency Information Collection Activities; Comment Request; Trade Adjustment Assistance (TAA) Efforts To Improve Outcomes

ACTION: Notice.

SUMMARY: The Department of Labor's (DOL's) Employment and Training Administration (ETA) is soliciting comments concerning a proposed extension for the authority to conduct the information collection request (ICR) titled, ''Trade Adjustment Assistance (TAA) Efforts to Improve Outcomes.'' This comment request is part of continuing Departmental efforts to reduce paperwork and respondent burden in accordance with the Paperwork Reduction Act of 1995 (PRA).

DATES: Consideration will be given to all written comments received by October 25, 2019.

ADDRESSES: A copy of this ICR with applicable supporting documentation, including a description of the likely respondents, proposed frequency of response, and estimated total burden, may be obtained free by contacting Robert Hoekstra, by telephone at 202–693–3522 (this is not a toll-free number), TTY 1–877–889–5627 (this is not a toll-free number), or by email at *hoekstra.robert@dol.gov.*

Submit written comments about, or requests for a copy of, this ICR by mail or courier to the U.S. Department of Labor, Employment and Training Administration, Office of Trade Adjustment Assistance, 200 Constitution Avenue NW, Room N–5428, Washington, DC 20210; by email: *taa.reports@dol.gov;* or by Fax 202–693–3584.

FOR FURTHER INFORMATION CONTACT: Robert Hoekstra by telephone at 202–693–3522 (this is not a toll-free number) or by email at *hoekstra.robert@dol.gov.*

SUPPLEMENTARY INFORMATION: DOL, as part of continuing efforts to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies an opportunity to comment on proposed and/or continuing collections of information before submitting them to the Office of Management and Budget (OMB) for final approval. This program helps to ensure requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements can be properly assessed.

On June 28, 2015, the Trade Adjustment Assistance Reauthorization Act of 2015 was signed into law. Under Section 239(j)(1)(c) of Title II, Chapter 2 of the Trade Act of 1974, as amended (19 U.S.C. 2271 *et seq.*), the Secretary is required to collect ''a description of efforts made to improve outcomes for workers . . .'' In addition to mandatory annual reporting, the Department collects these descriptions on a quarterly basis in order to track progress of efforts to improve outcomes and speed the identification of new state practices.

The Office of Trade Adjustment Assistance (OTAA) is revising the ICR for Trade Activity Participant Report (TAPR) (OMB control number 1205–0392). This ICR removes the collection requirement for the individual record reporting that constituted the bulk of the collection burden, but retains the quarterly reporting requirement of ''efforts made to improve outcomes''. Correspondingly, the collection title will be changed to ''Trade Adjustment Assistance (TAA) Efforts to Improve Outcomes.'' Section 239(j)(1)(c) of Title II, Chapter 2 of the Trade Act of 1974, as amended (19 U.S.C. 2271 *et seq.*) authorizes this information collection. This collection is being modified significantly as to no longer require the submission of individual participant

records under the TAPR. The prior TAPR data constituted the bulk of the burden of this collection, reducing the estimated total burden from 18,500 hours to 104 hours.

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 it is approved by OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. See 5 CFR 1320.5(a) and 1320.6.

Interested parties are encouraged to provide comments to the contact shown in the **ADDRESSES** section. Comments must be written to receive consideration, and they will be summarized and included in the request for OMB approval of the final ICR. In order to help ensure appropriate consideration, comments should mention OMB control number 1205–0392.

Submitted comments will also be a matter of public record for this ICR and posted on the internet, without redaction. DOL encourages commenters not to include personally identifiable information, confidential business data, or other sensitive statements/information in any comments.

DOL is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, (*e.g.,* permitting electronic submission of responses).

Agency: DOL–ETA.

Type of Review: Revision.

Title of Collection: Trade Adjustment Assistance (TAA) Efforts to Improve Outcomes.

Form: ETA–9173.

OMB Control Number: 1205–0392.

Affected Public: State Workforce Agencies.

Estimated Number of Respondents: 52.

Frequency: Quarterly.

Total Estimated Annual Responses: 208.

Estimated Average Time per Response: 0.5 hours based on estimated times provided by states who are currently providing this more limited collection.

Estimated Total Annual Burden Hours: 104 hours.

Total Estimated Annual Other Cost Burden: $0.

Authority: 44 U.S.C. 3506(c)(2)(A).

John Pallasch,

Assistant Secretary for Employment and Training, Labor.

[FR Doc. 2019–20743 Filed 9–24–19; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Federal-State Unemployment Compensation Program: Notice of Federal Agencies With Adequate Safeguards and an Appropriate Method of Payment or Reimbursement To Satisfy the Confidentiality Requirements of Agency Regulations

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice of Federal agencies with adequate safeguards and an appropriate method of payment or reimbursement for costs.

SUMMARY: In this notice, the Department of Labor (Department) recognizes that the exchange of information between State unemployment compensation (UC) agencies and the Internal Revenue Service (IRS) and the exchange of information between State UC agencies and the Department of Health and Human Services (HHS) meet the requirements of agency regulations. The Department has determined that the relative benefits of information received by State UC agencies from the IRS and the benefits of the information received by the IRS from State UC agencies are approximately equal. The Department has also determined that the relative benefits of information received by State UC agencies from HHS and the benefits of the information received by HHS from State UC agencies are approximately equal. Pursuant to this determination, it is not necessary for State UC agencies to satisfy the agreement requirements of agency regulations for the disclosure of confidential UC information to these two Federal agencies.

FOR FURTHER INFORMATION CONTACT: Gay M. Gilbert, Administrator, Office of Unemployment Insurance, Employment and Training Administration, (202) 693–3029 (this is not a toll-free number) or 1–877–889–5627 (TTY), or by email at *gilbert.gay@dol.gov.*

SUPPLEMENTARY INFORMATION: The Employment and Training Administration interprets Federal law requirements pertaining to the Federal-State UC program. Section 303(a)(1) of the Social Security Act, as implemented at 20 CFR part 603 (71 FR 56830), generally requires States to maintain the confidentiality of UC information. The regulation at 20 CFR 603.10 requires State UC agencies to enter into a written, enforceable agreement meeting certain requirements with any agency or entity requesting disclosure of such confidential UC information.

20 CFR 603.10(d) provides that the requirements of 20 CFR 603.10 do not apply to disclosures of confidential UC information to a Federal agency if the Department has determined, by notice published in the **Federal Register**, that the Federal agency has in place safeguards adequate to satisfy the requirements of 20 CFR 603.9 and an appropriate method of paying or reimbursing the State UC agency (which may involve a reciprocal cost arrangement) for costs involved in such disclosures as required in 20 CFR 603.8(d).

On November 15, 2006, the Department published notice in the **Federal Register** of its determination that the IRS has in place adequate safeguards for purposes of tax administration, including administration of the Federal unemployment tax and the Health Coverage Tax Credit (HCTC). 71 FR 66556. Section 6103 *et seq.* of the Internal Revenue Code, 26 U.S.C. 6103 *et seq.,* provides safeguards adequate to satisfy confidentiality requirements consistent with the Department's regulation. State UC agencies and the IRS exchange confidential UC information for purposes of the proper administration of the Federal unemployment tax and the HCTC, as well as the Questionable Employment Tax Practices initiative. With the current notice, the Department recognizes that the exchange of information between State UC agencies and the IRS for these purposes meets the requirements of 20 CFR 603.8(d)

because the relative benefits received by each are approximately equal.

The Department's November 15, 2006, notice also included its determination that wage and claim information disclosed to HHS for purposes of the National Directory of New Hires (NDNH) is protected by a ''security plan'' that provides safeguards adequate to meet the requirements of 20 CFR 603.9. 71 FR 66556. Laws governing information in the NDNH impose strict controls on redisclosure and disposal of information. See, *e.g.,* 42 U.S.C. 653(i), (j), (l), and (m). HHS provides NDNH information on reported new hire dates, which State UC agencies use to conduct cross matches to identify potential improper UC payments to individuals who have returned to work or failed to report earnings. With the current notice, the Department recognizes that the exchange of information between State UC agencies and HHS for these purposes meets the requirements of 20 CFR 603.8(d) because the relative benefits received by each are approximately equal.

This notice is published to inform the public of the Department's determination that it is not necessary for State UC agencies to satisfy the agreement requirements of 20 CFR 603.10 for the disclosure of confidential UC information to these two Federal agencies.

John Pallasch,

Assistant Secretary for Employment and Training.

[FR Doc. 2019–20843 Filed 9–24–19; 8:45 am]

BILLING CODE 4510–FW–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; State Training Provider Eligibility Collection

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting the Employment and Training Administration (ETA) sponsored information collection request (ICR) revision titled, ''State Training Provider Eligibility Collection,'' to the Office of Management and Budget (OMB) for review and approval for use in accordance with the Paperwork Reduction Act (PRA) of 1995. Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before October 25, 2019.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the *RegInfo.gov* website at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201907-1205-002* (this link will only become active on the day following publication of this notice) or by contacting Frederick Licari by telephone at 202–693–8073, TTY 202–693–8064, (these are not toll-free numbers) or sending an email to *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–ETA, Office of Management and Budget, Room 10235, 725 17th Street NW, Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW, Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Frederick Licari by telephone at 202–693–8073, TTY 202–693–8064, (these are not toll-free numbers) or sending an email to *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: This ICR seeks approval under the PRA for revisions to the State Training Provider Eligibility Collection. This ICR collects information from States pertaining to Eligible Training Provider (ETP) List and their retention of the data. This information collection is a revision because the collection has been updated to conform with the language in the Final Rule, in particular 20 CFR 680–470 and its operational refinements during implementation. The Workforce Innovation and Opportunity Act of 2014 authorizes this information collection. *See* Section 122 of Public Law 113–128.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB, under the PRA, approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1205–0523. The current approval is scheduled to expire on September 30, 2019; however, the DOL notes that existing information collection requirements submitted to the OMB will receive a month-to-month extension while they undergo review. New requirements would only take effect upon OMB approval. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on May 22, 2019 (84 FR 23583).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within thirty-(30) days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1205–0523. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility.
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Agency: DOL–ETA.

Title of Collection: State Training Provider Eligibility Collection.

OMB Control Number: 1205–0523.

Affected Public: State, Local and Tribal Governments.

Total Estimated Number of Respondents: 12,337.

Total Estimated Number of Responses: 12,337.

Total Estimated Annual Time Burden: 8,912 hours.

Total Estimated Annual Other Costs Burden: $0.

Authority: 44 U.S.C. 3507(a)(1)(D).

Dated: September 18, 2019.

Frederick Licari,

Departmental Clearance Officer.

[FR Doc. 2019–20745 Filed 9–24–19; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Claim for Reimbursement-Assisted Reemployment

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting the Office of Workers' Compensation Programs (OWCP) sponsored information collection request (ICR) titled, ''Claim for Reimbursement-Assisted Reemployment,'' to the Office of Management and Budget (OMB) for review and approval for continued use, without change, 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 agency receives on or before October 25, 2019.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the RegInfo.gov website at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201904-1240-001* (this link will only become active on the day following publication of this notice) or by contacting Frederick Licari by telephone at 202–693–8073, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–OWCP, Office of Management and Budget, Room 10235, 725 17th Street NW, Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW, Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Frederick Licari by telephone at 202–693–8073, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: This ICR seeks to extend PRA authority for the Claim for Reimbursement-Assisted Reemployment information collection. The Federal Employees' Compensation Act (FECA), in relevant part, provides vocational rehabilitation services to eligible injured Federal employees to facilitate their return to work. The costs of providing these vocational rehabilitation services are paid from the Federal Employees' Compensation Fund, and annual appropriations language provides the OWCP with legal authority to use amounts from the Fund to reimburse private sector employers for a portion of the salary of reemployed disabled Federal workers hired through the OWCP Assisted Reemployment Program. Employers submit Form CA–2231 to claim reimbursement for wages paid under the Assisted Reemployment Program. Federal Employees' Compensation Act section 8104(a) and the Consolidated Appropriations Act of 2016 authorize this information collection. *See* 5 U.S.C. 8104(a) and Public Law 114–113.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB under the PRA approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1240–0018.

OMB authorization for an ICR cannot be for more than three (3) years without renewal, and the current approval for this collection is scheduled to expire on September 30, 2019. The DOL seeks to extend PRA authorization for this information collection for three (3) more years, without any change to existing requirements. The DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on May 10, 2019 (84 FR 20661).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within thirty-(30) days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1240–0018. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility:
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Agency: DOL–OWCP.

Title of Collection: Claim for Reimbursement-Assisted Reemployment.

OMB Control Number: 1240–0018.

Affected Public: Private Sector—businesses or other for-profits.

Total Estimated Number of Respondents: 16.

Total Estimated Number of Responses: 64.

Total Estimated Annual Time Burden: 32 hours.

Total Estimated Annual Other Costs Burden: $37.

Authority: 44 U.S.C. 3507(a)(1)(D).

Dated: September 18, 2019.

Frederick Licari,

Departmental Clearance Officer.

[FR Doc. 2019–20746 Filed 9–24–19; 8:45 am]

BILLING CODE 4510–CH–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Migrant and Seasonal Farmworker (MSFW) Monitoring Report and Complaint/ Apparent Violation Form

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting the Employment and Training Administration (ETA) sponsored information collection request (ICR) revision titled, ''Migrant and Seasonal Farmworker (MSFW) Monitoring Report and Complaint/ Apparent Violation Form,'' to the Office of Management and Budget (OMB) for review and approval for use in accordance with the Paperwork Reduction Act (PRA) of 1995. Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before October 25, 2019.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the *RegInfo.gov* website at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201908-1205-002* (this link will only become active on the day following publication of this notice) or by contacting Frederick Licari by telephone at 202–693–8073, TTY 202–693–8064, (these are not toll-free numbers) or sending an email to *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–ETA, Office of Management and Budget, Room 10235, 725 17th Street NW, Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW, Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Frederick Licari by telephone at 202–693–8073, TTY 202–693–8064, (these are not toll-free numbers) or sending an email to *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: This ICR seeks approval under the PRA for revisions to the Migrant and Seasonal Farmworker (MSFW) Monitoring Report and Complaint/Apparent Violation Form. Form ETA–5148, Services to Migrant and Seasonal Farmworkers Report, collects data that monitors and measures how a State Workforce Agency delivers services to MSFWs. Form ETA–8429, One-Stop Career Center Compliance Referral Record, collects and documents complaints. This information collection is a revision because ETA is deleting the duplicative information in Form 5148 from Parts 3 and 4 through the Workforce Integrated Performance System. Additionally, for Form 8429, ETA is adding a box on page 1 for the complainant to check off authorizing someone else to act in his behalf, and adding two other boxes in Part II, Section 4 to track the types of complaints received (trafficking and sexual harassment/coercion/assault complaints). Wagner Peyser Act section 10(c)(1)authorizes this information collection. *See* 29 U.S.C. 49i(c)(1).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB, under the PRA, approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1205–0039. The current approval is scheduled to expire on September 30, 2019; however, the DOL notes that existing information collection requirements submitted to the OMB will receive a month-to-month extension while they undergo review. New requirements would only take effect upon OMB approval. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on March 7, 2019 (84 FR 8343).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within thirty-(30) days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1205–0039. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility.
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Agency: DOL–ETA.

Title of Collection: Migrant and Seasonal Farmworker (MSFW) Monitoring Report and Complaint/ Apparent Violation Form.

OMB Control Number: 1205–0039.

Affected Public: State, Local and Tribal Governments; Individuals and Households.

Total Estimated Number of Respondents: 6,266.

Total Estimated Number of Responses: 6,572.

Total Estimated Annual Time Burden: 8,813 hours.

Total Estimated Annual Other Costs Burden: $0.

Authority: 44 U.S.C. 3507(a)(1)(D).

Dated: September 18, 2019.

Frederick Licari,

Departmental Clearance Officer.

[FR Doc. 2019–20744 Filed 9–24–19; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

[Docket No. MSHA–2018–0015]

Escapeways and Refuges in Underground Metal and Nonmetal Mines

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Announcement of public meeting and extension of comment period.

SUMMARY: In response to requests from stakeholders, the Mine Safety and Health Administration (MSHA) is

announcing the date and location of a public meeting on a Program Policy Letter (PPL) on escapeways and refuges in underground metal and nonmetal mines, published on July 29, 2019 (84 FR 36623). The public comment period is extended until October 28, 2019, to give stakeholders additional time to provide input.

DATES: The meeting date and location is listed in the **SUPPLEMENTARY INFORMATION** section of this document. Comments must be received or postmarked by midnight Eastern Daylight Saving Time (EST) on October 28, 2019.

ADDRESSES: Submit comments and informational materials, identified by Docket No. MSHA–2018–0015, by one of the following methods:

- *Federal E-Rulemaking Portal: https://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Email:* zzMSHA-comments@*dol.gov.*
- *Email: GoodGuidance@dol.gov.*
- *Mail:* MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, Suite 4E401, Arlington, Virginia 22202–5452.
- *Hand Delivery or Courier:* 201 12th Street South, Suite 4E401, Arlington, Virginia, between 9:00 a.m. and 5:00 p.m. Monday through Friday, except Federal holidays. Sign in at the receptionist's desk on the 4th floor East, Suite 4E401.
- *Fax:* 202–693–9441.

Instructions: All submissions must include Docket No. MSHA–2018–0015. Do not include personal information that you do not want publicly disclosed.

Email Notification: To subscribe to receive email notification when MSHA publishes rulemaking documents in the **Federal Register**, go to *https://public.govdelivery.com/accounts/USDOL/subscriber/new.*

Availability of Information

Docket: For access to the docket to read comments received, go to *http://www.regulations.gov* or *http://arlweb.msha.gov/currentcomments.asp.* To read background documents, go to *http://www.regulations.gov.* Review the docket in person at MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, Arlington, Virginia, between 9:00 a.m. and 5:00 p.m. Monday through Friday, except Federal Holidays. Sign in at the receptionist's desk in Suite 4E401. [Docket Number: MSHA–2018–0015]

FOR FURTHER INFORMATION CONTACT: Sheila A. McConnell, Director, Office of Standards, Regulations, and Variances, MSHA, at *mcconnell.sheila.a@dol.gov* (email), 202–693–9440 (voice), or 202–693–9441 (fax). These are not toll-free numbers.

SUPPLEMENTARY INFORMATION:

Public Meeting

On July 29, 2019, MSHA published a **Federal Register** notice, Availability of Program Policy Letter (PPL) and Request for Comments (84 FR 36623), regarding escapeways and refuges in underground metal and nonmental (MNM) mines. Based on questions from underground MNM mine operators, MSHA believes that this PPL addresses a significant safety issue regarding the placement of a refuge in a location that provides miners access if they cannot escape.

MSHA will hold a public meeting to receive input from industry, labor, and other interested parties on the PPL. The public meeting will be held on October 10, 2019, at MSHA Headquarters, 201 12 Street South, Arlington, Virginia 22202–5452. The public meeting will begin at 9 a.m. local time and conclude at 5 p.m., or until the last speaker speaks. The meetings will be conducted in an informal manner. Speakers and other attendees may present information to MSHA for inclusion in the public docket. The verbatim transcript may be viewed at *https://www.regulations.gov/* and on MSHA's website at: *https://www.msha.gov/regulations/escapeways-and-refuges-underground-metal-and-nonmetal-mines.*

David G. Zatezalo,

Assistant Secretary for Mine Safety and Health Administration.

[FR Doc. 2019–20733 Filed 9–24–19; 8:45 am]

BILLING CODE 4520–43–P

NATIONAL LABOR RELATIONS BOARD

Sunshine Act Meetings

TIME AND DATE: Each Wednesday of every month through Fiscal Year 2020 at 2:00 p.m. Changes in date and time will be posted at *www.nlrb.gov.*

PLACE: Board Agenda Room, No. 5065, 1015 Half St. SE, Washington, DC.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Pursuant to § 102.139(a) of the Board's Rules and Regulations, the Board or a panel thereof will consider ''the issuance of a subpoena, the Board's participation in a civil action or proceeding or an arbitration, or the initiation, conduct, or disposition . . . of particular representation or unfair labor practice proceedings under section 8, 9, or 10 of the [National Labor Relations] Act, or any court proceedings collateral or ancillary thereto.'' See also 5 U.S.C. 552b(c)(10).

CONTACT PERSON FOR MORE INFORMATION: Roxanne Rothschild, Executive Secretary, 1015 Half Street SE, Washington, DC 20570. Telephone: (202) 273–2917.

Dated: September 25, 2019.

Roxanne Rothschild,

Executive Secretary, National Labor Relations Board.

[FR Doc. 2019–20916 Filed 9–23–19; 4:15 pm]

BILLING CODE 7545–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2019–0066]

Information Collection: NRC Form 314 Certificate of Disposition of Materials

AGENCY: Nuclear Regulatory Commission.

ACTION: Renewal of existing renewal information collection; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment on the renewal of Office of Management and Budget (OMB) approval for an existing collection of information. The information collection is entitled, ''NRC Form 314, Certificate of Disposition of Materials.'' NRC Form 314 is submitted by a materials licensee who wishes to terminate its license. The form provides information needed by NRC to determine whether the licensee has radioactive materials on hand which must be transferred or otherwise disposed of prior to expiration or termination of the license.

DATES: Submit comments by November 25, 2019. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

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

- *Federal Rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2019–0066. Address questions about NRC docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* David Cullison, Office of the Chief Information Officer, Mail Stop: T–6 A10M, U.S. Nuclear

Regulatory Commission, Washington, DC 20555–0001.

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: David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information.

Please refer to Docket ID NRC–2019–0066 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–2019–0066. A copy of the collection of information and related instructions may be obtained without charge by accessing Docket ID NRC–2019–0066 on this website.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in 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.* A copy of the collection of information and related instructions may be obtained without charge by accessing ADAMS Accession No. ML19261A742. The supporting statement is available in ADAMS under Accession No. ML19177A126.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.
- *NRC's Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting NRC's Clearance Officer, David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

B. Submitting Comments.

Please include Docket ID NRC–2019–0066 in the subject line of your comment submission, in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

The NRC cautions you not to include identifying or contact information in comment submissions 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, and the NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC is requesting public comment on its intention to request the OMB's approval for the information collection summarized below.

1. *The title of the information collection:* ''NRC Form 314, Certification of Disposition of Materials.''
2. *OMB approval number:* 3150–0028.
3. *Type of submission:* Extension.
4. *The form number, if applicable:* NRC Form 314.
5. *How often the collection is required or requested:* NRC Form 314 is submitted by a materials licensee who wishes to terminate its license. The form provides information needed by NRC to determine whether the licensee has radioactive materials on hand which must be transferred or otherwise disposed of prior to expiration or termination of the license.
6. *Who will be required or asked to respond:* Respondents are firms, institutions, and individuals holding an NRC license for the possession and use of radioactive material who do not wish to renew those licenses.
7. *The estimated number of annual responses:* 136.
8. *The estimated number of annual respondents:* 136.
9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 68 hours (36 × 0.5 hour = 68 hours).
10. *Abstract:* NRC Form 314 is submitted by a materials licensee who wishes to terminate its license. The form provides information needed by NRC to determine whether the licensee has radioactive materials on hand which must be transferred or otherwise disposed of prior to expiration or termination of the license.

III. Specific Requests for Comments

The NRC is seeking comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?
2. Is the estimate of the burden of the information collection accurate?
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?
4. How can the burden of the information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

Dated at Rockville, Maryland, this 20th day of September, 2019.

For the Nuclear Regulatory Commission.

David C. Cullison,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2019–20775 Filed 9–24–19; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 72–20; NRC–2017–0136]

U.S. Department of Energy Idaho Operations Office; Three Mile Island Unit 2; Independent Spent Fuel Storage Installation

AGENCY: Nuclear Regulatory Commission.

ACTION: License renewal; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has issued a renewed license to the U.S. Department of Energy Idaho Operations Office for Special Nuclear Materials (SNM) License No. SNM–2508 for the receipt, possession, transfer, and storage of radioactive material from the Three Mile Island Unit 2 (TMI–2) reactor core in the TMI–2 independent spent fuel storage installation (ISFSI). The TMI–2 ISFSI is located at the Idaho National Laboratory within the perimeter of the Idaho Nuclear Technology and Engineering Center site in Scoville, Butte County,

Idaho. The renewed license authorizes operation of the TMI–2 ISFSI in accordance with the provisions of the renewed license and its technical specifications. The renewed license expires on March 19, 2039.

DATES: The license referenced in this document is available as of September 16, 2019.

ADDRESSES: Please refer to Docket ID NRC–2017–0136 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2017–0136. Address questions about NRC docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *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.* For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the ''Availability of Documents'' section.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Kristina Banovac, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–7116, email: *Kristina.Banovac@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Discussion

Based upon the application dated March 6, 2017, as supplemented August 9, 2017, October 3, 2017, October 18, 2017, November 16, 2017, September 26, 2018, October 2, 2018, November 15, 2018, November 21, 2018, April 1, 2019, and May 21, 2019, the NRC has issued a renewed license to the licensee for the TMI–2 ISFSI, located in Scoville, Butte County, Idaho. The renewed license SNM–2508 authorizes and requires operation of the TMI–2 ISFSI in accordance with the provisions of the renewed license and its technical specifications. The renewed license will expire on March 19, 2039.

The licensee's application for a renewed license complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the NRC's rules and regulations. The NRC has made appropriate findings as required by the Act and the NRC's regulations in chapter 1 of title 10 of the *Code of Federal Regulations* (10 CFR), and sets forth those findings in the renewed license. The agency afforded an opportunity for a hearing in the Notice of Opportunity for a Hearing published in the **Federal Register** on June 9, 2017 (82 FR 26815). The NRC received no request for a hearing or petition for leave to intervene following the notice.

The NRC staff prepared a safety evaluation report for the renewal of the ISFSI license and concluded, based on that evaluation, the ISFSI will continue to meet the regulations in 10 CFR part 72. The NRC staff also prepared an environmental assessment and finding of no significant impact for the renewal of this license, which were published in the **Federal Register** on September 16, 2019 (84 FR 48651). The NRC staff's consideration of the impacts of continued storage of spent nuclear fuel (as documented in NUREG–2157, ''Generic Environmental Impact Statement for Continued Storage of Spent Fuel'') was included in the environmental assessment. The NRC staff concluded that renewal of this ISFSI license will not have a significant impact on the quality of the human environment.

II. Availability of Documents

The following table includes the ADAMS Accession Numbers for the documents referenced in this notice. For additional information on accessing ADAMS, see the **ADDRESSES** section of this document.

Document	ADAMS Accession No.
Licensee's application, dated March 6, 2017	ML19053A310
Submittal of Requested References, dated August 9, 2017	ML17248A347
Response to Request for Additional Information for the Environmental Review, dated October 3, 2017	ML17305A060
Submittal of Additional Requested Reference, dated October 18, 2017	ML17298A771
Submittal of Supplemental Information for the Environmental Review, dated November 16, 2017	ML17345A156
Response to Request for Additional Information for the Technical Review, dated September 26, 2018	ML18283A222
Submittal of Final Safety Analysis Report Information and Design Drawings, dated October 2, 2018	ML18303A125
Submittal of Additional Requested Reference, dated November 15, 2018	ML18331A337
Submittal of Additional TMI–2 Canister Drawings, dated November 21, 2018	ML18331A262
Response to Request for Clarification of Response to Technical Request for Additional Information, dated April 1, 2019.	ML19093B118
Response to Request for Additional Clarification, dated May 21, 2019	ML19143A217
Special Nuclear Materials License No. SNM–2508	ML19259A014, ML19259A016
SNM–2508 Technical Specifications	ML19259A017
NRC Safety Evaluation Report	ML19259A013
NRC Environmental Assessment	ML19122A285
NUREG–2157, ''Generic Environmental Impact Statement for Continued Storage of Spent Fuel'' Vol. 1	ML14196A105
NUREG–2157, ''Generic Environmental Impact Statement for Continued Storage of Spent Fuel'' Vol. 2	ML14196A107

Dated at Rockville, Maryland, this 20th day of September, 2019.

For the Nuclear Regulatory Commission.

Meraj Rahimi,

Chief, Renewals and Materials Branch, Division of Spent Fuel Management, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2019–20853 Filed 9–24–19; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2019–202 and CP2019–225]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning negotiated service agreements. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* September 27, 2019.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. Docketed Proceeding(s)

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3007.301.[1]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3010, and 39 CFR part 3020, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* MC2019–202 and CP2019–225; *Filing Title:* USPS Request to Add First-Class Package Service Contract 103 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* September 19, 2019; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3020.30 *et seq.,* and 39 CFR 3015.5; *Public Representative:* Christopher C. Mohr; *Comments Due:* September 27, 2019.

This Notice will be published in the **Federal Register**.

Darcie S. Tokioka,

Acting Secretary.

[FR Doc. 2019–20780 Filed 9–24–19; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL SERVICE

Product Change—First-Class Package Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* September 26, 2019.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on September 19, 2019, it filed with the Postal Regulatory Commission a *USPS Request to Add First-Class Package Service Contract 103 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2019–202, CP2019–225.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2019–20703 Filed 9–24–19; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Sunshine Act Meeting; Board of Governors

DATES AND TIMES: Thursday, October 3, 2019, at 10:00 a.m.

PLACE: Washington, DC.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

Thursday, October 3, 2019 at 9:00 a.m.

1. Strategic Items.
2. Financial Matters.
3. Compensation and Personnel Matters.
4. Administrative Items.
5. Executive Session—Discussion of prior agenda items and Board governance.

GENERAL COUNSEL CERTIFICATION: The General Counsel of the United States Postal Service has certified that the meeting may be closed under the Government in the Sunshine Act.

CONTACT PERSON FOR MORE INFORMATION: Michael J. Elston, Acting Secretary of the Board, U.S. Postal Service, 475 L'Enfant Plaza SW, Washington, DC 20260–1000. Telephone: (202) 268–4800.

Michael J. Elston,

Acting Secretary.

[FR Doc. 2019–20915 Filed 9–23–19; 4:15 pm]

BILLING CODE 7710–12–P

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87027; File No. SR–NYSECHX–2019–09]

Self-Regulatory Organizations; NYSE Chicago, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Extend the Pilot Related to the Market-Wide Circuit Breaker in Article 20, Rule 2

September 19, 2019.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on September 17, 2019, the NYSE Chicago, Inc. (''NYSE Chicago'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to extend the pilot related to the market-wide circuit breaker in Article 20, Rule 2. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

Article 20, Rule 2 provides a methodology for determining when to halt trading in all stocks due to extraordinary market volatility (*i.e.,* market-wide circuit breakers). The market-wide circuit breaker (''MWCB'') mechanism under Article 20, Rule 2 was approved by the Commission to operate on a pilot basis,[4] the term of which was to coincide with the pilot period for the Plan to Address Extraordinary Market Volatility Pursuant to Rule 608 of Regulation NMS (the ''LULD Plan''),[5] including any extensions to the pilot period for the LULD Plan.[6] The Commission recently approved an amendment to the LULD Plan for it to operate on a permanent, rather than pilot, basis.[7] In light of the proposal to make the LULD Plan permanent, the Exchange amended Article 20, Rule 2 to untie the pilot's effectiveness from that of the LULD Plan and to extend the pilot's effectiveness to the close of business on October 18, 2019.[8]

The Exchange now proposes to amend Article 20, Rule 2 to extend the pilot to the close of business on October 18, 2020. This filing does not propose any substantive or additional changes to Article 20, Rule 2. The Exchange will use the extension period to develop with the other SROs rules and procedures that would allow for the periodic testing of the performance of the MWCB mechanism, with industry member participation in such testing. The extension will also permit the exchanges to consider enhancements to the MWCB processes such as modifications to the Level 3 process.

The market-wide circuit breaker under Article 20, Rule 2 provides an important, automatic mechanism that is invoked to promote stability and investor confidence during a period of significant stress when securities markets experience extreme broad-based declines. All U.S. equity exchanges and FINRA adopted uniform rules on a pilot basis relating to market-wide circuit breakers in 2012 (''MWCB Rules''), which are designed to slow the effects of extreme price movement through coordinated trading halts across securities markets when severe price declines reach levels that may exhaust market liquidity.[9] Market-wide circuit breakers provide for trading halts in all equities and options markets during a severe market decline as measured by a single-day decline in the S&P 500 Index.

Pursuant to Article 20, Rule 2, a market-wide trading halt will be triggered if the S&P 500 Index declines in price by specified percentages from the prior day's closing price of that index. Currently, the triggers are set at three circuit breaker thresholds: 7% (Level 1), 13% (Level 2), and 20% (Level 3). A market decline that triggers a Level 1 or Level 2 halt after 9:30 a.m. ET and before 3:25 p.m. ET would halt market-wide trading for 15 minutes, while a similar market decline at or after 3:25 p.m. ET would not halt market-wide trading. A market decline that triggers a Level 3 halt, at any time during the trading day, would halt market-wide trading until the primary listing market opens the next trading day.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[10] in general, and furthers the objectives of Section 6(b)(5) of the Act,[11] 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. The market-wide circuit breaker mechanism under Article 20, Rule 2 is an important, automatic mechanism that is invoked to promote stability and investor confidence during a period of significant stress when securities markets experience extreme broad-based declines. Extending the market-wide circuit breaker pilot for an additional year would ensure the continued, uninterrupted operation of a consistent mechanism to halt trading across the U.S. markets while the Exchange, with the other SROs, consider and develop rules and procedures that would allow

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* Securities Exchange Act Release No. 67090 (May 31, 2012), 77 FR 33531 (June 6, 2012) (SR–CHX–2011–30).

[5] *See* Securities Exchange Act Release No. 67091 (May 31, 2012), 77 FR 33498 (June 6, 2012). The LULD Plan provides a mechanism to address extraordinary market volatility in individual securities.

[6] *See* Securities Exchange Act Release Nos. 67090 (May 31, 2012), 77 FR 33531 (June 6, 2012) (SR–CHX–2011–30) (Approval Order); and 68777 (January 31, 2013), 78 FR 8673 (February 6, 2013) (SR–CHX–2013) (Notice of Filing of Immediate Effectiveness of Proposed Rule Change Delaying the Operative Date of a Rule Change to CHX Article 20, Rule 2).

[7] *See* Securities Exchange Act Release No. 85623 (April 11, 2019), 84 FR 16086 (April 17, 2019).

[8] *See* Securities Exchange Act Release No. 85565 (April 9, 2019), 84 FR 15239 (April 15, 2019) (SR–NYSECHX–2019–05).

[9] *See* Securities Exchange Act Release No. 67090 (May 31, 2012), 77 FR 33531 (June 6, 2012) (SR–BATS–2011–038; SR–BYX–2011–025; SR–BX–2011–068; SR–CBOE–2011–087; SR–C2–2011–024; SR–CHX–2011–30; SR–EDGA–2011–31; SR–EDGX–2011–30; SR–FINRA–2011–054; SR–ISE–2011–61; SR–NASDAQ–2011–131; SR–NSX–2011–11; SR–NYSE–2011–48; SR–NYSEAmex-2011–73; SR–NYSEArca–2011–68; SR–Phlx–2011–129) (''MWCB Approval Order'').

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(5).

for the periodic testing of the performance of the MWCB mechanism, which would include industry member participation in such testing. The extension will also permit the exchanges to consider enhancements to the MWCB processes such as modifications to the Level 3 process.

The Exchange also believes that the proposed rule change promotes just and equitable principles of trade in that it promotes transparency and uniformity across markets concerning when and how to halt trading in all stocks as a result of extraordinary market volatility. Based on the foregoing, the Exchange believes the benefits to market participants from the MWCB under Article 20, Rule 2 should continue on a pilot basis because the MWCB will promote fair and orderly markets, and protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act because the proposal would ensure the continued, uninterrupted operation of a consistent mechanism to halt trading across the U.S. markets while the Exchange, in conjunction with the other SROs, consider and develop rules and procedures that would allow for the periodic testing of the performance of the MWCB mechanism. Furthermore, as noted above, the extension will permit the exchanges to consider enhancements to the MWCB processes such as modifications to the Level 3 process.

Further, the Exchange understands that FINRA and other national securities exchanges will file proposals to extend their rules regarding the market-wide circuit breaker pilot. Thus, the proposed rule change will help to ensure consistency across market centers without implicating any competitive issues.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [12] and Rule 19b–4(f)(6)(iii) thereunder.[13]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [14] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSECHX–2019–09 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–NYSECHX–2019–09. 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–NYSECHX–2019–09 and should be submitted on or before October 16, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Jill M. Peterson,

Assistant Secretary.

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[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] 15 U.S.C. 78s(b)(2)(B).

[15] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87019; File No. SR–IEX–2019–10]

Self-Regulatory Organizations: Investors Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Add a Corporate Discretionary Peg Order Type and Make Two Minor Non-Substantive Clarifying Changes to the Definition of a Discretionary Peg Order

September 19, 2019.

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 September 13, 2019, the Investors Exchange LLC (''IEX'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

by the Exchange. The Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [3] and Rule 19b–4(f)(6) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Pursuant to the provisions of Section 19(b)(1) under the Act,[5] and Rule 19b–4 thereunder,[6] IEX is filing with the Securities and Exchange Commission (''Commission'') a proposed rule change to add an additional Discretionary Peg order type (a ''Corporate Discretionary Peg'' or ''C-Peg'' order) that pegs to the less aggressive of (*i.e.,* the lower of) the Midpoint Price,[7] the consolidated last sale price, or the order's limit price, if any. The Exchange is also proposing to make two non-substantive, clarifying changes to the definition of a Discretionary Peg order. The Exchange has designated this rule change as ''non-controversial'' under Section 19(b)(3)(A) of the Act [8] and provided the Commission with the notice required by Rule 19b–4(f)(6) thereunder.[9] The text of the proposed rule change is available at the Exchange's website at *www.iextrading.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statement may be examined at the places specified in Item IV below. The self-regulatory organization 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 the Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this proposed rule filing is to amend IEX Rule 11.190 to add a new type of Discretionary Peg order type, a C-Peg order. As set forth in proposed Rule 11.190(b)(16), a C-Peg order is a non-displayed, pegged, buy order that upon entry into the System,[10] the price of the order is automatically adjusted to be equal to the less aggressive of (*i.e.,* the lower of) the Midpoint Price, the consolidated last sale price, or the order's limit price, if any. Furthermore, when unexecuted shares of a C-Peg order are posted to the Order Book,[11] consistent with the discretionary functionality of the order type, the price of the order is automatically adjusted by the System to be equal to and ranked at the less aggressive of one minimum price variant (''MPV'') [12] less than the NBB,[13] the consolidated last sale price, or the order's limit price, if any (the order's ''resting price'').

In order to meet the limit price of active orders on the Order Book, a C-Peg order will exercise the least amount of price discretion necessary from the C-Peg order's resting price to its discretionary price (*i.e.,* the less aggressive of the Midpoint Price, consolidated last sale price, or the C-Peg order's limit price, if any), except during periods of quote instability as defined in Rule 11.190(g), when a C-Peg order is only eligible to trade at its resting price, as discussed further below. When exercising price discretion, a C-Peg order maintains time priority at its resting price and is prioritized behind any non-displayed interest at the discretionary price for the duration of that book processing action. If multiple C-Peg orders are exercising price discretion during the same book processing action, they maintain their relative time priority at the discretionary price. In the event the NBB becomes locked or crossed, C-Peg orders resting on or posting to the Order Book are priced one (1) MPV less aggressive than the locking or crossing price.[14]

Pursuant to Rule 11.190(g), the Exchange utilizes real time relative quoting activity of certain Protected Quotations [15] and a proprietary mathematical calculation (the ''quote instability calculation'') to assess the probability of an imminent change to the current Protected NBB to a lower price (''quote instability factor'').[16] When the quoting activity meets predefined criteria and the quote instability factor calculated is greater than the Exchange's defined quote instability threshold, the System treats the quote as unstable and the crumbling quote indicator (''CQI'') is on at that price level for two milliseconds, or until the CQI triggers again. During all other times, the quote is considered stable, and the CQI is off. The System independently assesses the stability of the Protected NBB and Protected NBO for each security.

As proposed, when the CQI is on, resting C-Peg orders will not exercise price discretion to meet the limit price of an active (*i.e.,* taking) order. However, C-Peg orders are eligible for execution at their resting price when the CQI is on, if at or below the consolidated last sale price and the order's limit price (if any). Therefore, when IEX determines the quote to be unstable, C-Peg orders are protected from trading more aggressively at a price that appears to be unstable, and thus imminently stale, between the order's resting price and the Midpoint Price.

Further, C-Peg orders will not be executable until at least one consolidated last sale trade in the security has occurred on the current day.[17]

Otherwise, C-Peg orders would operate in the same manner as Discretionary Peg (''D-Peg'') orders. Specifically, both C-Peg and D-Peg orders:

- May have any TIF described in Rule 11.190(c) and as described in Rule 11.190(a)(3).
- Are not eligible for routing pursuant to Rule 11.230(b) and (c)(2).
- May not be ISOs, as defined in Rule 11.190(b)(12).
- May be submitted with a limit price or without a limit price.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

[5] 15 U.S.C. 78s(b)(1).

[6] 17 CFR 240.19b–4.

[7] *See* Rule 1.160(t).

[8] 15 U.S.C. 78s(b)(3)(A).

[9] 17 CFR 240.19b–4.

[10] *See* Rule 1.160(nn).

[11] *See* Rule 1.160(p).

[12] *See* Rule 11.210.

[13] The term ''NBB'' means the national best bid, as set forth in Rule 600(b) of Regulation NMS under the Act, determined as set forth in IEX Rule 11.410(b).

[14] *See* Rule 11.190(h)(3)(C)(ii) and (D)(ii) regarding how Discretionary Peg orders behave in locked and crossed markets.

[15] Pursuant to Rule 11.190(g), only the Protected Quotations of the New York Stock Exchange, Nasdaq Stock Market, NYSE Arca, Nasdaq BX, Cboe BZX Exchange, Cboe BYX Exchange, Cboe EDGX Exchange, and Cboe EDGA Exchange are considered in the calculation.

[16] Rule 11.190(g) also applies to quote instability involving sell orders, but because C-Peg orders are always buy orders, this rule filing only addresses the applicability of Rule 11.190(g) to buy orders.

[17] *See infra* discussion on Members' compliance obligations with respect to the safe harbor of Rule 10b–18 of the Exchange Act. 17 CFR 240.10b–18.

• Are eligible to trade during the Regular Market Session. If a C-Peg or D-Peg order is submitted pre-market with a TIF of DAY, the order will be queued by the System until the start of the Regular Market Session (and in the case of a C-Peg, until after at least one last sale eligible trade in the security has occurred).

• May be a MQTY, as defined in Rule 11.190(b)(11).

• Are always non-displayed.

• May be an odd lot, round lot, or mixed lot.

• Are eligible to be invited by the System to Recheck the Order Book to trade against interest resting at the Midpoint Price as described in Rule 11.230(a)(4)(D).

The Exchange believes that a C-Peg order can assist Members handling an issuer's (and/or its affiliated purchasers') repurchases (or ''buybacks'') of an issuer's common stock in managing compliance with certain aspects of the ''safe harbor'' under Rule 10b–18 of the Act (''Rule 10b–18'').[18] Rule 10b–18 provides an issuer (and its affiliated purchasers) with a ''safe harbor'' from liability for manipulation under Sections 9(a)(2) of the Act [19] and Rule 10b–5 under the Act [20] in connection with the issuer's buyback of its common stock in the market. For the safe harbor to apply, buybacks by or on behalf of the issuer must comply with four specific provisions with respect to the manner, time, price, and volume of the repurchases, and not be made as ''part of a plan or scheme to evade the federal securities laws.'' [21]

Although the Rule 10b–18 safe harbor conditions apply directly to issuers (and their affiliated purchasers), issuers retain broker-dealers to conduct buybacks on their behalf subject to the relevant conditions of Rule 10b–18. A C-Peg order may assist IEX's broker-dealer Members conducting buybacks on behalf of an issuer (or their affiliated purchasers) with their efforts to comply with two aspects of the price and timing conditions of the Rule 10b–18 safe harbor for securities traded on IEX as described below.[22]

First, a C-Peg order may assist Members' compliance with the price condition because a C-Peg order will not trade above the last transaction price reported in the consolidated system (*i.e.,* the ''consolidated last sale price'' [23]). The Member handling the order must separately manage compliance with whether the transaction meets the independence test since Exchange functionality will not validate whether the consolidated last sale price was an ''independent'' transaction with respect to the issuer.[24] A C-Peg order will also not peg to the highest independent bid, even if higher than the consolidated last sale price, notwithstanding that the price test of the Rule 10b–18 safe harbor would permit a trade at such a price. Second, a C-Peg order may assist Members' compliance with the first aspect of the timing condition of the Rule 10b–18 safe harbor because a C-Peg order will not execute until after the first trade in the stock is reported to the consolidated tape that day.

Further, use of a C-Peg order will not guarantee that Members meet all requirements of the Rule 10b–18 safe harbor, specifically that the issuer: (i) Use only one broker-dealer on any single day; (ii) not conduct repurchases at certain times prior to the close of a trading day; and (iii) not exceed certain purchase volume requirements. Additionally, issuers and their affiliated purchasers, if relying on the safe harbor for buybacks, remain fully responsible for their compliance with all of the safe harbor conditions.

Based on informal discussions with several Members, IEX believes there is significant interest in a Discretionary Peg order type that will assist Members with their compliance with the pricing and one of the timing conditions of Rule 10b–18, while providing the benefits of a Discretionary Peg order, namely the opportunity to execute issuer buybacks at the Midpoint Price (if at or lower than the last consolidated sale price) with protection from execution at a potentially stale price.

The Exchange notes that this proposed rule change is based on IEX's current D-Peg order type and has new features that are substantially similar to New York Stock Exchange (''NYSE'') Rules 7.31(i)(4) (Last Sale Peg Modifier) and 13(f)(4)(B) (Buy Minus Zero Plus) with several minor differences.[25] Specifically, the NYSE Last Sale Peg Modifier order pegs to the lower of the last consolidated sale price, the limit price of the order, or the Protected Best Offer,[26] as opposed to a C-Peg which pegs to the lower of the Midpoint Price, the consolidated last sale price, or the order's limit price, if any. Also, a Last Sale Peg Modifier order will be rejected if there is no last consolidated sale price (*i.e.,* the stock has not yet traded that day),[27] but a C-Peg will wait to execute until there is an initial transaction in the stock and then will be marketable.

Comparing the NYSE Buy Minus Zero Plus order to the C-Peg, a Buy Minus Zero Plus order can only be a limit order that trades at a price equal to or lower than the last consolidated sale price of the stock, as opposed to a C-Peg order which can be submitted with or without a limit price, and the C-Peg's resting price will shift as the spread shifts.

The C-Peg order type is also distinct from the NYSE Last Sale Peg and Buy

[18] *See* 17 CFR 240.10b–18. Use of a C-Peg order is merely a tool to assist Members (and issuers and their affiliated purchasers) with compliance with specified aspects of the Rule 10b–18 safe harbor. Use of a C-Peg order would not guarantee that such order meets all of the requirements of the safe harbor conditions, and Members submitting C-Peg orders on behalf of issuers and their affiliated purchasers remain fully responsible for all aspects of compliance with the Rule 10b–18 safe harbor. In addition, issuers and their affiliated purchasers, if relying on the safe harbor for buybacks, remain fully responsible for all aspects of their compliance with the safe harbor conditions. IEX also notes that this rule change proposal is unrelated to a petition for rulemaking that IEX submitted in 2018 seeking a modification of the pricing safe harbor condition to include executions priced at the midpoint of the NBBO. *See* Petition for Rulemaking from John Ramsay on behalf of IEX (March 27, 2018) (Petition Number 4–722).

[19] 15 U.S.C. 78i(a)(2).

[20] 17 CFR 240.10b–5.

[21] *See* Securities Exchange Act Release No. 48766 (November 10, 2003), 68 FR 64952, 64954 (November 17, 2003) (''Adopting Release'').

[22] The price condition provides that the Rule 10b–18 purchases must be effected at a purchase price that ''[d]oes not exceed the highest independent bid or the last independent transaction price, whichever is higher, quoted or reported in the consolidated system at the time the Rule 10b–18 purchase is effected.'' The timing conditions provide that any stock repurchases not be the ''opening (regular way) purchase reported in the consolidated system,'' not be made within 10 or 30 minutes of the market close (depending upon the volume or public float value of the stock), and only trade after market close if they meet certain criteria. 17 CFR 240.10b–18(b)(3)(i) and (b)(2).

[23] The consolidated last sale price is only based on round or mixed lot transactions reported to the applicable securities information processor (*i.e.,* the Consolidated Trade Association or Unlisted Trading Privileges Plans) which is consistent with the term as used in the price safe harbor condition. Since 2013, odd-lot transactions have been reported to the consolidated tape, but are not included in calculations of last sale prices. *See* Securities Exchange Act. Rel. No. 70793 (Oct. 31, 2013), 78 FR 66788 (November 6, 2013) (S7–24–89) and Securities Exchange Act. Rel. No. 70794 (Oct. 31, 2013), 78 FR 66789 (November 6, 2013) (SR–CTA–2013–05).

[24] IEX notes the Adopting Release includes discussion that the term ''independent'' would only include a transaction not effected by or on behalf of the issuer (or any of its affiliated purchasers). For example, the Adopting Release states that the ''price condition is intended to prevent the issuer from leading the market for the security through its repurchases by limiting the issuer to bidding for or buying its security at a price that is no higher than the highest independent published bid or last independent transaction price.'' Adopting Release, 68 FR at 64854.

[25] *See* Securities Exchange Act Release No. 85649 (April 15, 2019), 84 FR 16549 (April 19, 2019) (SR–NYSE–2019–16) and Securities Exchange Act Release No. 78679 (August 25, 2016), 81 FR 60080 (August 31, 2016) (SR–NYSE–2016–59).

[26] *See* NYSE Rule 7.31(i)(4).

[27] *Id.*

Minus Plus order types because it is a type of Discretionary Peg order, which means that it will exercise the minimum amount of price discretion between its resting price and discretionary price when seeking to execute at or near the Midpoint Price, except during periods of quote instability.

Housekeeping Changes to Rule 11.190(b)(10)

The Exchange is also proposing to make two non-substantive, clarifying changes to the definition of a Discretionary Peg order.[28] Specifically, the Exchange proposes to add text at the end of the clause about how a Discretionary Peg order behaves during periods of quote instability to explicitly state that the order is only eligible to trade at its resting price. While the Exchange believes that the existing text clearly provides by implication that during periods of quote instability a Discretionary Peg order is only eligible to trade at its resting price, the additional text will provide more fulsome clarity. The proposed new text is underlined below:

. . . In order to meet the limit price of active orders on the Order Book, a Discretionary Peg order will exercise the least amount of price discretion necessary from the Discretionary Peg order's resting price to its discretionary price (defined as the less aggressive of the Midpoint Price or the Discretionary Peg order's limit price, if any), except during periods of quote instability as defined in paragraph (g) below *when a Discretionary Peg order is only eligible to trade at its resting price.* . . .

The Exchange also proposes to delete the extraneous word ''that'' from Rule 11.190(b)(10)(F), as specified below with the deletion in brackets. The proposed deletion merely corrects a typographical error and has no impact on the meaning of the rule text.

Is eligible to trade only during the Regular Market Session. As provided in IEX Rule 11.190(a)(3)(D), any pegged order marked with a TIF of DAY that is submitted to the System before the opening of the Regular Market Session will be queued by the System until the start of the Regular Market Session; any pegged order [that] which is marked with a TIF other than DAY will be rejected when submitted to the System during the Pre-Market Session. Any pegged order submitted into the System after the closing of the Regular Market Session will be rejected.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[29] in general, and furthers the objectives of Section 6(b)(5),[30] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and 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. Specifically, the Exchange believes that the proposed rule change is consistent with the protection of investors and the public interest because it is designed to increase competition among execution venues for issuer buyback order flow, with the benefits of a Discretionary Peg order, as described in the Purpose section. While issuer buyback orders are conducted on IEX today, the Exchange believes that providing an order type that may assist Members' compliance with aspects of the Rule 10b–18 safe harbor will provide additional incentives for Members (as well as issuers and their affiliated purchasers) to conduct buybacks on IEX.

Further, IEX believes that the proposal is consistent with the protection of investors and the public interest in that the C-Peg order type may assist Members in their compliance with Rule 10b–18's safe harbor conditions when conducting issuer buybacks. By increasing the likelihood that an issuer's stock buybacks will execute at or near the Midpoint Price and decreasing the likelihood that the order will be executed at a stale price, IEX believes that the C-Peg order type may assist Members and the issuers (and affiliated purchasers) for whom they trade with their compliance with the federal securities laws while also helping foster enhanced execution quality for an issuer conducting a stock buyback.

In addition, as noted in the Purpose section, a C-Peg order will function very similarly to a Discretionary Peg buy order, except that a C-Peg order will not execute at a price higher than the consolidated last sale price for the security. Further, the proposed C-Peg order type contains new functionality that is substantially similar to existing NYSE order types, as described in the Purpose section.[31] Thus, IEX does not believe that the proposed changes raise any new or novel material issues that have not already been considered by the Commission in connection with existing order types offered by the IEX and other national securities exchanges.[32]

Also, the Exchange believes that providing for potential execution of issuer buybacks at or near the Midpoint Price may facilitate Members' compliance with their best execution obligations when acting as an agent on behalf of an issuer.[33] Specifically, as noted in FINRA Regulatory Notice 15–46 (Guidance on Best Execution Obligations in Equity, Options and Fixed Income Markets), when conducting its review of execution quality in any security, a firm should consider, among other things, whether it could obtain midpoint price improvement on one venue versus less price improvement on another venue.[34]

Further, the Exchange does not believe that the proposed rule change raises any concerns regarding unfair competition. All Members would be eligible to use a C-Peg order type, regardless of whether the Member is conducting an issuer buyback. While not every Member conducts a business involving representation of issuer buyback orders, there is no restriction on any Member conducting such activity.

Finally, the Exchange believes that the proposed nonsubstantive clarifying changes to Rule 11.190(b)(10) are consistent with the protection of investors and the public interest because they will have no impact on the functionality of Discretionary Peg orders, but rather simply provide additional clarity on how Discretionary Peg orders operate.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. To the contrary, IEX believes that introducing the C-Peg order type would continue to enhance competition and execution quality for Members conducting an issuer buyback among execution venues, by providing an order type that may assist Members with their compliance with the pricing conditions and one of the timing conditions of Rule 10b–18.

[28] Rule 11.190(b)(10).

[29] 15 U.S.C. 78f(b).

[30] 15 U.S.C. 78f(b)(5).

[31] *See supra* note 21 [sic].

[32] *See, e.g.,* Securities Exchange Act Release No. 85351 (March 18, 2019), 84 FR 10871 (March 18, 2019) (SR–IEX–2018–23).

[33] All IEX Members that handle customer orders as agent are required to be FINRA members, and therefore are subject to FINRA guidance. *See* 17 CFR 240.15b9–1(a).

[34] *See* FINRA Regulatory Notice 15–46, endnote 25 available at: *https://www.finra.org/sites/default/files/notice_doc_file_ref/Notice_Regulatory_15–46.pdf.*

The Exchange does not believe that the proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. Competing exchanges have and can continue to adopt similar order types, subject to the SEC rule change process, as discussed in the Purpose and Statutory Basis sections.[35] Moreover, there is no barrier to other national securities exchange adopting similar order types.

The Exchange also does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. All Members would be eligible to use a C-Peg order type, because the use of this particular order type will be available to any market participant, not just Members conducting issuer buybacks. While not every Member conducts a business involving representation of issuer buyback orders, there is no restriction on any Member conducting such activity.

Further, the proposed housekeeping changes to Rule 11.190(b)(10) are not designed to address any competitive issue, but rather to provide additional clarity on the operation of D-Peg orders.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the 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) of the Act[36] and subparagraph (f)(6) of Rule 19b–4 thereunder.[37]

The Exchange believes that the proposed rule change meets the criteria of subparagraph (f)(6) of Rule 19b–4[38] because it may assist Members with their compliance with the safe harbor of Rule 10b–18 and is substantially similar to order types previously approved or considered by the Commission and as discussed in the Statutory Basis and Burden on Competition sections.[39] Specifically, the proposed C-Peg order will function very similarly to a Discretionary Peg buy order, except that a C-Peg order will not execute at a price higher than the consolidated last sale price for the security.[40] Further, the proposed C-Peg order type contains new functionality that is substantially similar to existing NYSE order types, as described in the Purpose section.[41] Thus, IEX does not believe that the proposed changes raise any new or novel material issues that have not already been considered by the Commission in connection with existing order types offered by IEX and other national securities exchanges.

The Exchange will implement the proposed rule change within 90 days of filing, subject to the 30-day operative delay, and provide at least ten (10) days' notice to Members and market participants of the implementation timeline.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

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–IEX–2019–010 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–IEX–2019–010. 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–IEX–2019–010 and should be submitted on or before October 16, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[42]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–20700 Filed 9–24–19; 8:45 am]

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[35] *See supra* note 21 [sic].

[36] 15 U.S.C. 78s(b)(3)(A).

[37] 17 CFR 240.19b–4(f)(6). In addition, Rule19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[38] 17 CFR 240.19b–4(f)(6).

[39] *See supra* notes 21, 28 [sic].

[40] *See supra* note 28 [sic].

[41] *See supra* note 21 [sic].

[42] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No 34–87012; File No. SR–NASDAQ–2019–060]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Designation of Longer Period for Commission Action on Proposed Rule Change To Amend Rules 4120 and 4753

September 19, 2019.

On July 18, 2019, The Nasdaq Stock Market LLC (''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend Rules 4120 and 4753 to permit the Exchange to declare a regulatory halt in a security that traded in the over-the-counter market prior to its initial pricing on the Exchange and to allow for the initial pricing of such securities through the IPO Cross. The proposed rule change was published for comment in the **Federal Register** on August 6, 2019.[3] The Commission has received no comments on the proposal.

Section 19(b)(2) of the Act [4] provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day for this filing is September 20, 2019.

The Commission is extending the 45-day time period for Commission action on the proposed rule change. The Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change.

Accordingly, pursuant to Section 19(b)(2) of the Act,[5] the Commission designates November 4, 2019, as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR–NASDAQ–2019–060).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–20699 Filed 9–24–19; 8:45 am]

BILLING CODE 8011–01–P

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 86537 (July 31, 2019), 84 FR 38321.

[4] 15 U.S.C. 78s(b)(2).

[5] 15 U.S.C. 78s(b)(2).

[6] 17 CFR 200.30–3(a)(31).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87013; File No. SR–CBOE–2019–048]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing of a Proposed Rule Change To Adopt Rule 6.49C

September 19, 2019.

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 September 6, 2019, Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') filed with the Securities and Exchange Commission (''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

Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') proposes to adopt Rule 6.49C. The text of the proposed rule change is provided below. (additions are *italicized;* deletions are [bracketed])

* * * * *

Rules of Cboe Exchange, Inc.

* * * * *

Rule 6.49C. In-Kind Exchange of Options Positions and ETF Shares

Notwithstanding the prohibition set forth in Rule 6.49, positions in options listed on the Exchange may be transferred off the Exchange by a Trading Permit Holder in connection with transactions to purchase or redeem creation units of ETF shares between an authorized participant and the issuer of such ETF shares, which transfer occurs at a price related to the net asset value of such ETF shares. For purposes of this Rule:

(a) an ''authorized participant'' is an entity that has a written agreement with the issuer of ETF shares or one of its service providers, which allows the authorized participant to place orders for the purchase and redemption of creation units (i.e., specified numbers of ETF shares); and

(b) an ''issuer of ETF shares'' is an entity registered with the Commission as an open-end management investment company under the Investment Company Act of 1940.

* * * * *

The text of the proposed rule change is also available on the Exchange's website (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, 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 adopt Rule 6.49C to add a new exception to the Exchange's general requirement that transfers of options contracts listed on the Exchange be effected on an exchange, as set forth in Rule 6.49.[3] Rule 6.49A specifies the circumstances under which Trading Permit Holders may currently effect transfers of positions off the trading floor, notwithstanding the prohibition in Rule 6.49.

Background

As discussed further below, the ability to effect ''in kind'' transfers is a key component of the operational structure of an exchange-traded fund

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Rule 6.49(a) (Transactions Off the Exchange) generally requires transactions of option contracts listed on the Exchange for a premium in excess of $1.00 to be effected on the floor of the Exchange or on another exchange.

(''ETF''). Currently, in general, ETFs can effect in-kind transfers with respect to equity securities and fixed-income securities. The in-kind process is a major benefit to ETF shareholders and, in general, the means by which assets may be added to or removed from ETFs. In-kind transfers protect ETF shareholders from the undesirable tax effects of frequent ''creations and redemptions'' (described below) and improve the overall tax efficiency of the products. However, currently, the Exchange Rules do not allow ETFs to effect in-kind transfers of options off of the Exchange, resulting in tax inefficiencies for ETFs that hold them. As a result, the use of options by ETFs is substantially limited.

Current Rule 6.49A(a) lists the circumstances under which Trading Permit Holders may transfer their positions off of the Exchange. The circumstances currently listed include: (1) The dissolution of a joint account in which the remaining Trading Permit Holder assumes the positions of the joint account; (2) the dissolution of a corporation or partnership in which a former nominee of the corporation or partnership assumes the positions; (3) positions transferred as part of a Trading Permit Holder's capital contribution to a new joint account, partnership, or corporation; (4) the donation of positions to a not-for-profit corporation; (5) the transfer of positions to a minor under the Uniform Gifts to Minors Act; and (6) a merger or acquisition where continuity of ownership or management results.[4]

The Exchange proposes to add a new circumstance under which off-floor transfers of options positions would be permitted to occur. Specifically, under proposed Rule 6.49C, positions in options listed on the Exchange would be permitted to be transferred off the Exchange by a Trading Permit Holder in connection with transactions to purchase or redeem ''creation units'' of ETF shares between an ''authorized participant''[5] and the issuer[6] of such ETF shares,[7] which transfer would occur at the price used to calculate the net asset value (''NAV'') of such ETF shares. The NAV for ETF shares is represented by the traded price for ETFs holding options positions on days of creation or redemption, and an options pricing model on days in which creations and redemptions do not occur. This proposed new exception, although limited in scope, would have a significant impact in that it would help protect ETF shareholders from undesirable tax consequences and facilitate tax-efficient operations. The frequency with which ETFs and authorized participants would rely on the proposed exception would depend upon such factors as the number of ETFs holding options positions traded on the Exchange, the market demand for the shares of such ETFs, the redemption activity of authorized participants, and the investment strategies employed by such ETFs.

As described in further detail below, while ETFs do not sell and redeem individual shares to and from investors, they do sell large blocks of their shares to, and redeem them from, authorized participants in conjunction with what is known as the ETF creation and redemption process. Although currently prohibited in light of Rule 6.49, under the proposed exception, ETFs that hold options listed on the Exchange would be permitted to effect creation and redemption transactions with authorized participants on an ''in-kind'' basis, which is the process that may generally be utilized by ETFs for other asset types. This ability would allow such ETFs to function as more tax-efficient investment vehicles to the benefit of investors that hold ETF shares. In addition, it may also result in transaction cost savings for the ETFs, which may be passed along to investors.

While the Exchange recognizes that, in general, the execution of options transactions on exchanges provides certain benefits, such as price discovery and transparency, based on the circumstances under which proposed Rule 6.49C would apply, the Exchange does not believe that such benefits would be compromised. In this regard, as discussed more fully below, the Exchange notes that in conjunction with the creation and redemption process, positions would be transferred at a price related to the NAV of ETF shares. In addition, although options positions would be transferred off of the Exchange, they would not be closed or ''traded.'' Rather, they would reside in a different clearing account until closed in a trade on the Exchange or until they expire. Further, as discussed below, proposed Rule 6.49C would be clearly delineated and limited in scope, given that the proposed exception would apply only to transfers of options effected in connection with the creation and redemption process.

The ETF Creation and Redemption Process[8]

Due to their ability to effect in-kind transfers with authorized participants in conjunction with the creation and redemption process described below, ETFs have the potential to be significantly more tax-efficient than other pooled investment products, such as mutual funds. ETFs issue shares that may be purchased or sold during the day in the secondary market at market-determined prices. Similar to other types of investment companies, ETFs invest their assets in accordance with their investment objectives and investment strategies, and ETF shares represent interests in an ETF's underlying assets. ETFs are, in certain respects, similar to mutual funds in that they continuously offer their shares for sale. In contrast to mutual funds, however, ETFs do not sell or redeem individual shares. Rather, through the creation and redemption process referenced above, authorized participants that have contractual arrangements with an ETF and/or its service provider (*e.g.,* its distributor)

[4] The Exchange notes that other options exchanges have adopted rules that provide for off-floor transfers under similar circumstances. *See, e.g.,* Nasdaq OMX PHLX LLC Rule 1058(a); and NYSE Arca, Inc. Rule 6.78–O(d)(1). The Exchange recently proposed changes to Rule 6.49A, which rule filing is currently pending with the Securities and Exchange Commission (the ''Commission''). *See* Securities Exchange Act Release No. 86400 (July 17, 2019), 84 FR 35438 (July 23, 2019) (SR–CBOE–2019–035).

[5] The Exchange is proposing that, for purposes of proposed Rule 6.49C, the term ''authorized participant'' would be defined as an entity that has a written agreement with the issuer of ETF shares or one of its service providers, which allows the authorized participant to place orders for the purchase and redemption of creation units (*i.e.,* specified numbers of ETF shares). While an authorized participant may be a Trading Permit Holder and directly effect transactions in options on the Exchange, an authorized participant that is not a Trading Permit Holder may effect transactions in options on the Exchange through a Trading Permit Holder on its behalf.

[6] The Exchange is proposing that, for purposes of proposed 6.49C, any issuer of ETF shares would be registered with the Commission as an open-end management investment company under the Investment Company Act of 1940 (the ''1940 Act'').

[7] An ETF share is a share or other security traded on a national securities exchange and defined as an NMS stock, as set forth in Rule 5.3, Interpretation and Policy .06, which includes open-end management investment companies registered with the Commission. *See* Rule 1.1.

[8] The following summary of the ETF creation and redemption process is based largely on portions of the discussion set forth in Investment Company Act Release No. 33140 (June 28, 2018), 83 FR 37332 (July 31, 2018) (the ''Proposed ETF Rule Release'') in which the Commission proposed a new rule under the 1940 Act that would permit ETFs registered as open-end management investment companies that satisfy certain conditions to operate without the need to obtain an exemptive order. The proposed rule is currently pending.

purchase and redeem shares directly from that ETF in large aggregations known as ''creation units.'' In general terms, to purchase a creation unit of ETF shares from an ETF, in return for depositing a ''basket'' of securities and/or other assets identified by the ETF on a particular day, the authorized participant will receive a creation unit of ETF shares. The basket deposited by the authorized participant is generally expected to be representative of the ETF's portfolio [9] and, when combined with a cash balancing amount (*i.e.,* generally an amount of cash intended to account for any difference between the value of the basket and the NAV of a creation unit), if any, will be equal in value to the aggregate NAV of the shares of the ETF comprising the creation unit. After purchasing a creation unit, an authorized participant may then hold individual shares of the ETF and/or sell them in secondary market transactions. Investors may purchase individual ETF shares in the secondary market. In connection with effecting redemptions, the creation process described above is reversed. More specifically, the authorized participant will redeem a creation unit of ETF shares to the ETF in return for a basket of securities and/or other assets (along with any cash balancing amount).

The ETF creation and redemption process, coupled with the secondary market trading of ETF shares, facilitates arbitrage opportunities that are intended to help keep the market price of ETF shares at or close to the NAV per share of the ETF. Authorized participants play an important role because of their ability, in general terms, to add ETF shares to, or remove them from, the market. In this regard, if shares of an ETF are trading at a discount (*i.e.,* below NAV per share), an authorized participant may purchase ETF shares in the secondary market, accumulate enough shares for a creation unit and then redeem them from the ETF in exchange for the ETF's more valuable redemption basket. Accordingly, the authorized participant will profit because it paid less for the ETF shares than it received for the underlying assets. The reduction in the supply of ETF shares available on the secondary market, together with the sale of the ETF's basket assets, may cause the price of ETF shares to increase, the price of the basket assets to decrease, or both, thereby causing the market price of the ETF shares and the value of the ETF's holdings to move closer together. In contrast, if the ETF shares are trading at a premium (*i.e.,* above NAV per share), the transactions are reversed (and the authorized participant would deliver the creation basket in exchange for ETF shares), resulting in an increase in the supply of ETF shares which may also help to keep the price of the shares of an ETF close to the value of its holdings.

In comparison to other pooled investment vehicles, one of the significant benefits associated with an ETF's in-kind redemption feature is tax efficiency. In this regard, by effecting redemptions on an in-kind basis (*i.e.,* delivering certain assets from the ETF's portfolio instead of cash), there is no need for the ETF to sell assets and potentially realize capital gains that would be distributed to shareholders. As indicated above, however, because there is currently no applicable exception from Rule 6.49(a), ETFs that invest in options traded on the Exchange are generally required to substitute cash in lieu of such options when effecting redemption transactions with authorized participants. Because they must sell the options to obtain the requisite cash, such ETFs (and, therefore, investors that hold shares of those ETFs) are not able to benefit from the tax efficiencies afforded by in-kind transactions.

An additional benefit associated with the in-kind feature is the potential for transaction cost savings. In this regard, by transacting on an in-kind basis, ETFs may avoid certain transaction costs they would otherwise incur in connection with purchases and sales of securities and other assets. Again, however, without an exception to Rule 6.49(a), this benefit is not available to ETFs with respect to their options holdings.

Discussion

The Exchange notes that the Commission approved Rule 6.49A in 1995 because the Exchange recognized, and the Commission agreed, that under certain circumstances, off-floor transfers were justified.[10] The Exchange believes that it is appropriate to permit off-floor transfers of options positions in connection with the creation and redemption process and recognizes that the prevalence and popularity of ETFs have increased greatly since the adoption of Rule 6.49A. Currently, ETFs serve both as popular investment vehicles and trading tools [11] and, as discussed above, the creation and redemption process, along with the arbitrage opportunities that accompany it, are key ETF features. Accordingly, the Exchange believes that providing an additional, narrow exception to the prohibition of off-exchange transfers of option positions to make it possible for ETFs that invest in options to effect creations and redemptions on an in-kind basis is justified.

The Exchange submits that the proposed exception is clearly delineated and limited in scope and not intended to facilitate ''trading'' options off of the Exchange in order to circumvent the current prohibition of Rule 6.49. In this regard, the proposed exception would be available solely in the context of transfers of options positions effected in connection with transactions to purchase or redeem creation units of ETF shares between ETFs and authorized participants.[12] As a result of this process, such transfers would occur at a price related to the NAV of the applicable ETF shares (as discussed above), which removes the need for price discovery on an Exchange for pricing these transfers. Moreover, as described above, ETFs and authorized participants are not seeking to effect the opening or closing of new options positions in connection with the creation and redemption process. Rather, the options positions would reside in a different clearing account until closed in a trade on the Exchange or until they expire.

The proposed transfers, while occurring between two different parties, will occur off the Exchange and will not be considered transactions (as is the case for current off-floor transfers

[9] Under certain circumstances, however, and subject to the provisions of its exemptive relief from various provisions of the 1940 Act obtained from the Commission, an ETF may substitute cash and/or other instruments in lieu of some or all of the ETF's portfolio holdings. For example, currently, because there is no applicable exception from Rule 6.49(a), positions in options traded on the Exchange would be generally substituted with cash.

[10] *See* Exchange Act Release No. 36647 (December 28, 1995), 61 FR 566 (January 8, 1996) (Order Approving and Notice of Filing and Order Granting Accelerated Approval of Amendments No. 1 and 2 to a Proposed Rule Change Relating to the Transfer of Positions on the Floor of the Exchange in Cases of Dissolution and other Situations) (File No. SR–CBOE–95–36).

[11] As noted in the Proposed ETF Rule Release, during the first quarter of 2018, trading in U.S.-listed ETFs comprised approximately 18.75% of U.S. equity trading by share volume and 28.2% of U.S. equity trading by dollar volume (based on trade and quote data from the New York Stock Exchange and Trade Reporting Facility data from the Financial Industry Regulatory Authority, Inc. (FINRA)). *See* the Proposed ETF Rule Release at 83 FR 37334.

[12] *See supra* note 3. The term ''authorized participant'' is specific and narrowly defined. As noted in the Proposed ETF Rule Release, the requirement that only authorized participants of an ETF may purchase creation units from (or sell creation units to) an ETF ''is designed to preserve an orderly creation unit issuance and redemption process between ETFs and authorized participants.'' Furthermore, an ''orderly creation unit issuance and redemption process is of central importance to the arbitrage mechanism.'' *See* Proposed ETF Rule Release at 83 FR 37348.

permitted by Rule 6.49A).[13] While the prices of options transactions effected on the Exchange are disseminated to OPRA, back-office transfers of options positions in clearing accounts held at The Options Clearing Corporation (''OCC'') (in accordance with OCC Rules)[14] are not disseminated to OPRA or otherwise publicly available, as they are considered position transfers, rather than executions.[15] The Exchange believes that price transparency is important in the options market. However, the Exchange expects any transfers pursuant to the proposed rule will constitute a minimal percentage of average daily volume of options. Additionally, as noted above, the NAV for the transfers will generally be based on the disseminated closing price for an option series on the day of a creation or redemption, and thus the price (although not the time or quantity of the transfer) at which these transfers will generally be effected will be publicly available. Further, the Exchange generally expects creations or redemptions to include corresponding transactions by the authorized participant that will occur on an exchange and be reported to OPRA.[16] Therefore, the Exchange expects that any impact the proposed rule change could have on price transparency in the options market would be de minimis.

Other than the transfers covered by the proposed exception, transactions involving options, whether held by an ETF or an authorized participant, would be fully subject to Rule 6.49 (except as provided by any other applicable exceptions) and all other applicable trading Rules.[17] Accordingly, the Exchange does not believe that the proposed new exception would compromise price discovery or transparency.

Further, the Exchange believes that providing an additional exception to make it possible for ETFs that invest in options to effect creations and redemptions on an in-kind basis is justified because, while the proposed exception would be limited in scope, the benefits that may flow to ETFs that hold options and their investors may be significant. Specifically, the Exchange expects such ETFs and their investors would benefit from increased tax efficiencies and potential transaction cost savings. By making such ETFs more attractive to both current and prospective investors, the proposed rule change would enable them to compete more effectively with other ETFs that, due to their particular portfolio holdings, may effect in-kind creations and redemptions without restriction.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[18] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[19] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The Exchange believes that permitting off-floor transfers in connection with the in-kind ETF creation and redemption process promotes just and equitable principles of trade and helps remove impediments to and perfect the mechanism of a free and open market and a national market system, as it would permit ETFs that invest in options traded on the Exchange to utilize the in-kind creation and redemption process that is available for ETFs that invest in equities and fixed-income securities. This process represents a significant feature of the ETF structure generally, with advantages that distinguish ETFs from other types of pooled investment vehicles. In light of the associated tax efficiencies and potential transaction cost savings, the Exchange believes the ability to utilize an in-kind process would make such ETFs more attractive to both current and prospective investors and enable them to compete more effectively with other ETFs that, based on their portfolio holdings, may effect in-kind creations and redemptions without restriction. In addition, the Exchange believes that because it would permit ETFs that invest in options traded on the Exchange to benefit from tax efficiencies and potential transaction cost savings afforded by the in-kind creation and redemption process, which benefits the Exchange expects would generally be passed along to investors that hold ETF shares, the proposed rule change would protect investors and the public interest.

Moreover, the Exchange submits that the proposed exception is clearly delineated and limited in scope and not intended to facilitate ''trading'' options off the Exchange in order to circumvent the current prohibition of Rule 6.49. Other than the transfers covered by the proposed exception, transactions involving options, whether held by an ETF or an authorized participant, would be fully subject to Rule 6.49 (except as provided by any other applicable exceptions) and all other applicable trading Rules. Additionally, the transfers covered by the proposed exception would occur at a price related to the NAV of the applicable ETF shares, which removes the need for price discovery on an Exchange. Accordingly, the Exchange does not believe that the proposed rule change would compromise price discovery or transparency.

When Congress charged the Commission with supervising the development of a ''national market system'' for securities, Congress stated its intent that the ''national market system evolve through the interplay of competitive forces as unnecessary regulatory restrictions are removed.[20] Consistent with this purpose, Congress and the Commission have repeatedly stated their preference for competition, rather than regulatory intervention to determine products and services in the

[13] For this reason, the Exchange notes that Rule 6.51(c) does not require reporting of off-floor transfers effected pursuant to Rule 6.49A, or that would be effected pursuant to proposed Rule 6.49C.

[14] OCC has informed the Exchange that it has the operational capabilities to effect the proposed position transfers. All transfers pursuant to proposed Rule 6.49C would be required to comply with OCC rules. *See* Rule 4.2 (which requires all TPHs that are members of OCC to comply with OCC's Rules).

[15] For example, any transfers effected pursuant to the current exemptions to Rule 6.49 contained in Rule 6.49A are not disseminated to OPRA.

[16] The Exchange notes that for in-kind creations, an authorized participant will acquire the necessary options positions in an on-exchange transaction that will be reported to OPRA. For in-kind redemptions, the Exchange generally expects that an authorized participant will acquire both the shares necessary to effect the redemption and an options position to offset the position that it will receive as proceeds for the redemption. Such an options position would likely be acquired in an on-exchange transaction that would be reported to OPRA. Such transactions are generally identical to the way that creations and redemptions work for equities and fixed income transactions—while the transfer between the authorized participant and the fund is not necessarily reported, there are generally corresponding transactions that would be reported, providing transparency into the transactions.

[17] As indicated above, the operation of the arbitrage mechanism accompanying the creation and redemption process generally contemplates ongoing interactions between authorized participants and the market in transactions involving both ETF shares and the assets comprising an ETF's creation/redemption basket.

[18] 15 U.S.C. 78f(b).

[19] 15 U.S.C. 78f(b)(5).

[20] *See* H.R. Rep. No. 94–229, at 92 (1975) (Conf. Rep.).

securities markets.[21] This consistent and considered judgment of Congress and the Commission is correct, particularly in light of evidence of robust competition among exchanges. The fact that an exchange proposed something new is a reason to be receptive, not skeptical — innovation is the life-blood of a vibrant competitive market — and that is particularly so given the continued internalization of the securities markets, as exchanges continue to implement new products and services to compete not only in the United States but throughout the world. Exchanges continuously adopt new and different products and trading services in response to industry demands in order to attract order flow and liquidity to increase their trading volume. This competition has led to a growth in investment choices, which ultimately benefits the marketplace and the public.

Currently, the Exchange Rules do not allow ETFs to effect in-kind transfers of options off of the Exchange, resulting in tax inefficiencies for ETFs that hold them. As a result, the use of options by ETFs is substantially limited. While the proposed exception would be limited in scope, the Exchange believes the benefits that may flow to ETFs that hold options and their investors may be significant. Specifically, the Exchange expects that such ETFs and their investors could benefit from increased tax efficiencies and potential transaction cost savings. By making such ETFs more attractive to both current and prospective investors, the proposed rule change would enable them to compete more effectively with other ETFs that, due to their particular portfolio holdings, may effect in-kind creations and redemptions without restriction. This may lead to further development of ETFs that invest in options, thereby fostering competition and resulting in additional choices for investors, which ultimately benefits the marketplace and the public.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. Utilizing the proposed exception would be voluntary, and the exception is not intended as a competitive trading tool. As an alternative to the normal auction process, the proposed rule change would provide market participants with an efficient and effective means to transfer positions under the specified circumstances. The proposed exception would enable all ETFs that hold options to enjoy the benefits of in-kind creations and redemptions already available to other ETFs (and to pass these benefits along to investors). The proposed rule change would apply in the same manner to all entities that meet the definition of ''authorized participant.''

The Exchange does not believe the proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. As indicated above, it is intended to provide an additional clearly delineated and limited exception to the requirement that options positions be transferred on the floor of an exchange. Further, the Exchange believes the proposed rule change will eliminate a significant competitive disadvantage for ETFs that invest in options. Finally, as indicated above, in light of the significant benefits provided (*e.g.,* tax efficiencies and potential transaction cost savings), the proposed exception may lead to further development of ETFs that invest in options, thereby fostering competition and resulting in additional choices for investors, which ultimately benefits the marketplace and the public. Other options exchanges in their discretion may pursue the adoption of similar exceptions.

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 written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission will:

A. By order approve or disapprove such proposed rule change, or

B. institute proceedings to determine whether the proposed rule change should be disapproved.

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–CBOE–2019–048 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–CBOE–2019–048. 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

[21] *See* S. Rep. No. 94–75, 94th Cong., 1st Sess. 8 (1975) (''The objective [in enacting the 1975 amendments to the Exchange Act] would be to enhance competition and to allow economic forces, interacting within a fair regulatory field, to arrive at appropriate variations in practices and services.''); Order Approving Proposed Rule Change Relating to NYSE Arca Data, Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770 (December 9, 2008) (''The Exchange Act and its legislative history strongly support the Commission's reliance on competition, whenever possible, in meeting its regulatory responsibilities for overseeing the [self-regulatory organizations] and the national market system. Indeed, competition among multiple markets and market participants trading the same products is the hallmark of the national market system.''); and Regulation NMS, 70 FR at 37499 (observing that NMS regulation ''has been remarkably successful in promoting market competition in [the] forms that are most important to investors and listed companies'').

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–CBOE–2019–048, and should be submitted on or before October 16, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[22]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–20708 Filed 9–24–19; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87030; File No. SR–NASDAQ–2019–077]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Order Routing Rule in NOM Chapter VI, Section 11

September 19, 2019.

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 September 12, 2019, The Nasdaq Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend The Nasdaq Options Market LLC Rules at Chapter VI, Section 11, titled ''Order Routing''.

The text of the proposed rule change is available on the Exchange's website at *http://nasdaq.cchwallstreet.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

[22] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

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 amend NOM Chapter VI, Section 11, titled ''Order Routing'' to conform the rule text of NOM's Chapter VI, Section 11, where applicable, to Nasdaq Phlx LLC (''Phlx'') Rule 1093 and Nasdaq BX, Inc. (''BX'') Chapter VI, Section 11 where the routing behavior is identical. Phlx and BX recently amended their routing rules.[3] The Exchange notes that the proposed amendments to NOM Chapter VI, Section 11 reflect the current operation of the System. The Exchange proposes to provide additional scenarios and outcomes when routing on NOM.

The Exchange proposes to provide rule text within proposed NOM Chapter VI, Section 11(a)[4] similar to Phlx Rule 1093(a) and BX Chapter VI, Section 11(a). Phlx offers FIND and SRCH routing strategies, NOM and BX offer SEEK and SRCH routing strategies.[5] Some other differences among the three markets include: (1) Phlx's All-or-None[6] Order type differs from NOM;[7] (2) unlike Phlx and BX, NOM does not have an exposure notification;[8] (3) unlike Phlx and BX where Immediate or Cancel Orders will not route, NOM Immediate or Cancel (''IOC'') Orders are considered for routing and will cancel if not executed on NOM or an away market[9] and (4) NOM defines a Public Customer at Chapter I, Section 1(a)(49) similar to BX, while Phlx defines Public Customer within Rule 1093(a).[10]

Further, the Exchange is amending NOM Chapter VI, Section 11 to add more clarity to the current Rule. The proposed changes will be discussed below in greater detail. The Exchange notes that the amendments to NOM Chapter VI, Section 11 reflect the current operation of the System.

The Exchange proposes to capitalize the term ''system'' as that term is defined within Chapter VI, Section 1(a) throughout the rule.

Chapter VI, Section 11(a)

Current NOM Chapter VI, Section (a)(1)(C) language concerning the Route Timer is being relocated into proposed NOM Chapter VI, Section 11(a). The SEEK and SRCH routing functions describe the manner in which the Order Book is checked, this sentence is not necessary in this introductory paragraph.

The Exchange proposes a new second paragraph at NOM Chapter VI, Section

[3] *See* Securities Exchange Act Release Nos. 85655 (April 16, 2019), 77 FR 16709 (April 22, 2019) (SR–Phlx–2019–06); and 86060 (June 6, 2019), 84 FR 27374 (June 12, 2019) (SR–BX–2019–017).

[4] Proposed NOM Chapter VI, Section 11(a) would provide, ''NOM offers two routing strategies, SEEK and SRCH. Each of these routing strategies will be explained in more detail below. An order may in the alternative be marked Do Not Route or ''DNR''. The Exchange notes that for purposes of this rule the System will route SEEK and SRCH Orders with no other contingencies. The System checks the Order Book for available contracts for potential execution against the SEEK or SRCH orders. After the System checks the Order Book for available contracts, orders are sent to other available market centers for potential execution. For purposes of this rule, a Route Timer shall not exceed one second and shall begin at the time orders are accepted into the System, and the System will consider whether an order can be routed at the conclusion of each Route Timer. For purposes of this rule, NOM's opening process is governed by Chapter VI, Section 8 and includes an opening after a trading halt (''Opening Process'').''

[5] NOM and BX do not have a FIND routing strategy similar to Phlx.

[6] *See* Phlx Rule 1078. Phlx's All-or-None Order is non-displayed. This order type could cause Phlx's Order Book to differ from the displayed PBBO. NOM has no such non-displayed order type.

[7] *See* NOM Chapter VI, Section 1(e)(10). ''All-or-none'' shall mean a market or limit order which is to be executed in its entirety or not at all. All-or-None Orders are treated as having a time-in-force designation of Immediate or Cancel. All-or-None Orders received prior to the opening cross or after market close will be rejected.

[8] Both Phlx and BX offer an exposure notification during the Route Timer. This notification alerts options participants that interest is available and currently subject to a Route Timer. The notification provides information on price, size, and side of interest that is available for execution.

[9] *See* NOM Chapter VI, Section 1(g)(2). ''Immediate Or Cancel'' or ''IOC'' shall mean for orders so designated, that if after entry into the System a marketable order (or unexecuted portion thereof) becomes non-marketable, the order (or unexecuted portion thereof) shall be canceled and returned to the entering participant. IOC Orders shall be available for entry from the time prior to market open specified by the Exchange on its website until market close and for potential execution from 9:30 a.m. until market close. IOC Orders entered between the time specified by the Exchange on its website and 9:30 a.m. Eastern Time will be held within the System until 9:30 a.m. at which time the System shall determine whether such orders are marketable.

[10] BX and NOM Rules at Chapter 1, Section 1(a)(49) provide, ''The term ''Public Customer'' means a person that is not a broker or dealer in securities.''

11(a)[11] similar to BX Chapter VI, Section 11(a) and Phlx Rule 1093. The first sentence of current NOM Chapter VI, Section 11(a)[12] is being amended and relocated to proposed NOM Chapter VI, Section 11(a). The first sentence currently provides, ''For System securities, the order routing process shall be available to Participants from 9:30 a.m. Eastern Time until market close and shall route orders as described below.'' The amendment to the rule text is not substantive. The Exchange proposes to relocate the remainder of current NOM Chapter VI, Section 11(a) to the first sentence of the second paragraph of proposed NOM Chapter VI, Section 11(a). Finally, the Exchange proposes to relocate current NOM Chapter VI, Section 11(a)(1)[13] to the second paragraph of proposed Chapter VI, Section 11(a) and amend the term ''routing options'' to ''routing instructions.''

Proposed NOM Chapter VI, Section 11(a)(i)[14] is being relocated from current NOM Chapter VI, Section 11(c)[15] with some minor non-substantive changes to the rule text to conform the paragraph to Phlx Rule 1093(a)(i) and BX Chapter VI, Section 11(a)(i).

Current NOM Chapter VI, Section 11(d)[16] is proposed to be relocated to proposed NOM Chapter VI, Section 11(a)(ii) with some minor non-substantive changes. The Exchange proposes to relocate NOM Chapter VI, Section 11(e) and (f) to proposed NOM Chapter VI, Section 11(a)(ii)(A)–(F). Current Chapter VI, Section 11(g), ''Cancellation of Orders and Error Account'' is being re-lettered from ''g'' to ''b'' with no changes to the rule text.

DNR Orders

The Exchange proposes to add a new NOM Chapter VI, Section 11(a)(iii)[17] with the following text, ''The following order types are available:''. The Exchange proposes to adopt a new paragraph at NOM Chapter VI, Section 11(a)(iii)(A) to describe the manner in which a DNR Order would be handled by the System. Current Chapter VI, Section 11(a) provides Participants can designate orders as either available for routing or not available for routing but offers no other detail. While the proposed new paragraph is similar to NOM and BX, the Exchange notes that unlike Phlx Rule 1093(a)(iii)(A) and BX Chapter VI, Section 11(a)(iii)(A), any references to exposure would not be included in the NOM DNR Order description as NOM does not offer an exposure notification. The Exchange notes that the NOM DNR Order description provides detail as to the manner in which DNR Orders are handled currently by the System. A DNR Order would be repriced in the case of a locked or crossed market. The Exchange displays the DNR Order at one MPV away in compliance with Regulation NMS. An order will not be executed at a price that trades through another market or displayed at a price that would lock or cross another market. An order that is designated by a member as non-routable will be re-priced in order to comply with applicable Trade-Through and Locked and Crossed Markets restrictions.[18] The Exchange also provides details as to the price at which a DNR Order would rest on the Order Book and/or execute. While the ABBO can improve when it crosses a DNR Order the updated ABBO cannot be utilized to execute the DNR Order. However, if the DNR order locks or crosses the BBO, the DNR order will immediately execute. This proposed new paragraph will add greater transparency as to the handling of DNR Orders. The Exchange believes that the proposed language will benefit market participants because it provides greater information. Specifically, the Exchange proposes to make clear that any incoming order interacting with such a resting DNR Order will execute at the ABBO price, unless (1) the ABBO is improved to a price which crosses the DNR's displayed price, in which case the incoming order will execute at the previous ABBO price; (2) the ABBO is improved to a price which locks the DNR's displayed price, in which case the incoming order will execute at the DNR's displayed price. This proposed rule text provides the scenarios of when the ABBO, if improved, would cause the DNR Order to execute and at what price depending on whether the ABBO was locked or crossed.

SEEK Order

The Exchange proposes to relocate SEEK Orders which are currently within NOM Chapter VI, Section 11(a)(1)(A) into proposed new NOM Chapter VI,

[11] The second paragraph of proposed NOM Chapter VI, Section 11(a) would provide, ''Routing instructions may be combined with all available order types and times-in-force, with the exception of order types and times-in-force whose terms are inconsistent with the terms of a particular routing instruction. The term ''System routing table'' refers to the proprietary process for determining the specific trading venues to which the System routes orders and the order in which it routes them. The Exchange reserves the right to maintain a different System routing table for different routing instructions and to modify the System routing table at any time without notice. The order routing process shall be available to Participants from 9:30 a.m. Eastern Time until market close and shall route orders as described below. Participants can designate orders as either available for routing or not available for routing. All routing of orders shall comply with Chapter XII, Options Order Protection and Locked and Crossed Market Rules.''

[12] Proposed NOM Chapter VI, Section 11(a) provides, ''For System securities, the order routing process shall be available to Participants from 9:30 a.m. Eastern Time until market close and shall route orders as described below. Participants can designate orders as either available for routing or not available for routing. All routing of orders shall comply with Chapter XII, Options Order Protection and Locked and Crossed Market Rules.''

[13] Current NOM Chapter VI, Section 11(a)(1) provides, ''The system provides a number of routing options pursuant to which orders are sent to other available market centers for potential execution, per the entering firm's instructions. Routing options may be combined with all available order types and times-in-force, with the exception of order types and times-inforce whose terms are inconsistent with the terms of a particular routing option. The term ''System routing table'' refers to the proprietary process for determining the specific trading venues to which the System routes orders and the order in which it routes them. The Exchange reserves the right to maintain a different System routing table for different routing options and to modify the System routing table at any time without notice. The system routing options are:''.

[14] Current NOM Chapter VI, Section 11(b) is reserved and is being deleted.

[15] Current NOM Chapter VI, Section 11(c) provides, ''Priority of Routed Orders. Orders sent by the System to other markets do not retain time priority with respect to other orders in the System and the System shall continue to execute other orders while routed orders are away at another market center. Once routed by the System, an order becomes subject to the rules and procedures of the destination market including, but not limited to, order cancellation. A routed order can be for less than the original incoming order's size. If a routed order is subsequently returned, in whole or in part, that routed order, or its remainder, shall receive a new time stamp reflecting the time of its return to the System, unless any portion of the original order remains on the System, in which case the routed order shall retain its timestamp and its priority.''

[16] Current NOM Chapter VI, Section 11(d) provides, ''Options Participants whose orders are routed to away markets shall be obligated to honor such trades that are executed on away markets to the same extent they would be obligated to honor a trade executed on NOM.''

[17] Proposed NOM Chapter VI, Section 11(a)(iii)(A) provides, ''A DNR Order will never be routed outside of the Exchange regardless of the prices displayed by away markets. A DNR Order may execute on the Exchange at a price equal to or better than, but not inferior to, the best away market price but, if that best away market remains, the DNR Order will remain in the Exchange book and be displayed at a price one minimum price variation (''MPV'') away from that ABBO. Any incoming order interacting with such a resting DNR Order will execute at the ABBO price, unless (1) the ABBO is improved to a price which crosses the DNR's displayed price, in which case the incoming order will execute at the previous ABBO price; (2) the ABBO is improved to a price which locks the DNR's displayed price, in which case the incoming order will execute at the DNR's displayed price. Should the best away market move to an inferior price level, the DNR Order will automatically re-price from its one MPV inferior to the original away best bid/offer price to one MPV away from the new away best bid/offer price or its original limit price.''

[18] Also, an order that is designated by the member as routable will be routed in compliance with applicable Trade-Through and Locked and Crossed Markets restrictions. *See* NOM Chapter XII.

Section 11(a)(iii)(B) similar to BX Chapter VI, Section 11(a)(1)(A).[19]

The first two sentences of current NOM Chapter VI, Section 11(a)(1)(A) provide, ''SEEK is a routing option pursuant to which an order will first check the System for available contracts for execution. After checking the System for available contracts, orders are sent to other available market centers for potential execution, per the entering firm's instructions.'' The Exchange proposes to amend and relocate this rule text into proposed NOM Chapter VI, Section 11(a)(iii)(B).[20] The Exchange proposes to modify the second sentence of current NOM Chapter VI, Section 11(a)(1)(A) and simply provide that the SEEK Order will be sent to other available market centers for execution.

The Exchange proposes to provide information as to the manner in which a SEEK Order will be handled by the System. The Exchange proposes to add a new proposed paragraph at NOM Chapter VI, Section 11(a)(iii)(B)(1) to provide, ''If a SEEK is received during the Opening Process it may route immediately after the Opening Cross pursuant to Chapter VI, Section 8(b)(7).'' This new text describes the interplay of routing at the end of the Opening Process.[21] The Exchange utilizes the word ''may'' because circumstances may change during the course of the Route Timer which may prevent the SRCH Order from routing (*e.g.* a halt). Further, there may be other routable orders with a higher time or price priority which may cause other SRCH Orders to not route because the away market may not have enough volume to satisfy all the SRCH Orders or the away market price may become inferior. The Exchange proposes to introduce the defined term ''Opening Process'' within proposed NOM Chapter VI, Section 11(a).[22]

The Exchange proposes to add a new proposed paragraph at NOM Chapter VI, Section 11(a)(iii)(B)(2) which provides, ''A SEEK Order received after the Opening Process that is marketable against the ABBO will route immediately after exhausting all Exchange BBO interest at the same or better price.'' Any SEEK Order received after the Opening Process, provided it is marketable against the ABBO, will immediately route after exhausting all Exchange BBO interest priced the same or better than the ABBO. The Exchange notes that during the Route Timer the SEEK Order is displayed as part of the BBO, unless it locks or crosses.

The Exchange proposes a to state at NOM Chapter VI, Section 11(a)(iii)(B)(3),

> If the SEEK Order still has remaining size after an initial route attempt, it may: (i) Trade at the next Exchange BBO price (or prices) if the SEEK Order price is locking or crossing that price (or prices) up to the next ABBO price, and/or (ii) be entered into the Order Book at its limit price if not locking or crossing the Exchange BBO or the ABBO, except a Price Improving SEEK Order will book at its limit price and display one MPV inferior to its limit price. If the SEEK Order trades at the next Exchange BBO price (or prices) and the SEEK Order still has remaining size after the execution, then it may start a Route Timer if the SEEK Order is locking or crossing the ABBO, provided the SEEK Order is not booked at its limit price.

The current rule provides that the order will post to the Order Book and initiate a Route Timer. The Exchange proposes to make clear that several scenarios are possible. First, the SEEK Order may trade at the next Exchange BBO price (or prices) if the SEEK Order price is locking or crossing that price (or prices) up to the next ABBO price. Second, the SEEK Order may be entered into the Order Book at its limit price if not locking or crossing the Exchange BBO or the ABBO. Third, if the SEEK Order trades at the next BBO price (or prices) and the SEEK Order still has remaining size after the execution, then it may start a Route Timer if the SEEK Order is locking or crossing the ABBO, provided the SEEK Order is not booked at its limit price. Current NOM Chapter VI, Section 11(a)(1)(C) provides, ''If an order was routed with either the SEEK or SRCH routing option, and has size after such routing, it will execute against contra side interest in the book, post in the book, and route again pursuant to the process described above, if applicable, if the order's limit price would lock or cross another market center(s).'' The proposed rule text provides more detail as to each of these outcomes.

The Exchange is adding detail about Price Improving Orders.[23] Specifically, the Exchange proposes to state that Price Improving Orders when booked at its limit price are displayed one MPV away. This is consistent with the description of the order type within NOM Chapter VI, Section 1(a)(6).

The Exchange proposes the following circumstances to inform Participants about the various possible outcomes that may occur with SEEK Orders. The proposed amendments to NOM Chapter VI, Section 11 reflect the current operation of the System. As noted herein, the BX rule text is not identical to the NOM rule text because NOM does not have exposure notifications and the Route Timers therefore initiate differently. The Exchange believes that memorializing these various outcomes will provide market participants with greater transparency as to manner in which SEEK Orders will be handled by the System.

Proposed new Chapter VI, Section 11(a)(iii)(B)(4) provides,

> If during the Route Timer, the ABBO markets move such that the SEEK Order is no longer marketable against the ABBO, it may: (i) Trade at the next Exchange BBO price (or prices) if the SEEK Order price is locking or crossing that price (or prices), and/or (ii) be entered into the Order Book at its limit price (or one MPV inferior to its limit price for Price Improving Orders) if not locking or crossing the Exchange BBO. A SEEK Order will be included in the displayed Exchange BBO, unless the SEEK Order locks or crosses the ABBO, in which case it will be entered into the Order Book at the ABBO price and displayed one MPV inferior to the ABBO. If there exists a locked ABBO when the SEEK Order is entered onto the Order Book, the SEEK Order will display at the locked ABBO price. If during the Route Timer any new interest arrives opposite the SEEK Order that is marketable against the SEEK Order, such interest will trade against the SEEK Order at the ABBO price unless the ABBO is improved to a price which crosses the SEEK Order's displayed price, in which case the incoming order will execute at the previous ABBO price. When checking the Order Book, the System will seek to execute at the price at which it would send the order to an away market. Eligible unexecuted orders will continue to be routed as described in paragraph (B)(3).

The Exchange proposes various scenarios that may occur during the Route Timer which would impact order routing. First, the Exchange addresses the scenario where the SEEK Order may not be marketable. If the SEEK Order is not marketable against the ABBO, it

[19] As noted herein, Phlx does not have SEEK Orders.

[20] Proposed NOM Chapter VI, Section 11(a)(iii)(B) provides, ''SEEK Order. SEEK is a routing option pursuant to which an order will first check the System for available contracts for execution, and then is sent to other available market centers for potential execution.''

[21] Proposed NOM Chapter VI, Section 11(a)(iii)(B)(1) provides, ''If a SEEK is received during an Opening Process it may route as part of the Opening Cross pursuant to Chapter VI, Section 8(b)(7).''

[22] The last sentence of the first paragraph of proposed Nasdaq Chapter VI, Section 11(a) provides, ''For purposes of this rule NOM's opening process is governed by Chapter VI, Section 8 and includes an opening after a trading halt (''Opening Process'').''

[23] Price Improving Orders are orders to buy or sell an option at a specified price at an increment smaller than the minimum price variation in the security. Price Improving Orders may be entered in increments as small as one cent. Price Improving Orders that are available for display shall be displayed at the minimum price variation in that security and shall be rounded up for sell orders and rounded down for buy orders. *See* NOM Chapter VI, Section 1(a)(6).

may: (i) Trade at the next Exchange BBO price (or prices) if the SEEK Order price is locking or crossing that price (or prices), and/or (ii) be entered into the Order Book at its limit price (or an MPV inferior to its limit price for Price Improving Orders) if not locking or crossing the Exchange BBO. The Exchange believes the addition of this scenario brings more detail to the current NOM rule.

The Exchange further notes that a SEEK Order will be included in NOM's displayed BBO at its limit price, unless the SEEK Order locks or crosses the ABBO in which case the order will be repriced. The SEEK Order would be placed on the Order Book at the ABBO price and displayed one MPV inferior to the ABBO. If there exists a locked ABBO when the SEEK Order is entered on the Order Book, the SEEK Order will display at the locked ABBO price. The Exchange reprices orders to avoid locking or crossing an away market.

Finally, the Exchange proposes to also note that if during the Route Timer, any new interest arrives opposite the SEEK Order that is marketable against the SEEK Order, such interest will trade against the SEEK Order at the ABBO price unless the ABBO is improved to a price which crosses the SEEK Order's displayed price. In this case the incoming order will execute at the previous ABBO price. The current NOM rule text at Chapter VI, Section 11(a)(1)(C) provides, ''If, during the Route Timer, any new interest arrives opposite the order that is equal to or better than the ABBO price, the order will trade against such new interest at the ABBO price.'' The Exchange's proposed language considers the possibility that the ABBO may cross the SEEK Order displayed price and provides for that scenario as well. The Exchange proposes to make clear that better priced incoming interest will execute against the SEEK Order unless the ABBO crosses the SEEK Order, in which case any new interest will execute at the SEEK Order price.

The following sentence, ''When checking the Order Book, the System will seek to execute at the price at which it would send the order to a destination market center'' is contained within NOM Chapter VI, Section 11(a)(1)(A) and modified to state ''Order Book''. The current rule text at NOM Chapter VI, Section 11(a)(1)(C) provides, ''Eligible unexecuted orders will be routed at the end of the Route Timer provided the order was not filled and the order's limit price would continue to lock or cross the ABBO.'' The Exchange proposes to refer instead back to proposed Chapter VI, Section 11(a)(iii)(B)(3) which includes the additional scenarios.

Current NOM Chapter VI, Section 11(a)(1)(A)[24] is relocated in part. The Exchange proposes to add detail to current rule text within proposed new Chapter VI, Section 11(a)(iii)(B)(5) which provides,

> SEEK Orders booked at their limit price will subsequently be treated as DNR and will not be eligible for routing until the next time the option series is subject to an Opening Process pursuant to Chapter VI, Section 8.

The Exchange is retaining current language, in part, and adding rule text specifically concerning Price Improving Orders. The last sentence of current NOM Chapter VI, Section 11(a)(1)(A), provides, ''SEEK Orders will not be eligible for routing until the next time the option series is subject to a new opening or reopening'' will be relocated to proposed Chapter VI, Section 11(a)(iii)(B)(5) with the defined term ''Opening Process'' utilized to refer to the opening and reopening process. The Exchange proposes to modify current rule text to state that ''SEEK Orders booked at their limit price will subsequently be treated as DNR and will not be eligible for routing until the next time the option series is subject to an Opening Process pursuant to Chapter VI, Section 8.''

The Exchange's proposed rule text expands on this current rule text and provides for whether the order is marketable or not and whether the ABBO locks or crosses the SEEK Order. The Exchange believes that the proposed new rule text provides more context for Participants.

SRCH Order

The Exchange proposes to relocate SRCH Orders which are currently in NOM Chapter VI, Section 11(a)(1)(B) to proposed NOM Chapter VI, Section 11(a)(iii)(C). As noted herein, Phlx and NOM SRCH Orders differ. NOM SRCH Orders are similar to those of BX described within Chapter VI, Section 11(a)(1)(B).

The Exchange proposes to relocate the first two sentences of current NOM Chapter VI, Section 11(a)(1)(B) to proposed NOM Chapter VI, Section 11(a)(iii)(C).[25]

The Exchange proposes to state within proposed NOM Chapter VI, Section 11(a)(iii)(C)(1), ''If a SRCH Order is received during an Opening Process it may route as part of the Opening Cross pursuant to Chapter VI, Section 8(b)(7).'' Similar to the SEEK Order, this language will distinguish the Opening Process from intra-day.

The Exchange proposes a new paragraph at proposed NOM Chapter VI, Section 11(a)(iii)(C)(2), which provides,

> A SRCH Order received after the Opening Process that is marketable against the ABBO will route immediately after exhausting all Exchange BBO interest at the same or better price.

Similar to SEEK Orders, the Exchange proposes to make clear the manner in which a marketable order would route depending on the ABBO in relation to the Exchange BBO price.

The Exchange proposes to add new text at NOM Chapter VI, Section 11(a)(iii)(C)(3) which provides,

> If the SRCH Order still has remaining size after an initial route attempt, it may: (i) Trade at the next Exchange BBO price (or prices) if the SRCH Order price is locking or crossing that price (or prices) up to the next ABBO price, and/or (ii) be entered into the Order Book at its limit price if not locking or crossing the Exchange BBO or the ABBO, except a Price Improving SRCH Order will book at its limit price and display one MPV inferior to its limit price. If the SRCH Order trades at the next Exchange BBO price (or prices) and the SRCH Order still has remaining size after the execution, then it may start a Route Timer if the SRCH Order is locking or crossing the ABBO.

Current NOM Chapter VI, Section 10(a)(1)(B) provide, ''If contracts remain un-executed after routing, they are posted on the book. Once on the book, should the order subsequently be locked or crossed by another market center, it will re-route.'' Similar to SEEK Orders, the Exchange proposes to expand on the various scenarios if the SRCH Order still has remaining size after an initial route attempt within NOM Chapter VI, Section 11(a)(iii)(C)(3). If the SRCH Order still has remaining size after an initial route attempt, it may: (i) Trade at the next Exchange BBO price if the SRCH Order price is locking or crossing that price (or prices) up to the next ABBO price, and/or be entered into the Order Book at its limit price if not locking or crossing the Exchange BBO or the ABBO, except a Price Improving SRCH Order will book at its limit price and display one MPV inferior to its limit price. The Exchange proposes these scenarios where the SRCH Order may

[24] The fifth and sixth sentence of current NOM Chapter VI, Section 11(a)(1)(A) provide, ''If contracts remain un-executed after routing, they are posted on the book at its limit price. While on the book, should the order subsequently be locked or crossed by another market center, the System will not route the order to the locking or crossing market center.''

[25] Proposed NOM Chapter VI, Section 11(a)(iii)(C) provides, ''SRCH Order is a routing option pursuant to which an order will first check the System for available contracts for execution, and then is sent to other available market centers for potential execution.''

not be marketable to bring more detail to the NOM rule. The Exchange then notes that if the SRCH Order trades at the next Exchange BBO price (or prices) and the SRCH Order still has remaining size after the execution, then it may start a Route Timer if the SRCH Order is locking or crossing the ABBO. The Exchange believes that explaining each scenario and the potential outcome will provide market participants with greater information as to the manner in which NOM's System will handle an order marked ''SRCH.'' The proposed amendments to NOM Chapter VI, Section 11 reflect the current operation of the System.

NOM proposes to add new text at NOM Chapter VI, Section 11(a)(iii)(C)(4) which provides,

> If during the Route Timer, the ABBO markets move such that the SRCH Order is no longer marketable against the ABBO, it may: (i) Trade at the next Exchange BBO price (or prices) if the SRCH Order price is locking or crossing that price (or prices), and/or (ii) be entered into the Order Book at its limit price (or one MPV inferior to its limit price for Price Improving Orders) if not locking or crossing the Exchange BBO. A SRCH Order will be included in the displayed Exchange BBO, unless the SRCH Order locks or crosses the ABBO, in which case it will be entered into the Order Book at the ABBO price and displayed one MPV inferior to the ABBO. If there exists a locked ABBO when the SRCH Order is entered onto the Order Book, the SRCH Order will display at the locked ABBO price. If during the Route Timer any new interest arrives opposite the SRCH Order that is marketable against the SRCH Order, such interest will trade against the SRCH Order at the ABBO price, unless the ABBO is improved to a price which crosses the SRCH Order's displayed price, in which case the incoming order will execute at the previous ABBO price. When checking the Order Book, the System will seek to execute at the price at which it would send the order to an away market. Eligible unexecuted orders will continue to be routed as described in paragraph (C)(3).

Similar to SEEK Orders, the Exchange proposes to describe the scenario where during the Route Timer, the ABBO moves and the SRCH Order is no longer marketable against the ABBO. In this scenario, the SRCH Order may: (i) Trade at the next Exchange BBO price (or prices) if the SRCH Order price is locking or crossing that price (or prices), and/or (ii) be entered into the Order Book at its limit price (or one MPV inferior to its limit price for Price Improving Orders) if not locking or crossing the Exchange BBO.

Similar to SEEK Orders, the Exchange notes that the SRCH Order will be included in the displayed Exchange BBO at its limit price, unless the SRCH Order locks or crosses the ABBO, in which case it will be entered into the Order Book at the ABBO price and displayed one MPV inferior to the ABBO. If there is a locked ABBO when the SRCH Order is entered onto the Order Book, the SRCH Order will display at the locked ABBO price. This proposed rule text, similar to rule text for SEEK Orders provides market participants with information as to away bids and offers that are marketable against the SRCH Order. As stated in the DNR Order section, the Exchange would display the SRCH Order at one MPV away in compliance with Regulation NMS. An order will not be executed at a price that trades through another market or displayed at a price that would lock or cross another market. An order that is designated by a member as non-routable will be re-priced in order to comply with applicable Trade-Through and Locked and Crossed Markets restrictions.[26]

The Exchange proposes to relocate and amend current NOM Chapter VI, Section 11(a)(1)(C) provides, ''If, during the Route Timer, any new interest arrives opposite the order that is equal to or better than the ABBO price, the order will trade against such new interest at the ABBO price'' into proposed NOM Chapter VI, Section 11(a)(iii)(C)(4). The Exchange proposes to provide that if during the Route Timer any new interest arrives opposite the SRCH Order that is marketable against the SRCH Order, such interest will trade against the SRCH Order at the ABBO price. However, the Exchange also proposes to add the scenario where the ABBO is improved to a price which crosses the SRCH Order's displayed price, in which case the incoming order will execute at the previous ABBO price. Similar to SEEK Orders the Exchange is providing for a scenario where the SRCH Order is crossed.

The Exchange proposes to relocate the third sentence from current NOM Chapter VI, Section 11(a)(1)(B) and modify it to state, ''When checking the Order Book, the System will seek to execute at the price at which it would send the order to a destination market center.'' Also, the Exchange proposes to relocate and modify the third sentence from current NOM Chapter VI, Section 11(a)(1)(C) and instead, similar to SEEK Orders, provide for eligible unexecuted orders by referring back to the proposed new rule text within NOM Chapter VI, Section 11(a)(iii)(C)(3).

The Exchange proposes new NOM Chapter VI, Section 11(a)(iii)(C)(5) which provides,

> While on the Order Book at the limit price, should the SRCH Order subsequently be locked or crossed by another market center, it may attempt to route at the conclusion of the Route Timer.

Current rule text within NOM Chapter VI, Section 11(a)(1)(B) provides, ''If contracts remain un-executed after routing, they are posted on the book. Once on the book, should the order subsequently be locked or crossed by another market center, it will re-route.'' This sentence is being modified to provide, at the end of NOM Chapter VI, Section 11(a)(iii)(C)(5), ''While on the Order Book at the limit price, should the SRCH Order subsequently be locked or crossed by another market center, it may attempt to route at the conclusion of the Route Timer.'' The addition of ''while on the Order Book at its limit price'' provides some context to the scenario that is being described.

The Exchange proposes all of the following circumstances to inform Participants about the various possible outcomes that may occur with SRCH Orders. The proposed amendments to NOM Chapter VI, Section 11 reflect the current operation of the System. The Exchange believes that memorializing these various outcomes will provide market participants with greater transparency as to manner in which SRCH Orders will be handled by the System.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[27] in general, and furthers the objectives of Section 6(b)(5) of the Act,[28] in particular, in that it is designed to promote just and equitable principles of trade and to protect investors and the public interest because the Exchange is adding more detail to its routing rule to provide market participants with greater transparency. The Exchange believes the added scenarios will provide more context to routing in general and for the specific routing strategies for the benefit of investors and the public interest. Also, in defining terms and utilizing consistent language throughout the rule, the Exchange believes the proposed rule will provide transparency with respect to the manner in which NOM routes orders. The Exchange continues to offer various choices to its market participants with respect to routing. The Exchange notes that the proposed amendments to NOM Chapter VI, Section 11 reflect the current operation of the System.

[26] *See* NOM Chapter XII.

[27] 15 U.S.C. 78f(b).

[28] 15 U.S.C. 78f(b)(5).

Chapter VI, Section 11

The Exchange's proposal to utilize the term ''System'' will conform this rule to other NOM rules that utilize that term. Explaining the Route Timer at the beginning of this proposed rule will provide context to use of the term throughout the rule and avoid repetitiveness. Defining minimum price variation and Opening Process will bring greater transparency to proposed Chapter IV, Section 11. The Exchange believes that it is consistent with the Act to refer to the Opening Process within Chapter VI, Section 8 when referring to routing during the Opening Process to avoid confusion with respect to governing rules. The Exchange's proposal to add the concept of DNR at the beginning of the rule to make clear up-front that this option is available when selecting a routing strategy is a structural non-substantive change intended to bring greater clarity to the rule. The remainder of the rule changes in the introduction are non-substantive rule changes that simply seek to reorganize and add transparency to the current rule text.

Proposed NOM Chapter VI, Section 11(a)(i) is being relocated from current NOM Chapter VI, Section 11(c) with some minor non-substantive changes to the rule text to conform the paragraph to Phlx Rule 1093(a)(i) and BX Chapter VI, Section 11(a)(i). Relocating NOM Chapter VI, Section 11(d)–(f) are non-substantive changes. The Exchange believes that these amendments are consistent with the Act because they will bring greater clarity to NOM Chapter VI, Section 11.

DNR Orders

The Exchange's proposal to add a new NOM Chapter VI, Section 11(a)(iii)(A) to describe the handling of DNR Orders on NOM will bring greater transparency to the Rule. Current Chapter VI, Section 11(a) provides Participants can designate orders as either available for routing or not available for routing but offers no other detail. The new paragraph would be similar to Phlx Rule 1093(a)(iii)(A) and BX Chapter VI, Section 11(a)(iii)(A). The Exchange notes that unlike Phlx Rule 1093(a)(iii)(A) and BX Chapter VI, Section 11(a)(iii)(A), any references to exposure would not be included in the NOM DNR Order description as NOM does not offer an exposure notification. The Exchange believes that providing detail as to the manner in which a DNR Order would be repriced in the case of a locked or crossed market is consistent with the Act. The Exchange displays the DNR Order at one MPV away in compliance with Regulation NMS. An order will not be executed at a price that trades through another market or displayed at a price that would lock or cross another market. An order that is designated by a member as non-routable will be re-priced in order to comply with applicable Trade-Through and Locked and Crossed Markets restrictions.[29] The Exchange also provides details as to the price at which a DNR Order would rest on the Order Book and/or execute. While the ABBO can improve when it crosses the DNR Order the updated ABBO cannot be utilized to execute the DNR Order. However, if the DNR order locks or crosses the BBO, the DNR order will immediately execute. This proposed new paragraph will add greater transparency as to the handling of DNR Orders. The Exchange believes that the proposed language is consistent with the Act and will benefit market participants by providing greater information regarding DNR Orders.

SEEK and SRCH Order

The Exchange is relocating SEEK Orders, currently within NOM Chapter VI, Section 11(a)(1)(A), into proposed new NOM Chapter VI, Section 11(a)(iii)(B) and amending the rule text to simply note the manner in which a SEEK Order routes and include other information into proposed Chapter VI, Section 11(a)(iii)(B)(1)–(5). The Exchange is similarly relocating SRCH Orders which are currently in NOM Chapter VI, Section 11(a)(1)(B) to proposed NOM Chapter VI, Section 11(a)(iii)(C).

The Exchange's proposal to delete the second sentence of current NOM Chapter VI, Section 11(a)(i)(B) which states, '' After checking the System for available contracts, orders are sent to other available market centers for potential execution, per the entering firm's instructions'' is consistent with the Act because this sentence is unnecessary and does not provide additional information as to how a SEEK Order is routed. The Exchange's proposed new rule text provides information as to the manner in which an SEEK Order will be handled by the System in various situations. The Exchange's proposal to add proposed Chapter VI, Section 11(a)(iii)(B) will clarify that a marketable SEEK Order would immediately route, if the ABBO is better priced than the BX BBO. The Exchange proposes the same sentence for SRCH Orders at Chapter VI, Section 11(a)(iii)(C)(1). The Exchange makes clear that an order will not be executed at a price that trades through another market or displayed at a price that would lock or cross another market. An order that is designated by a member as non-routable will be re-priced in order to comply with applicable Trade-Through and Locked and Crossed Markets restrictions.[30] The Exchange proposes to add new text at NOM Chapter VI, Section 11(a)(iii)(B)(1) to describe the interplay of routing at the end of the Opening Process. The Exchange proposes to add the same sentence for SRCH Orders at NOM Chapter VI, Section 11(a)(iii)(C)(1). The Exchange's proposal to replace the remainder of the rule text within current NOM Chapter VI, Section 11(a)(1)(A) with new rule text that provides greater detail is consistent with the Act because the new text will provide greater transparency to the current handling of SEEK Orders.

The Exchange proposes for both SEEK and SRCH Orders to provide for all scenarios when the SEEK or SRCH Order has remaining size and provides for remaining size when the ABBO is locked or crossed.[31] The Exchange also accounts for ABBO movement during the Route Timer such that the SEEK or SRCH Order is no longer marketable against the ABBO and provides the potential scenarios.[32] The Exchange notes if a locked ABBO existed when the SEEK Order was entered onto the Order Book, the price at which the order would display. The rule text also makes clear that better priced incoming interest will execute against the SEEK or SRCH Order unless the ABBO crosses the SEEK or SRCH Order and then new interest will execute at the previous ABBO price.[33]

The Exchange's proposal to provide for additional scenarios within the current rule text for both SEEK and SRCH Orders is consistent with the Act because Participants will be informed about various potential outcomes when marking their orders as SEEK or SRCH. The Exchange's proposal would continue to allow such orders to trade when marketable, but would not permit trade-throughs. The rule text brings greater transparency to the rule by proposing various routing scenarios. The Exchange believes that memorializing these various outcomes will provide market participants with greater transparency as to manner in

[29] *See* NOM Chapter XII.

[30] *See* NOM Chapter XII.

[31] *See* proposed NOM Chapter VI, Section 11(a)(iii)(B)(3) and (C)(3).

[32] *See* proposed NOM Chapter VI, Section 11(a)(iii)(B)(4) and (C)(4).

[33] *Id.*

which SEEK and SRCH Orders will be handled by the System.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposed routing rules apply to all market participants including routing during an Opening Process. The Exchange believes that adding greater detail to its rules does not impose an undue burden on competition, rather it provides greater transparency as to the potential outcomes when utilizing different routing strategies. Further, the Exchange notes that market participants may elect not to route their orders. The Exchange continues to offer various options to its market participants with respect to routing. The Exchange notes that the amendments to NOM Chapter VI, Section 11 reflect the current operation of the System.

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) of the Act [34] and Rule 19b–4(f)(6) thereunder.[35]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act [36] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii) [37] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay so that the proposed rule change may become operative upon filing. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest, as it will allow the Exchange to immediately provide members with greater information and transparency on potential order routing strategies available on the Exchange. For this reason, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.[38]

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–NASDAQ–2019–077 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–2019–077. 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–NASDAQ–2019–077, and should be submitted on or before October 16, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[39]

Jill M. Peterson,

Assistant Secretary.

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[34] 15 U.S.C. 78s(b)(3)(A).

[35] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[36] 17 CFR 240.19b–4(f)(6).

[37] 17 CFR 240.19b–4(f)(6)(iii).

[38] For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[39] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87018; File No. SR–CboeBZX–2019–068]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change To List and Trade Shares of the iShares California Short Maturity Muni Bond ETF of the iShares U.S. ETF Trust Under Rule 14.11(i), Managed Fund Shares

September 19, 2019.

On July 19, 2019, Cboe BZX Exchange, Inc. (''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade shares of the iShares California Short Maturity Muni Bond ETF of the iShares U.S. ETF Trust

[1] 15 U.S.C.78s(b)(1).

[2] 17 CFR 240.19b–4.

under Rule 14.11(i). The proposed rule change was published for comment in the **Federal Register** on August 7, 2019.[3] The Commission has received no comment letters on the proposed rule change.

Section 19(b)(2) of the Act[4] provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding, or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is September 21, 2019. The Commission is extending this 45-day time period.

The Commission finds it appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[5] designates November 5, 2019 as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR–CboeBZX–2019–068).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–20697 Filed 9–24–19; 8:45 am]

BILLING CODE 8011–01–P

[3] *See* Securities Exchange Act Release No. 86546 (Aug. 1, 2019), 84 FR 38689.

[4] 15 U.S.C. 78s(b)(2).

[5] *Id.*

[6] 17 CFR 200.30–3(a)(31).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87016; File No. SR–NYSE–2019–51]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Extend the Pilot Related to the Market-Wide Circuit Breaker in Rules 80B and 7.12

September 19, 2019.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on September 17, 2019, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to extend the pilot related to the market-wide circuit breaker in Rules 80B and 7.12. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

Rules 80B and 7.12 provide a methodology for determining when to halt trading in all stocks due to extraordinary market volatility (*i.e.,* market-wide circuit breakers). The market-wide circuit breaker (''MWCB'') mechanism under Rule 80B was approved by the Commission to operate on a pilot basis,[4] the term of which was to coincide with the pilot period for the Plan to Address Extraordinary Market Volatility Pursuant to Rule 608 of Regulation NMS (the ''LULD Plan''),[5] including any extensions to the pilot period for the LULD Plan.[6] The Commission recently approved an amendment to the LULD Plan for it to operate on a permanent, rather than pilot, basis.[7] In light of the proposal to make the LULD Plan permanent, the Exchange amended Rule 80B to untie the pilot's effectiveness from that of the LULD Plan and to extend the pilot's effectiveness to the close of business on October 18, 2019.[8]

The Exchange now proposes to amend Rules 80B and 7.12 to extend the pilot to the close of business on October 18, 2020. This filing does not propose any substantive or additional changes to Rules 80B or 7.12. The Exchange will use the extension period to develop with the other SROs rules and procedures that would allow for the periodic testing of the performance of the MWCB mechanism, with industry member participation in such testing. The extension will also permit the exchanges to consider enhancements to the MWCB processes such as modifications to the Level 3 process.

The market-wide circuit breaker under Rules 80B and 7.12 provide an important, automatic mechanism that is invoked to promote stability and investor confidence during a period of significant stress when securities markets experience extreme broad-based declines. All U.S. equity exchanges and FINRA adopted uniform rules on a pilot basis relating to market-wide circuit breakers in 2012 (''MWCB Rules''), which are designed to slow the effects of extreme price movement through coordinated trading halts across securities markets when severe price

[1] 15 U.S.C.78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* Securities Exchange Act Release No. 67090 (May 31, 2012), 77 FR 33531 (June 6, 2012) (SR–NYSE–2011–48).

[5] *See* Securities Exchange Act Release No. 67091 (May 31, 2012), 77 FR 33498 (June 6, 2012). The LULD Plan provides a mechanism to address extraordinary market volatility in individual securities.

[6] *See* Securities Exchange Act Release Nos. 67090 (May 31, 2012), 77 FR 33531 (June 6, 2012) (SR–NYSE–2011–48) (Approval Order); and 68784 (January 31, 2013), 78 FR 8662 (February 6, 2013) (SR–NYSE–2013–10) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change Delaying the Operative Date of a Rule Change to NYSE Rule 80B).

[7] *See* Securities Exchange Act Release No. 85623 (April 11, 2019), 84 FR 16086 (April 17, 2019).

[8] *See* Securities Exchange Act Release No. 85560 (April 9, 2019), 84 FR 15247 (April 15, 2019) (SR–NYSE–2019–19) (''Rule 80B pilot extension filing''). At the time of the Rule 80B pilot extension filing, Rule 7.12 existed but was not operative with respect to Exchange-listed securities and was not amended to extend its effectiveness through October 18, 2019. Now that all Exchange-listed securities have transitioned to the Pillar trading platform, Rule 7.12 is operative with respect to all securities trading on the Exchange. *See* Securities Exchange Act Release No. 85962 (May 29, 2019), 84 FR 26188 (June 5, 2019) (SR–NYSE–2019–05). Although Rule 80B is not applicable to trading of any securities on the Exchange, the Exchange believes that amending Rule 80B in this filing would reduce the potential for confusion.

declines reach levels that may exhaust market liquidity.[9] Market-wide circuit breakers provide for trading halts in all equities and options markets during a severe market decline as measured by a single-day decline in the S&P 500 Index.

Pursuant to Rules 80B and 7.12, a market-wide trading halt will be triggered if the S&P 500 Index declines in price by specified percentages from the prior day's closing price of that index. Currently, the triggers are set at three circuit breaker thresholds: 7% (Level 1), 13% (Level 2), and 20% (Level 3). A market decline that triggers a Level 1 or Level 2 halt after 9:30 a.m. ET and before 3:25 p.m. ET would halt market-wide trading for 15 minutes, while a similar market decline at or after 3:25 p.m. ET would not halt market-wide trading. A market decline that triggers a Level 3 halt, at any time during the trading day, would halt market-wide trading until the primary listing market opens the next trading day.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[10] in general, and furthers the objectives of Section 6(b)(5) of the Act,[11] 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. The market-wide circuit breaker mechanism under Rules 80B and 7.12 is an important, automatic mechanism that is invoked to promote stability and investor confidence during a period of significant stress when securities markets experience extreme broad-based declines. Extending the market-wide circuit breaker pilot for an additional year would ensure the continued, uninterrupted operation of a consistent mechanism to halt trading across the U.S. markets while the Exchange, with the other SROs, consider and develop rules and procedures that would allow for the periodic testing of the performance of the MWCB mechanism, which would include industry member participation in such testing. The extension will also permit the exchanges to consider enhancements to the MWCB processes such as modifications to the Level 3 process.

The Exchange also believes that the proposed rule change promotes just and equitable principles of trade in that it promotes transparency and uniformity across markets concerning when and how to halt trading in all stocks as a result of extraordinary market volatility. Based on the foregoing, the Exchange believes the benefits to market participants from the MWCB under Rules 80B and 7.12 should continue on a pilot basis because the MWCB will promote fair and orderly markets, and protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act because the proposal would ensure the continued, uninterrupted operation of a consistent mechanism to halt trading across the U.S. markets while the Exchange, in conjunction with the other SROs, consider and develop rules and procedures that would allow for the periodic testing of the performance of the MWCB mechanism. Furthermore, as noted above, the extension will permit the exchanges to consider enhancements to the MWCB processes such as modifications to the Level 3 process.

Further, the Exchange understands that FINRA and other national securities exchanges will file proposals to extend their rules regarding the market-wide circuit breaker pilot. Thus, the proposed rule change will help to ensure consistency across market centers without implicating any competitive issues.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.[12]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[13] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSE–2019–51 on the subject line.

Paper Comments

- Send paper comments in triplicate to: Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2019–51. 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

[9] *See* Securities Exchange Act Release No. 67090 (May 31, 2012), 77 FR 33531 (June 6, 2012) (SR–BATS–2011–038; SR–BYX–2011–025; SR–BX–2011–068; SR–CBOE–2011–087; SR–C2–2011–024; SR–CHX–2011–30; SR–EDGA–2011–31; SR–EDGX–2011–30; SR–FINRA–2011–054; SR–ISE–2011–61; SR–NASDAQ–2011–131; SR–NSX–2011–11; SR–NYSE–2011–48; SR–NYSEAmex-2011–73; SR–NYSEArca-2011–68; SR-Phlx-2011–129) (''MWCB Approval Order'').

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(5).

[12] 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 short time as designated by the Commission. The Exchange has satisfied this requirement.

[13] 15 U.S.C. 78s(b)(2)(B).

public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2019–51 and should be submitted on or before October 16, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–20709 Filed 9–24–19; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87015; File No. SR–CBOE–2019–060]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule To Amend Its Rules Related to the Electronic Processing of Complex Orders and To Move Them to the Shell Rulebook That Will Become Effective Upon the Migration of the Exchange's Trading Platform to the Same System Used by the Cboe Affiliated Exchanges

September 19, 2019.

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 September 6, 2019, Cboe Exchange, Inc. (''Exchange'' or ''Cboe Options'') filed with the Securities and Exchange Commission (''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

Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') proposes to amend its Rule related to the electronic processing of complex orders and move it from the currently effective Rulebook (''current Rulebook'') to the shell structure for the Exchange's Rulebook that will become effective upon the migration of the Exchange's trading platform to the same system used by the Cboe Affiliated Exchanges (as defined below) (''shell Rulebook''). The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, 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

In 2016, the Exchange's parent company, Cboe Global Markets, Inc. (formerly named CBOE Holdings, Inc.) (''Cboe Global''), which is also the parent company of Cboe C2 Exchange, Inc. (''C2''), acquired Cboe EDGA Exchange, Inc. (''EDGA''), Cboe EDGX Exchange, Inc. (''EDGX'' or ''EDGX Options''), Cboe BZX Exchange, Inc. (''BZX'' or ''BZX Options''), and Cboe BYX Exchange, Inc. (''BYX'' and, together with Cboe Options, C2, EDGX, EDGA, and BZX, the ''Cboe Affiliated Exchanges''). The Cboe Affiliated Exchanges are working to align certain system functionality, retaining only intended differences between the Cboe Affiliated Exchanges, in the context of a technology migration. Cboe Options intends to migrate its trading platform to the same system used by the Cboe Affiliated Exchanges, which the Exchange expects to complete on October 7, 2019. Cboe Options believes offering similar functionality to the extent practicable will reduce potential confusion for market participants.

In connection with this technology migration, the Exchange has a shell Rulebook that resides alongside its current Rulebook, which shell Rulebook will contain the Rules that will be in place upon completion of the Cboe Options technology migration. The proposed rule change first moves and amends it rules regarding the electronic processing of complex orders from the current Rulebook to the shell Rulebook. Specifically, proposed Rule 5.33 modifies the Exchange's current complex order functionality (as set forth in current Rule 6.53C) to substantially conform to the complex order functionality that is used by C2 and EDGX Options. Electronic trading of complex orders will be subject to all other Rules applicable to trading of orders, unless otherwise provided in proposed Rule 5.33. This is true today, and the proposed rule change merely states this in the Rules.

The proposed rule change amends and moves the following definitions related to the electronic processing of complex orders from the current Rulebook to proposed Rule 5.33(a) in the shell Rulebook. The proposed rule change also adds certain definitions.[3] In addition to the substantive changes described below, the proposed rule change makes additional nonsubstantive changes to these Rules, including to make the rule text plain English, simplify the rule provisions, update cross-references and paragraph numbering and lettering, reorganize certain provisions, and eliminate redundant provisions.

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[14] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The proposed rule change adds a definition of ''Legging'' to proposed Rule 5.33(a), which is just a cross-reference to proposed paragraph (g), which is described further below.

Rule provision	Current rule (current rulebook)	Proposed rule (shell rulebook)	Proposed substantive changes
Definition of complex order	Rule 6.53C(a)(1)	Rule 5.33(a) (which refers to Rule 1.1, which has already been moved to the shell Rulebook).	The proposed rule change moves the provision that for purposes of applying ratios to complex orders comprised of legs for both mini-options and standard options, ten mini-option contracts represent one standard option contract from the definition of complex order for electronic purposes to the general definition of complex order, as the same application applies to all complex orders, whether traded electronically or in open outcry.
Definition of stock-option order	Rule 6.53C(a)(2)	Rule 5.33(b)(5)	The proposed rule change states that stock-option orders trade in the same manner as all other complex orders, except as specified in Rule 5.33. This is true today, and the proposed rule change merely makes this explicit in the Rules.
Definition of Complex Order Auction (''COA'')	Rule 6.53C(d)(i)(1)	Rule 5.33(a)	Proposed Rule 5.33 no longer refers to a COA as a request for responses (''RFR''). This is merely a change in terminology.
Definition of Complex Order Book (''COB'') (the Exchange's electronic book of complex orders maintained by the System, which single book is used during both the Regular Trading Hours (''RTH'') and global trading hours (''GTH'') trading sessions).	N/A	Rule 5.33(a)	The current Rulebook does not contain a definition of COB. However, the proposed definition is consistent with current COB functionality, except that currently there is a separate COB for each trading session. Following the migration, there will no longer be a need for a separate COB.[4]
Definition of complex strategy: The term ''complex strategy'' means a particular combination of components and their ratios to one another. New complex strategies can be created as a result of the receipt of a complex instrument creation request or complex order for a complex strategy that is not currently in the System. The Exchange may limit the number of new complex strategies that may be in the System at a particular time.	N/A	Rule 5.33(a)	The Exchange is thus proposing two methods to create a new complex strategy, one of which is a message that a Trading Permit Holder can send to create the strategy and the other is a message a Trading Permit Holder can send that will generate the strategy and that is also an order in that same strategy. These methods will be equally available to all Trading Permit Holders, but the Exchange anticipates that Trading Permit Holders and other liquidity providers who anticipate providing larger amounts of trading activity in complex strategies are the most likely to send in a complex instrument creation request (i.e., to prepare for their trading in the complex strategy throughout the day), whereas other participants are more likely to simply send a complex order that simultaneously creates a new strategy.[5]
Definition of Regular trading: The term ''regular trading'' means trading of complex orders that occurs during a trading session other than (a) at the opening of the COB or re-opening of the COB for trading following a halt (described in proposed paragraph or (b) during the COA process (described in proposed paragraph (d)).	N/A	Rule 5.33(a)	This is an additional term used in other portions of proposed Rule 5.33.[6]
Definition of Synthetic Best Bid or Offer (''SBBO'')	Rule 1.1	Rule 5.33(a)	SBBO is currently referred to in the current Rulebook as ''Exchange Spread Market.''
Definition of Synthetic National Best Bid or Offer (''SNBBO'').	Rule 1.1	Rule 5.33(a)	SNBBO is currently referred to in the current Rulebook as ''National Spread Market.''

The definitions in the table above are substantively the same as the corresponding definitions in C2 Rule 6.13(a) and EDGX Options Rule 21.20(a), and merely add terminology to the Rule rather than impact the trading of complex orders on the Exchange.[7]

Proposed Rule 5.33(b) states that complex orders are available in all classes listed for trading on the Exchange. Current Rule 6.53C(c)(i) provides the Exchange with flexibility to determine which classes are eligible for complex orders. The Exchange currently makes complex order functionality available in all classes, and no longer needs this flexibility, so is eliminating it from the Rules. Complex orders may be market or limit orders (this is consistent with current functionality, and current Rule 6.53C in various places references handling of both complex orders with prices (*i.e.,* limit orders) and complex market orders).[8]

Proposed Rule 5.33(b)(1) states the Exchange determines which Times-in-Force of Day, good-til-cancelled (''GTC''), good-til-date (''GTD''), immediate-or-cancel (''IOC''), or at the open (''OPG'')[9] are available for complex orders (including for eligibility to enter the COB and initiate a COA). Current Rule 6.53C(b) permits complex orders to be entered as FOK,[10] IOC, and GTC, and current Rule 6.53C(c)(iii) permits complex orders to be designated

[4] *See* definition of Book and Simple Book in Rule 1.1 of the shell Rulebook (which has a similar definition).

[5] This proposed definition is the same as the corresponding definition in C2 Rule 6.13(a) and EDGX Options Rule 21.20(a).

[6] *Id.*

[7] The Exchange notes C2 Rule 6.13(a) and EDGX Options Rule 21.20(a) include additional defined terms that are not in proposed Rule 5.33(a), because the Exchange defines those terms in other Rules (*e.g.,* the Exchange defines BBO (the best bid or offer disseminated by the Exchange) in Rule 1.1 in the shell Rulebook, while EDGX Options defines that term in Rule 21.20(a)).

[8] *See also* C2 Rule 6.13(b) (which does not restrict the classes in which complex orders are available) and EDGX Options Rule 21.20(b).

[9] *See* Rule 5.6(d) of the shell Rulebook for definitions of these Times-in-Force; *see also* C2 Rule 6.13(b) and EDGX Options Rule 21.20(b).

[10] An order designated as FOK must execute in its entirety as soon as the System receives it and, if not so executed, is cancelled (and thus not rest in the Book for potential execution). *See* Rule 5.6(d) in the shell Rulebook. As discussed below, the Exchange will permit complex orders to be designated as AON, but they may only execute following a COA (if not executed, they will route to PAR for manual handling or be cancelled, subject to the User's instructions). Because AON complex orders will not be permitted to rest in the Book, the Exchange believes offering a FOK designation for complex orders is unnecessary. Additionally, a User could designate an AON complex order as IOC, which would have the same effect as an FOK (and it would be handled like all AONs, as further described below).

as day (the Exchange does not currently offer a GTD Time-in-Force, but will following the technology migration). The Exchange proposes to retain this flexibility to modify Times-in-Force (and Capacities, as noted below) available on the Exchange in order to address any changes in market conditions and remain competitive.[11]

Proposed Rule 5.33(b)(2) states the Exchange will determine which Capacities (*i.e.,* non-broker-dealer customers, broker-dealers that are not market-makers on an options exchange, or market-makers on an options exchange) are eligible for COA or for entry into the COB. This is consistent with the Exchange's current authority under Rule 6.53C(c)(i) (with respect to eligibility for COB entry) and (d)(i)(2) (with respect to eligibility for COA). Complex orders with Capacities not eligible for COA or entry into to the COB will route to PAR for manual handling or are cancelled, subject to a User's instructions.[12] The proposed rule change moves the provision that permits the Exchange to determine that a complex order with Capacity M or N to enter the COB in certain circumstances in a class in which the Exchange determined complex orders with those Capacities are not eligible for entry into the COB from current Rule 6.53C(c)(i) to proposed Rule 5.33(b)(2)(A).

Proposed Rule 5.33(b)(3) states that Users may designate complex orders as Attributable or Non-Attributable. This relates only to information that User wants, or does not want, included when a complex order is displayed, and has no impact on how complex orders are processed or execute. As they do for simple orders, certain Users want the ability to track their orders, such as which of the resting orders in the COB or which COA'd order is theirs. The Attributable designation means this information will appear in market data feeds and auction messages, permitting these Users to track their own orders. This is consistent with current Rule 6.53 and current functionality. Current Rule 6.53 permits the Exchange to determine which order types (including Attributable and Non-Attributable) in that rule are available on a system-by-system basis (which includes COB and COA). Pursuant to that rule, the Exchange current permits complex orders to be designated as Attributable or Non-Attributable.[13]

Proposed Rule 5.33(b)(4) states that Users may not submit complex orders through bulk ports.[14] In connection with the technology migration, the Exchange is replacing its current quoting functionality with bulk message [15] functionality, which bulk messages may be submitted through bulk ports. The Exchange does not currently offer complex quoting functionality (and Market-Makers are not required to quote on the COB), so this proposed rule change is consistent with current functionality.[16]

Proposed Rule 5.33(b)(5) lists additional order instructions that will be available for complex orders:

- *All Sessions:* The proposed definition of an ''All Sessions'' complex order corresponds to the definition of an ''All Sessions'' simple order in Rule 5.6(c) in the shell Rulebook. The Exchange makes complex orders available for trading during GTH, and a User may apply this instruction to an order in an All Sessions class if the User wants the complex order to be available for execution during the GTH trading session.[17] A User may not designate an All Sessions order as Direct to PAR, because PAR is not available during the Global Trading Hours trading session (which is an electronic-only trading session).[18]
- *AON:* An AON (all-or-none) complex order is a complex order that is to be executed in its entirety or not at all. The Exchange currently makes AON complex orders available.[19] An AON complex order may only execute following a COA, and is not eligible to rest in the COB. The Exchange currently does not permit AON complex order to rest in the COB, so the proposed rule change is consistent with current functionality.[20]
- *Book Only:* The proposed definition of a ''Book Only'' complex order corresponds to the definition of a ''Book Only'' simple order in Rule 5.6(c) in the shell Rulebook. Because complex orders are not routable, all complex orders submitted to the Exchange today for electronic processing are the equivalent of Book Only.[21] A User may not designate a Book Only complex order as Direct to PAR, as the purpose of a Book Only complex order is to rest in the COB if it does not execute upon entry.
- *COA-Eligible and Do-Not-COA Orders:* The Exchange proposes to allow all types of orders to initiate a COA but proposes to have certain types of orders default to initiating a COA upon arrival with the ability to opt-out of initiating a COA and other types of orders default to not initiating a COA upon arrival with the ability to opt-in to initiating a COA.[22] Current Rule 6.53C(d)(ii)(B) permits TPHs to request that an order not initiate a COA, so the proposed rule change is consistent with current functionality.
  - A ''COA-eligible'' complex order is a buy (sell) complex order with User instructions to (or which default to) initiate a COA that is priced (i) equal to or lower (higher) than the SBO (SBB) provided that if any of the bids or offers on the Simple Book that comprise the SBO (SBB) is represented by a Priority Customer order, the complex order must be priced at least one minimum increment lower (higher) than the SBO (SBB) and (ii) lower (higher) than the price of sell (buy) complex orders resting at the top of the COB. Current Rule 6.53C(d)(ii)(A) indicates a COA will initiate if the COA-eligible order is marketable against the SBBO, so the proposed marketability requirement in the definition of a COA-eligible is consistent with current COA rules as well as the proposed rule provisions regarding the priority of complex orders with respect to orders in the Simple Book.[23]
  - A ''do-not-COA'' complex order is a complex order with User instructions not to (or which default not to) initiate a COA or that does not satisfy the COA-eligibility requirements in the preceding bulleted paragraph. The Exchange believes that this will continue to give

[11] *See also* C2 Rule 6.13(b)(1) and EDGX Options Rule 21.20(b)(1).

[12] *See* current Rule 6.53C(c)(i) and (d)(vi). Proposed Rule 5.33 identifies the various circumstances in which a PAR-eligible complex order may route to PAR. *See also* C2 Rule 6.13(b) and EDGX Options Rule 21.20(b).

[13] *See also* C2 Rule 6.13(b) and EDGX Options Rule 21.20(b).

[14] *See* Rule 5.5(c)(3) in the shell Rulebook for a definition of bulk ports.

[15] *See* Rule 1.1 in the shell Rulebook for a definition of bulk messages.

[16] *See also* C2 Rule 6.13(b) and EDGX Options Rule 21.20(b).

[17] *Id.*

[18] *Id.*

[19] *See* current Rule 6.53C(b).

[20] *See* Cboe Options Regulatory Circular RG17–042 (March 24, 2017), available at *https://www.cboe.com/publish/RegCir/RG17-042.pdf. See also* EDGX Options Rule 21.20(b). Other options exchanges require AON complex orders to be IOC, and thus similarly do not permit AON complex orders to rest in a complex order book. It is not clear from their rules whether such orders may enter a complex order auction on those exchanges. *See, e.g.,* Nasdaq ISE, LLC (''ISE'') Options 3, Section 14(b)(2).

[21] *See also* C2 Rule 6.13(b) and EDGX Options Rule 21.20(b).

[22] Current Rule 6.53C(d)(i)(2) permits the Exchange to determine which order types may initiate a COA, so the proposed rule change is consistent with this Rule. Current Rule 6.53C(d)(i)(2) also permits the Exchange to impose size eligibility requirements on COA-eligible orders. The Exchange does not currently impose any size requirement for an order to be eligible to COA, and the Exchange no longer believes it needs this flexibility, so the proposed rule change deletes it from the Rules.

[23] *See* proposed Rule 5.33(f)(2).

market participants extra flexibility to control the handling and execution of their complex orders by the System by giving them the additional ability to determine whether they wish to have their complex order initiate a COA.

○ Upon receipt of an IOC complex order, the System does not initiate a COA unless a User marked the order to initiate a COA, in which case the System cancels any unexecuted portion at the end of the COA. Upon receipt of a complex order with any Time-in-Force other than IOC (except OPG [24]), the System initiates a COA unless a User marked the order to not initiate a COA. The Exchange further believes this is consistent with the terms of an IOC order, which is intended to execute immediately upon entry or be cancelled, whereas COA is a process that includes a short delay in order to broadcast and provide participants time to respond).

○ A Post Only complex order with any Time-in-Force does not initiate a COA, and if a User marks a Post Only complex order to initiate a COA, the System cancels the order. This is consistent with the purposes of a Post Only complex order, which is to add liquidity to the COB, and an auction order is treated as a ''taker.''

○ An incoming AON complex order initiates a COA, and if a User marks an AON complex order to not initiate a COA, or an AON complex order does not satisfy the COA eligibility criteria described above, the System cancels the AON order. The Exchange believes that, like AON simple orders, AON complex orders that would rest on the COB would have last priority, and would have even fewer execution opportunities because they would not be able to execute at the same price as resting interest until after both simple and complex order interest executed. Therefore, an AON complex order resting on the COB would have minimal execution opportunities given its size contingency. The Exchange believes there would be little value, in terms of executing opportunities, in permitting AON complex orders to rest in the COB. As discussed above, the Exchange does not currently permit AON complex orders to rest in the COB.[25]

• *Complex Only Orders:* A ''Complex Only'' order is a Day or IOC complex order a Market-Maker may designate to execute only against complex orders in the COB and may not Leg into the Simple Book. Unless designated as Complex Only, and for all other Times-in-Force and Capacities, a complex order may execute against complex orders in the COB and may Leg into the Simple Book. The Exchange believes the proposed functionality is analogous to other types of functionality the Exchange currently provides Trading Permit Holders, including Market-Makers, such as the ability to direct the Exchange to not to route their orders away from the Exchange (Book Only). Similar to such analogous features, the Exchange believes that Market-Makers may utilize Complex Only Order functionality as part of their strategies to maintain additional control over their executions, in connection with their attempt to provide and not remove liquidity, or in connection with applicable fees for executions.[26]

• *MTP Modifiers:* Users may apply the following MTP Modifiers to complex orders: MTP Cancel Newest, MTP Cancel Oldest, and MTP Cancel Both. If a complex order would execute against a complex order in the COB with an MTP Modifier and the same Unique Identifier, the System handles the complex orders with these MTP Modifiers as described in Rule 5.6(c) of the shell Rulebook. If a complex order with an MTP Modifier would Leg into the Simple Book and execute against any leg on the Simple Book with an MTP Modifier and the same Unique Identifier, the System cancels the complex order. This will allow a User to avoid trading complex orders against its own complex orders or orders of affiliates, providing Users with an additional way to maintain control over their complex order executions.[27]

• *Post Only:* The proposed definition of a ''Post Only'' complex order corresponds to the definition of a ''Post Only'' simple order in Rule 5.6(c) in the shell Rulebook. The proposed rule change provides Users with the ability to exercise more control over the circumstances in which their complex orders are executed and be encouraged to add liquidity in the complex order market. Any additional liquidity will subsequently benefit all participants who trade complex orders on the Exchange.[28] A User may not designate a Post Only complex order as Direct to PAR, as the purpose of a Post Only complex order is to rest in the COB to provide liquidity.

• *RTH Only:* The proposed definition of an ''RTH Only'' complex order corresponds to the definition of an ''RTH Only'' simple order in Rule 5.6(c) in the shell Rulebook. This provides a User with the ability to ensure a complex order will only execute during the RTH trading session if the User does not want a complex order to be available for execution during the GTH trading session.[29]

• *QCC with Stock Order:* The proposed rule change adds this definition to proposed Rule 5.33(b).[30] A User may not designate a QCC with Stock Order as Direct to PAR, because the purpose of a QCC with Stock Order is to execute immediately upon entry without exposure.

Proposed Rule 5.33(b) is substantively the same as the corresponding provisions in C2 Rule 6.13(b) and EDGX Options Rule 21.20(b), except those rules do not include references to PAR, as those exchanges only offer electronic trading.[31]

Proposed Rule 5.33(c) describes the process used to open the COB at the beginning of each trading session and after a trading halt. The proposed COB opening process is substantively the same as the COB Opening Process used on C2 and EDGX Options.[32] The System will accept complex orders for inclusion in the COB Opening Process at the times set forth in Rules 5.7 and 5.31(b) of the shell Rulebook, except the Queuing Period for complex orders ends when the complex strategy opens. Complex orders entered during the Queuing Period are not eligible for execution until the initiation of the COB Opening Process. This is similar to current functionality, which permits orders to be entered at 2:00 a.m. Eastern Time.

Beginning at (1) 2:00 a.m. Eastern Time for All Sessions classes for the GTH trading session and (2) 8:30 a.m. for RTH Only classes and 9:15 a.m. for All Sessions classes for the RTH trading

[24] An OPG order is cancelled if it does not execute during the opening process. *See* Rule 5.6(d) of the shell Rulebook.

[25] *See also* EDGX Options Rule 21.20(b).

[26] *See also* C2 Rule 6.13(b) and EDGX Options Rule 21.20(b).

[27] *Id.*

[28] *Id.*

[29] *Id.*

[30] *See also* EDGX Options Rule 21.20(b). The current definition of QCC with Stock Orders is in Rule 6.53 of the current Rulebook. The Exchange previously deleted Rule 6.53 from the current Rulebook (to be effective on October 7, 2019) in a separate filing, with the intention of including the definition of QCC with Stock Orders in the proposed rule, so that all types of complex orders (which QCC with Stock is) are included within the same rule in the shell Rulebook. *See* Securities Exchange Act Release No. 86173 (June 20, 2019), 84 FR 30267 (June 26, 2019) (SR–CBOE–2019–027).

[31] The Exchange notes that C2 Rule 6.13(b) also makes Complex Reserve Orders available. The Exchange currently offers complex reserves orders, but does not intend to make those available following the technology migration due to lack of demand on the Exchange. The Exchange currently has authority pursuant to Rule 6.53 and 6.53C to determine which order types are available for complex order trading, and therefore no longer making complex reserve orders available is consistent with that authority.

[32] *See* C2 Rule 6.13(c) and EDGX options Rule 21.20(c).

session, and updated every five seconds thereafter until the initiation of the COB Opening Process, the Exchange disseminates indicative prices and order imbalance information based on complex orders queued in the System for the COB Opening Process. This is new functionality that will provide Users with information regarding the expected COB opening, which the Exchange believes may contribute additional transparency and price discovery to the COB Opening Process.[33]

The System initiates the COB Opening Process for a complex strategy after a number of seconds (which number the Exchange determines) after all legs of the strategy in the Simple Book are open for trading. This is consistent with the current COB Opening Process, as set forth in current Interpretation and Policy .11(a). All complex orders the System receives prior to opening a complex strategy pursuant to the COB Opening Process, including any delay applied by the Exchange, are eligible to be matched in the COB Opening Process and not during the Opening Process described in Rule 5.31 in the shell Rulebook.[34] The Exchange similarly applies a delay period during the regular Opening Process, as set forth in current Rule 6.2 (which the Exchange has proposed to amend and move to Rule 5.31 in the shell Rulebook).[35]

If there are matching complex orders in a complex strategy, the System determines the COB opening price, which is the price at which the most complex orders can trade. If there are multiple prices that would result in the same number of complex orders executed, the System chooses the price that would result in the smallest remaining imbalance as the COB opening price. If there are multiple prices that would result in the same number of complex orders executed and the same ''smallest'' imbalance, the System chooses the price closest to the midpoint of the (i) SNBBO or (ii) if there is no SNBBO available, the highest and lowest potential opening prices as the COB opening price. If the midpoint price would result in an invalid increment, the System rounds the COB opening price up to the nearest permissible increment. If the COB opening price equals the SBBO, the System adjust the COB opening price to a price that is better than the corresponding bid or offer in the Simple Book by at least one minimum increment. If the COB opening price would require printing at the same price as a Priority Customer on any leg in the Simple Book, the System adjusts the COB opening price to a price that is better than the corresponding bid or offer in the marketplace by at least one minimum increment.[36]

After the System determines a COB opening price, the Exchange executes matching complex orders in price priority (*i.e.,* orders better than the COB opening price are executed first and thereafter orders at the COB opening price are executed), and then pursuant to the allocation algorithm applicable to the class pursuant as set forth in proposed subparagraph (d)(5)(A)(ii) below. Therefore, all complex interest in a class will execute in accordance with the same allocation algorithm, which provides simplicity and consistency regarding the execution of complex orders to Users. The System enters any remaining complex orders (or unexecuted portions) into the COB, subject to a User's instructions.[37]

If there are no matching complex orders in a complex strategy, the System opens the complex strategy without a trade. If after an Exchange-established period of time that may not exceed 30 seconds, the System cannot match orders because (i) the System cannot determine a COB opening price (*i.e.,* all queued orders are market orders) or (ii) the COB opening price is outside the SNBBO, the System opens the complex strategy without a trade. In both cases, the System enters any orders in the complex strategy in the COB (in time priority), subject to a User's instructions, except it Legs any complex orders it can into the Simple Book. The proposed rule change provides additional detail regarding how the COB will open if there are no matching trades. Additionally, the Exchange believes the proposed configurable time period is important because the opening price protections are relatively restrictive (*i.e.,* based on the SNBBO), and the configurable time period provides the Exchange with the ability to periodically review the process and modify it as necessary to ensure there is sufficient opportunity to have Opening Process executions without also waiting too long to transition to regular trading.[38]

Currently on the Exchange, the System opens the COB in a similar manner, however it first attempts to match complex orders against orders in the Simple Book, then matches complex orders against each other. As proposed, complex orders will not leg into the book upon the COB open (unless there are no matching complex orders and a complex strategy opens without a trade); however, the COB opening price must improve the SBBO by at least one minimum increment if there is a Priority Customer order on any leg, thus providing protection to Priority Customers in the leg markets. The proposed matching process for complex orders on the COB is similar to the process in current Interpretation and Policy .11(a)(ii). Additionally, the Exchange currently restricts valid opening trade prices to be within the SBBO rather than the SNBBO as the proposed opening process does. The Exchange believes using the SNBBO is an enhancement to the COB opening process, as it reflects the then-current prices throughout the entire market, rather than just on the Exchange, and thus the Exchange believes it is a better measure to use for purposes of determining the reasonability of the prices of orders.

Proposed Rule 5.33(c) is substantively the same as the corresponding provisions in C2 Rule 6.13(c) and EDGX Options Rule 21.20(c), except the times at which opening auction messages begin to disseminate pursuant to the proposed rule are different than the times in the C2 and EDGX Options Rules, as the Exchange's GTH trading session begins at 3:00 a.m. Eastern Time, while the GTH trading session on those Cboe Affiliated Exchanges begins at 8:30 a.m. Eastern Time. Additionally, because C2 does not have a Priority Customer overlay, C2 Rule 6.13(c) does not include references to Priority Customers as proposed Rule 5.33(c) does. The proposed rule change also provides that the allocation algorithm applied to complex orders during the COB opening process may vary by class (which is consistent with current Rule 6.53C, Interpretation and Policy .011(a)), as C2 does, while EDGX Options will always apply price-time. Additionally, the proposed rule change references an applicable minimum increment, while the C2 Rule and EDGX Options Rule each reference $0.01. Pursuant to Rule 5.4(b) in the shell Rulebook, the Exchange may determine the minimum increment for complex orders eligible for electronic processing, which must be at least $0.01. As set forth in C2 Rule 6.13(f) and EDGX Options Rule 21.20(f),

[33] *See also* C2 Rule 6.13(c)(1) and EDGX Options Rule 21.20(c)(1).

[34] *See* current Rule 6.53C, Interpretation and Policy .11(a).

[35] *See also* C2 Rule 6.13(c)(2) and EDGX Options Rule 21.20(c)(2).

[36] *See also* C2 Rule 6.13(c)(2)(A) and EDGX Options Rule 21.20(c)(2)(A).

[37] *See also* C2 Rule 6.13(c)(2)(B) and EDGX Options Rule 21.20(c)(2)(B).

[38] *See also* C2 Rule 6.13(c)(2)(C) and EDGX Options Rule 21.20(c)(2)(C).

the minimum increment for complex orders in all classes is $0.01.

Proposed Rule 5.33(d) describes the COA process for COA-eligible orders. Orders in all classes will be eligible to participate in COA.[39] Upon receipt of a COA-eligible order, the System initiates the COA process by sending a COA auction message to all subscribers to the Exchange's data feeds that deliver COA auction messages.[40] A COA auction message identifies the COA auction ID, instrument ID (*i.e.,* complex strategy), quantity, and side of the market of the COA-eligible order.[41] The Exchange may also determine to include in COA auction messages the price, which will be the limit order price or the SBBO (if initiated by a market complex order), or the drill-through price if the order is subject to the drill-through protection in Rule 5.34(b) of the shell Rulebook.[42]

Currently, only one COA in a complex strategy may occur at the same time (while this is not codified in current rules, it is consistent with current functionality). Pursuant to proposed Rule 5.33(d)(2), the System may initiate a COA in a complex strategy even though another COA in that complex strategy is ongoing. This concurrent COA functionality is substantively the same as corresponding functionality in C2 Rule 6.13(d)(2) and EDGX Options Rule 21.20(d)(2). The Exchange believes it will increase price improvement and execution opportunities for complex orders following the technology migration. The Exchange notes at the outset that based on how Exchange Systems operate (and computer processes generally), it is impossible for COAs to occur ''simultaneously'', meaning that they would commence and conclude at exactly the same time. Thus, although it is possible as proposed for one or more COAs to overlap, each COA will be started in a sequence and with a time that will determine its processing. Thus, even if there are two COAs that commence and conclude at nearly the same time, each COA will have a distinct conclusion at which time the COA will be allocated.

If there are multiple COAs ongoing for a specific complex strategy, each COA concludes sequentially based on the time each COA commenced, unless terminated early as described below. At the time each COA concludes, the System allocates the COA-eligible order pursuant to proposed paragraph (d)(3) below and takes into account all COA Responses for that COA, orders in the Simple Book, and unrelated complex orders on the COB at the time the COA concludes. If there are multiple COAs ongoing for a specific complex strategy that are each terminated early as described below, the System processes the COAs sequentially based on the order in which they commenced. If a COA Response is not fully executed at the end of the identified COA to which the COA Response was submitted, the System cancels or rejects it at the conclusion of the specified COA.

In turn, when the first COA concludes, orders on the Simple Book and unrelated complex orders that then exist will be considered for participation in the COA. If unrelated orders are fully executed in such COA, then there will be no unrelated orders for consideration when the subsequent COA is processed (unless new unrelated order interest has arrived). If instead there is remaining unrelated order interest after the first COA has been allocated, then such unrelated order interest will be considered for allocation when the subsequent COA is processed. As another example, each COA Response is required to specifically identify the COA for which it is targeted and if not fully executed will be cancelled at the conclusion of the COA. Thus, COA Responses will only be considered in the specified COA.

Proposed Rule 5.33(d)(3) defines the Response Time Interval as the period of time during which Users may submit responses to the COA auction message (''COA Responses''). The Exchange determines the duration of the Response Time Interval, which may not exceed 500 milliseconds. This is similar to current Rule 6.53C(d)(iii)(2), except the proposed rule change reduces the maximum time period from three seconds to 500 milliseconds. The Exchange believes that 500 milliseconds is a reasonable amount of time within which participants can respond to a COA auction message. The current timer on the Exchange is 100 milliseconds, and therefore the Exchange believes a maximum response time of 500 milliseconds is sufficient to respond to auctions.[43]

However, the Response Time Interval terminates prior to the end of that time duration:

(1) When the System receives a non-COA-eligible order on the same side as the COA-eligible order that initiated the COA but with a price better than the COA price, in which case the System terminates the COA and processes the COA-eligible order as described below and posts the new order to the COB;

(2) when the System receives an order in a leg of the complex order that would improve the SBBO on the same side as the COA-eligible order that initiated the COA to a price equal to or better than the COA price, in which case the System terminates the COA and processes the COA-eligible order as described below, posts the new order to the COB, and updates the SBBO; or

(3) if the System receives a Priority Customer order that would join or improve the SBBO on the same side as the COA in progress to a price equal to or better than the COA price, in which case the System terminates the COA and processes the COA-eligible order as described below, posts the new order to the Simple Book, and updates the SBBO.

Current Rule 6.53C(d)(viii)(3) describes how the System currently handles incoming COA-eligible orders on the same side of the original COA order at a better price. The proposed rule change deletes that provision, as it is being replaced by the functionality above (which order terminates a COA in that circumstance rather than joins the COA, but still provides execution opportunities for the new incoming order by placing it on the COB). The proposed rule change deletes the remainder of current Rule 6.53C(d)(viii), which describes current circumstances that cause a COA to end early, as those will no long apply following the technology migration. The proposed rule change deletes current Rule 6.53C(d)(viii)(1) and (2) regarding incoming COA-eligible orders received during the Response Time Interval, as those orders may initiate a separate COA under the proposed rule change

[39] Current Rule 6.53C(d)(i)(2) provides that the Exchange may make COA available on a class-by-class basis. The Exchange makes COA available in any class in which it makes complex order functionality available, so the Exchange no longer believes it needs separate flexibility for COA. *See also* C2 Rule 6.13(d)(1) and EDGX Options Rule 21.20(d)(1).

[40] *See* current Rule 6.53C(d)(ii)(A). The Exchange notes this current provision imposes additional eligibility requirements based on the number of legs in the complex order. As discussed below, the proposed rule change replaces those protective measures with certain Legging restrictions.

[41] Current Rule 6.53C(d)(ii) states the current COA notification messages (referred to as RFR messages in the current Rulebook) include the component series (*i.e.,* complex strategy), size, side of the market, and contingencies. The proposed rule change adds that the notification messages will include the Auction ID, and potentially the Capacity and price (including detail regarding what the auction price will be), but will not include any contingencies. This is the same information that may be included in the COA notification messages under C2 Rule 6.13(d)(1) and EDGX Options Rule 21.20(d)(1) (the EDGX Options rule refers to origin code rather than Capacity), except the Exchange will not include Capacity on COA notification messages (which it currently does not include pursuant to current Rule 6.53C(d)(ii)(A).

[42] Rule 5.34(b) in the shell Rulebook will be substantially similar to Rule 6.13(b)(v)(B) in the current Rulebook.

[43] *See also* C2 Rule 6.13(d)(3) and EDGX Options Rule 21.20(d)(3).

that permits concurrent COAs. The proposed rule change deletes current 6.53C(d)(viii)(4) and (5) relating to incoming do-not-COA orders and changes in the leg markets that would terminate an ongoing COA, as under the proposed rules, those new orders would not terminate a COA but would be eligible to execute against the COA-eligible order at the end of the COA) (see proposed subparagraph (d)(5), which states execution will occur against orders in the Simple Book and COB at the time the COA concludes). Ultimately, these incoming orders are eligible for execution against a COA-eligible order under current and proposed rules. The proposed rule change merely changes the potential execution time to the end of the full response interval time from an abbreviated response interval time.[44]

Proposed Rule 5.33(d)(4) describes COA Responses that may be submitted during the Response Time Interval for a specific COA. The Exchange determines on a class-by-class basis whether all Users or Market-Makers with an appointment in the class and TPHs acting as agent for orders resting at the top of the COB in the relevant complex strategy may submit COA Responses.[45] The System accepts a COA Response(s) with a permissible Capacity in the applicable minimum increment during the Response Time Interval.[46] A COA Response must specify the price, size, side of the market (*i.e.,* a response to a buy COA as a sell or a response to a sell COA as a buy) and COA auction ID for the COA to which the User is submitting the COA Response. While this is not included in current Rule 6.53C, it is consistent with System entry requirements for COA Responses. The System aggregates the size of COA Responses and complex orders on the COB submitted at the same price for an EFID, and caps the size of the aggregated COA Responses and complex orders at the size of the COA-eligible order. This provision is similar to current Rule 6.53(d)(v), which caps order and response sizes for allocation purposes to prevent Trading Permit Holders from taking advantage of a pro-rata allocation by submitting responses larger than the COA-eligible order to obtain a larger allocation from that order.

During the Response Time Interval, COA Responses are not firm, and Users can modify or withdraw them at any time prior to the end of the Response Time Interval, although the System applies a new timestamp to any modified COA Response (unless the modification was to decrease its size), which will result in loss of priority. The Exchange does not display COA Responses. At the end of the Response Time Interval, COA Responses are firm (*i.e.,* guaranteed at their price and size). A COA Response may only execute against the COA-eligible order for the COA to which a User submitted the COA Response. The System cancels or rejects any unexecuted COA Responses (or unexecuted portions) at the conclusion of the COA. This is substantively the same as current Rule 6.53C(d)(vii).

Proposed Rule 5.33(d)(4) is substantively the same as C2 Rule 6.13(d)(4) and EDGX Options Rule 5.33(d)(4), except, as noted above, the proposed rule change provides flexibility regarding Capacities that may submit COA Responses, which C2 and EDGX Options do not, and the proposed rule change accounts for classes potentially having different minimum increments.

Proposed Rule 5.33(d)(5) describes how COA-eligible orders are processed at the end of the Response Time Interval. At the end of the Response Time Interval, the System executes a COA-eligible order (in whole or in part) against contra-side interest in price priority. If there is contra-side interest at the same price, the System allocates the contra side interest as follows:

(1) Priority Customer orders resting on the Simple Book for the individual leg components of the complex order through Legging (subject to proposed paragraph (g), as described below) in time priority;

(2) COA Responses and unrelated orders on the COB pursuant to the allocation algorithm applicable to the class, or another allocation algorithm from Rule 5.32 in the shell Rulebook determined by the Exchange on a class-by-class basis; and

(3) remaining orders in the Simple Book for the individual leg components of the complex order through Legging (subject to proposed paragraph (g), as described below), which the System allocates in accordance with the base allocation algorithm applicable to the class pursuant to Rule 5.32(b).

This allocation is similar to the current allocation priority on the Exchange following a COA, as set forth in current Rule 6.53C(d)(iv) and (v), except the proposed rule change prioritizes Priority Customer orders on the Simple Book first (rather than all interest on the Simple Book), and non-Priority Customer orders on the Simple Book may execute after any complex order interest at the same price. Additionally, the Exchange may determine on a class-by-class basis whether to apply the Priority Customer overlay to complex interest. This will provide consistency for executions of complex interest in all settings, as executions of complex orders in the COB occur pursuant to the allocation algorithm applicable the class, or another algorithm as determined by the Exchange on a class-by-class basis.[47] The proposed priority is consistent with general customer priority principles, as it protects Priority Customer orders on the Simple Book. It is also the same as the priority order in EDGX Options Rule 21.20(d)(5), although the Exchange notes that EDGX Options applies different allocation algorithms to complex interest and simple interest.

Notwithstanding the foregoing, at the conclusion of a COA of an AON complex order, the AON complex order may only execute against COA Responses and unrelated orders on the COB pursuant to the allocation algorithm applicable to the class pursuant to proposed paragraph (d)(5)(A)(ii) if there is sufficient size to satisfy the AON complex order (and may not execute against orders in the Simple Book). If there is insufficient size to satisfy the AON complex order, the System routes the order to PAR for manual handling or cancels the order, subject to a User's instructions.[48]

As provided above, following a COA, a complex order will be allocated first in price priority and then at each price level against Priority Customer orders in the Simple Book, COA responses and complex orders in the COB, and then remaining individual orders in the Simple Book. The Simple Book and the COB are separate, and orders on each do not interact unless a complex order Legs into the Simple Book. As a result, the System is not able to calculate the aggregate size of COA responses and complex orders on the COB and the size of simple orders in the legs that comprise the complex strategy at each potential execution price (as executions may occur at multiple prices) prior to execution of an order following a COA. Following a COA, the System first looks to determine whether there are Priority Customer orders resting in the Simple

[44] *See also* C2 Rule 6.13(d)(3) (which does not include a provision that corresponds to proposed subparagraph (d)(3)(C) because it relates to prioritizing Priority Customer orders, which have no allocation priority on C2); and EDGX Rule 21.20(d)(3).

[45] *See* current Rule 6.53C(d)(iii).

[46] *See* current Rule 6.53C(d)(iii)(1).

[47] *See* current Rule 6.53C(c)(i)(2); *see also* proposed Rule 5.34(e).

[48] *See* EDGX Options Rule 21.20(d)(5)(A), which handles AON complex orders in the same manner (except EDGX Options does not have the option to route an unexecuted AON complex order to PAR, as EDGX Options is an electronic only exchange).

Book at the final auction price (and in the applicable ratio). If there are, the System executes the complex order against those simple orders. Following that execution, the System then looks back at the COA responses and complex orders resting in the COB to determine whether there is interest against which the order can execute. If there is, the System executes the remaining portion of the complex order against that complex contra-side interest. Finally, if there is any size left, the System looks back at the Simple Book to determine whether any orders in the legs are able to trade against any remaining contracts in the complex order. If there is, the System executes the remaining portion of the complex order again against orders in the Simple Book.

Because of this process, prior to execution against any Priority Customer orders, the System would not know whether there is sufficient aggregate interest in both the Simple book and COB to satisfy the entire size of the AON. Additionally, it is possible for a complex order to execute at multiple price levels. This process would have to occur at each price level. Therefore, if the Exchange were to permit Legging of AON complex orders into the Simple Book, it would be possible for a partial execution to occur, which is inconsistent with the AON instruction. The Exchange notes there would be significant technical complexities associated with reprogramming priority within the System to permit AON complex orders to Leg into the Simple Book and provide AON orders with priority consistent with these standard priority principles. Only permitting an AON complex order to execute against COA responses and complex orders in the COB ensures the size contingency of the AON complex order can be satisfied.[49] To ensure protection of orders on the Simple Book given this restriction on Legging, an AON complex order may only execute following a COA if it improves the then-current (*i.e.,* existing at the conclusion of the COA) SBBO.[50]

Proposed Rule 5.33(d)(5)(B) states the System enters any COA-eligible order (or unexecuted portion) that does not execute at the end of the COA that is eligible to rest into the COB, and applies a timestamp based on the time it enters the COB.[51] The System routes to PAR for manual handling or cancels any COA-eligible order (or unexecuted portion) that does not execute at the end of the COA if not eligible for entry into the COB, subject to the User's instructions. Once in the COB, the order may execute pursuant to proposed paragraph (e) following evaluation pursuant to proposed paragraph (i), both as described below, and remain on the COB until they execute or are cancelled or rejected.

Proposed Rule 5.33(d)(5) is substantively the same as EDGX Options Rule 21.20(d)(5), except the proposed rule change permits the Exchange to apply allocations algorithms on a class-by-class basis to the execution of complex orders following a COA, which is consistent with current Exchange authority. Additionally, the proposed rule change provides that complex orders may route to PAR for manual handling in certain circumstances, while those orders would be cancelled on EDGX Options, as it is an electronic only exchange.

Proposed Rule 5.33(e) describes how the System will handle Do-Not-COA orders (*i.e.,* orders that do not initiate a COA upon entry to the System) and orders resting in the COB. Upon receipt of a do-not-COA order, or if the System determines an order resting on the COB is eligible for execution following evaluation as described below, the System executes it (in whole or in part) against contra-side interest in price priority. If there is contra side interest at the same price, the System allocates the contra-side interest as follows:

(1) Priority Customer orders resting on the Simple Book for the individual leg components of the complex order through Legging (as described below) in time priority;

(2) unrelated complex orders resting on the COB, which the System allocates pursuant to the allocation algorithm set forth in proposed subparagraph (d)(5)(A)(ii) (as described above); and

(3) remaining orders in the Simple Book for the individual leg components of the complex order through Legging (as described below), which the System allocations in accordance with the base allocation algorithm applicable to the class pursuant to Rule 5.32(b) in the shell Rulebook.

The System enters any do-not-COA order (or unexecuted portion) that cannot execute against the individual leg markets or complex orders and is eligible to rest into the COB, and applies a timestamp based on the time it enters the COB. The System routes to PAR for manual handling or cancels any do-not-COA order (or unexecuted portion) that would execute at a price outside of the SBBO or equal to the SBBO when there is a Priority Customer order at the SBBO and is not eligible for entry into the COB, subject to the User's instructions. Complex orders resting on the COB may execute pursuant to proposed paragraph (e) following evaluation pursuant to proposed paragraph (i), both as described below, and remain on the COB until they execute or are cancelled or rejected.

The proposed rule change is similar to current Rule 6.53C(c)(i), except as discussed above, the Exchange will prioritize Priority Customer orders on the Simple Book, and then execute any non-Priority Customer orders on the Simple Book after complex interest has executed. The proposed priority is consistent with general customer priority principles, as it protects Priority Customer orders on the Simple Book.[52]

Proposed Rule 5.33(f)(1)(A) states the minimum increment for bids and offers on a complex order, and the increments at which components of a complex order may be executed, is set forth in Rule 5.4(b) in the shell Rulebook.[53] This is consistent with current Rule 6.53C(c)(i). Proposed Rule 5.33(f)(1)(B) states that Users may express bids and offers for a stock-option order (including a QCC with Stock Order, as discussed below) in any decimal price the Exchange determines. The option leg(s) of a stock-option order may be executed in the minimum increment applicable to the class pursuant to proposed subparagraph (A), as discussed above, and the stock leg of a stock-option order may be executed in any decimal price permitted in the equity market.[54] Smaller minimum increments are appropriate for stock-option orders as the stock component can trade at finer decimal increments permitted by the equity market. Furthermore, the

[49] The Exchange does not currently restrict AON orders from legging into its simple book, because the current priority is different than it will be as proposed. However, other options exchanges restrict AON orders from legging into the simple book during the complex order opening process, from the complex order book, and following a complex order price improvement auction (similar to COA). *See, e.g.,* EDGX Options Rule 21.20(d)(5) and (f)(2)(A)(ii); and Nasdaq Phlx LLC (''Phlx'') Rule 1098(d)(ii)(C)(2), (e)(vi)(A), (e)(viii)(C)(3), and (f)(iii)(A). Phlx also only permits non-broker-dealer customers to submit AON complex orders. *See* Phlx Rule 1098(b)(v).

[50] *See* proposed Rule 5.34(f)(2)(A)(ii).

[51] *See* current Rule 6.53C(d)(vi).

[52] *See also* EDGX Options Rule 21.20(e).

[53] Rule 5.4(b) in the shell Rulebook that the minimum increment for bids and offers on complex orders with any ratio equal to or greater than one-three and less than or equal to three-to-one is $0.01 or greater, which may be determined by the Exchange on a class-by-class basis, and the legs may be executed in $0.01 increments. Pursuant to the definition of complex orders in Rule 1.1 of the shell Rulebook, only complex orders with these ratios are eligible for electronic trading.

[54] This is consistent with the flexibility in current Rule 6.53C(c)(ii). Other options exchanges have the same minimum increment requirements for stock-option orders. *See* EDGX Options Rule 21.20(f)(1)(B); and Nasdaq ISE, LLC (''ISE'') Options 3, Section 14(c)(1).

Exchange notes that even with the flexibility provided in the proposed rule, the individual options and stock legs must trade at increments allowed by the Commission in the options and equities markets.

Proposed Rule 5.33(f)(2)(A) provides that the System does not execute a complex order pursuant to Rule 5.33 at a net price (1) that would cause any component of the complex strategy to be executed at a price of zero, (2) worse than the SBBO or equal to the SBBO when there is a Priority Customer order at the SBBO, except AON complex orders may only execute at prices better than the SBBO (as discussed above), (3) that would cause any component of the complex strategy to be executed at a price worse than the individual component price on the Simple Book, (4) worse than the price that would be available if the complex order Legged into the Simple Book, or (5) that would cause any component of the complex strategy to be executed at a price ahead of a Priority Customer order on the Simple Book without improving the BBO on at least one component by at least one applicable minimum increment.

The option component of a stock-option order executes in accordance with same priority principles as any other option order. Pursuant to proposed Rule 5.33(f)(2)(B), for a stock-option order with one option leg, the option leg may not trade at a price worse than the individual component price on the Simple Book or at the same price as a Priority Customer Order on the Simple Book. For a stock-option order with more than one option leg, the option legs must trade at prices consistent with priority applicable to a complex order with all option legs as set forth above.[55]

A stock-option order may only execute if the stock leg is executable at the price(s) necessary to achieve the desired net price.[56] To facilitate the execution of the stock leg and option leg(s) of an executable stock-option order at valid increments pursuant to proposed subparagraph (f)(1)(B), as described above, the legs may trade outside of their expected notional trade value by a specified amount (which the Exchange determines). In a small subset of cases, generally as a result of unusual leg ratios, in calculating the total notional value a stock leg may result in a price outside of the NBBO, thus cannot execute pursuant to proposed Rule 5.33(f)(2)(B).[57] In order to allow for the strategy to execute, the proposed rule change would offer functionality that allows the legs of the stock option order to trade outside of their expected notional value by a specified amount determined by the Exchange.[58] Therefore, the System could ensure that options legs and stock leg were priced in line with the other provisions of proposed Rule 5.33(f)(2), as described above. Although this would result in a negligible difference (*i.e.* residual amount) between the expected notional value of the trade and the actual trade value, Users generally prefer not to forgo an execution for their stock-option strategies when the residual amount is miniscule compared to the total value of the trade. The value allowance would work, for example, as follows:

- Assume the Exchange has determined a trade value allowance of $0.50 from the expected trade value.
- Assume also that:

(Equity) NBBO: 10.00 × 11.00
(Option) NBBO: 1.00 × 1.05, BBO: 1.00 × 1.05
SNBBO: 7.70 × 8.32 (*i.e.,* bid = (47 × 10.00/100) + (3 × 1.00) = 7.70, and offer = (47 × 11.00/100) + (3 × 1.05) = 8.32)

- A User enters a stock-option order to Buy 47 shares of XYZ stock and Buy 3 June 10 XYZ calls with a net price of 8.30 and a quantity of 3.
- The order matches with corresponding contra order on the COB.
- The expected trade value based on the order's limit price, quantity and a contract multiplier of 100 is $2,490.00 (*i.e.,* 8.30 × 3 × 100).
- The calculated options match price is 1.00 based on market prices and the stock match price is 11.2766 (rounded four decimals), therefore, outside of the NBBO.
- The trade value allowance then calculates the stock match price that results in a total notional trade value of $2489.9934:

Options leg notional = $1.05 × 100 × 3 × 3 = $945
Stock leg notional = $10.9574 × 47 × 3 = $1,544.9934
Notional trade value = $2,489.9934, which is within the $0.50 trade value allowance.

The Exchange notes that a valid trade price within the NBBO for the stock leg with the smallest residual between the difference in actual trade value and expected notional trade value is $10.9574. Therefore, in this example, the corresponding options leg match price would be $1.05 because it is the options match price that could be paired with a valid stock trade price that would also allow for the smallest residual between the difference in actual trade value and expected notional trade value. If, for example, the next allowable options increment[59] within the BBO ($1.04) was used, the stock leg notional trade value matched to meet the notional value closest to the expected trade value would be $11.0213, and therefore still outside of the NBBO.[60] The Exchange also notes that $1.05 is consistent with the BBO in this example.

Under the proposed rule, the System will not apply the trade value allowance to orders with a ''C'' capacity code (for the account of a Priority Customer). This limitation is intended to function as an additional protection for customers who may not have the same levels of trading sophistication or technological and informational advantages as that of Professionals or broker-dealers. Therefore, customers may not have measures in place to assume any level of risk that may be associated with trading outside of the expected trade value (which risk the Exchange believes is de minimis given that the Exchange will impose a reasonable cap, as described below, on the amount by which the actual trade value may differ from the expected trade level). As a result, the Exchange believes that not applying the trade value allowance to customer orders will further protect customers from assuming this potential risk for which they may not have calculated.

Overall, this proposed functionality is a helpful feature which will allow Users to receive an expeditious execution, and trade the stock and options components of a stock-option strategy in a moving

[55] *See* current Rule 6.53C, Interpretation and Policy .06(b); *see also* EDGX Options Rule 21.20(f).

[56] *See* current Rule 6.53C, Interpretation and Policy .06(a).

[57] Pursuant to proposed Rule 5.33(f)(2)(B), the System will only execute the stock leg of a stock-option order up to a buffer amount outside of the stock leg NBBO and that the execution price of the buy (sell) stock leg of a QCC with Stock Order may be any price (including outside the NBBO for the stock leg). While the QCT exemption permits a stock leg to execute outside of the NBBO, the Exchange still offers price protections to prevent execution too far away from the NBBO, which it understands is consistent with market participants' desire. The Exchange intends to set this buffer to zero, so the Exchange will not permit execution of the stock leg of a stock-option order outside of the NBBO (other than a QCC with stock order, which will execute immediately without exposure and thus is unlikely to trade too far outside of the NBBO). Current rules of other exchanges (such as Cboe Options) prevent execution of the stock component from being too far away from the NBBO, as do the rules of stock exchanges.

[58] The Exchange announces determinations to market participants pursuant to Rule 1.5 in the shell Rulebook.

[59] *See* proposed Rule 5.33(f)(1)(B), which states that the option leg(s) of a stock-option order may be executed in $0.01 increments.

[60] The notional trade value would be: ($1.04 × 100 × 3 × 3) + ($11.0213 × 47 × 3) = $2,490.0033.

market without introducing legging risk. Without this functionality members would be forced to resubmit their orders and potentially receive a much worse price or miss an execution. The Exchange will announce to all market participants the determined trade value allowance amount pursuant to Rule 1.5. The Exchange would determine an allowance amount that would reasonably account for the average differences in notional trade values as well as the cost benefit to market participants between the differences in actual trade value versus expected notional trade value and the imposition of resubmitting their orders and potentially receiving a much worse price or missing an execution.[61] The Exchange notes that, if, however, a User determines that the trade value allowance is more attractive or favorable on another venue, Users are free to execute on other such venues. The proposed Exchange determination of a value allowance outside of the expected notional value is currently in place on other exchanges.[62]

If a stock-option order can execute, the System executes the buy (sell) stock leg of a stock-option order pursuant to proposed Rule 5.33(f)(2)(B) up to a buffer amount above (below) the NBO (NBB), which amount the Exchange determines.[63] The Exchange believes that Users may be willing to trade a stock-option order with the stock leg at a price outside of the NBBO (which is permissible pursuant to the QCT exemption) of the stock leg in order to achieve the desired net price. However, the buffer may prevent execution with a stock price ''too far'' away from the market price, which may be inconsistent with then-current market conditions.[64] This may ultimately prevent execution at potentially erroneous prices. This is similar to the Exchange's current fat finger protection (which will not permit a complex order to be more than a specified amount outside of the SNBBO, which will include the NBBO of the stock leg,[65] except it also applies a buffer to the individual stock leg as opposed to the net price.

Proposed Rule 5.33(f)(3) states the System executes complex orders without consideration of any prices for the complex strategy that might be available on other exchanges trading the same complex strategy;[66] provided, however, that such complex order price may be subject to the drill-through price protection in current Rule 6.53C, Interpretation and Policy .08 Proposed Rule 5.33(f) is the same as EDGX Rule 21.20(f), except the proposed rule change, as noted above, incorporates the fact that the Exchange has (and will continue to have) flexibility to determine the minimum increment for complex orders on a class-by-class basis.

Proposed Rule 5.33(g) adopts restrictions on the ability of complex orders to Leg into the Simple Book. Specifically, a complex order may Leg into the Simple Book pursuant to proposed subparagraphs (d)(5)(A) and (e), subject to the restrictions in proposed paragraph (g), if it can execute in full or in a permissible ratio[67] and if it has no more than a maximum number of legs (which the Exchange determines on a class-by-class basis and may be two, three or four)[68] (''Legging''), subject to the following restrictions:

(1) All two leg COA-eligible Customer complex orders may Leg into the Simple Book without restriction.

(2) Complex orders for any other Capacity with two option legs that are both buy or both sell and that are both calls or both puts may not Leg into the Simple Book. These orders may execute against other complex orders on the COB.

(3) All complex orders with three or four option legs that are all buy or all sell (regardless of whether the option legs are calls or puts) may not Leg into the Simple Book. These orders may execute against other complex orders on the COB.

(4) Post Only complex orders and AON complex orders may not Leg into the Simple Book.

(5) Stock-option orders may not Leg into the Simple Book and may only execute against other stock-option orders.[69]

(6) If the Exchange determines to list SPX or VIX on a group basis pursuant to Rule 4.14, a complex order consisting of legs in different groups of series in the class may not Leg into the Simple Book. A complex order consisting of legs in the same group may Leg, subject to the other restrictions in proposed paragraph (g).[70]

Proposed paragraph (g) is the same as EDGX Options Rule 21.20(g) (except that Rule does not reference the ability to list classes on a group basis, as EDGX Options does not have a Rule that permits that type of listing). These restrictions serve the same purpose as the protection included in current 6.53C(d)(ii), which is to ensure that Market-Makers providing liquidity do not trade above their established risk tolerance levels. Currently, liquidity providers (typically Market Makers, though such functionality is not currently limited to registered Market Makers) in the Simple Book are protected by way of the Quote Risk Monitor (''QRM'') by limiting the number of contracts they execute as described above. QRM allows Market-Makers and other liquidity providers to provide liquidity across potentially hundreds of options series without executing the full cumulative size of all such quotes before being given adequate opportunity to adjust the price and/or size of their quotes.

All of a participant's quotes in each option class are considered firm until such time as QRM's threshold has been equaled or exceeded and the participant's quotes are removed by QRM in all series of that option class. Thus the Legging of complex orders presents higher risk to Market-Makers and other liquidity providers as compared to simple orders being entered in multiple series of an options class in the simple market, as it can result in such participants exceeding their established risk thresholds by a greater number of contracts. Although Market-Makers and other liquidity providers can limit their risk through the use of QRM, the participant's quotes are not removed until after a trade is executed. As a result, because of the way complex orders leg into the regular market as a single transaction, Market-Makers and other liquidity providers may end up trading more than the cumulative risk thresholds they have established, and are therefore exposed to greater risk. The Exchange believes that Market Makers and other liquidity providers may be compelled to change their quoting and trading behavior to

[61] The Exchange expects this value to be initially set at $0.50 as represented in the example above.

[62] *See* ISE Options 3, Section 14, Supplementary Material .03; and Nasdaq MRX, LLC (''MRX'') Options 3, Section 14, Supplementary Material .03.

[63] *See* proposed Rule 5.33(f)(2)(B).

[64] As noted above, the Exchange expects the buffer amount to be initially set at zero. The Exchange may change the buffer amount in the future by announcing it pursuant to Rule 1.5 of the shell Rulebook.

[65] *See* current Rule 6.12(a)(4) in the current Rulebook. Additionally, stock exchanges provide similar protections for execution prices of stock orders. *See, e.g.,* NASDAQ Stock Market Rule 4757(c) (which prevents stock limit orders from being accepted at prices outside of pre-set standard limits, which is based on the NBBO).

[66] *See* current Rule 6.53C(c)(i).

[67] *See* current Rule 6.53C(c)(i)(1) and (d)(v)(1).

[68] *See* current Rule 6.53C(a)(1).

[69] *See* current Rule 6.53C, Interpretation and Policy .06. Current Rule 6.53C, Interpretation and Policy .06(d) provides the Exchange with authority to determine on a class-by-class basis to permit unexecuted option legs of stock-option market orders to leg following a COA. The Exchange does not permit this legging in any class and does not intend to following the technology migration, and therefore the proposed rule change deletes that provision.

[70] *See* current Rule 6.53C, Interpretation and Policy .02.

account for this additional risk by widening their quotes and reducing the size associated with their quotes, which would diminish the Exchange's quality of markets and the quality of the markets in general.

Proposed Rule 5.33(h) contains additional provisions regarding the handling of complex orders:[71]

• A complex market order or a limit order with a price that locks or crosses the then-current opposite side SBBO and does not execute because the SBBO is the best price but not available for execution (because it does not satisfy the complex order ratio or the complex order cannot Leg into the Simple Book) enters the COB with a book and display price that (a) is one minimum increment away from the then-current opposite side SBBO if it includes a Priority Customer order on any leg or (b) locks the then-current opposite side SBBO if it does not include a Priority Customer order on any leg. If the SBBO changes, the System continuously reprices the complex order's book and display price based on the new SBBO (up to the limit price, if it is a limit order), subject to the drill-through price protection in current Rule 6.13(b)(v) (to be moved to Rule 5.34(b) of the shell Rulebook), until: (A) The complex order has been executed in its entirety; or (B) the complex order (or unexecuted portion) of the complex order is cancelled or rejected. This provision is the same as EDGX Options Rule 21.20(h)(1), except that, as noted above, the Exchange may apply a different minimum increment for complex orders in a class other than $0.01 (on EDGX Options, each class will have a minimum increment of $0.01 for complex orders). The purpose of using the calculated SBBO is to enable the System to determine a valid trading price range for complex strategies and to protect orders resting on the Simple Book by ensuring that they are executed when entitled. Additionally, this process ensures the System will not execute any component of a complex order at a price that would trade through an order on the Simple Book. The Exchange believes that this is reasonable because it prevents the components of a complex order from trading at a price that is inferior to a price at which the individual components may be traded on the Exchange or ahead of the leg markets.

• The System cancels or rejects an incoming Post Only complex order if it locks or crosses a resting complex order in the COB or the then-current opposite side SBBO. The System cancels a resting Post Only complex limit order after evaluation pursuant to proposed paragraph (i), as discussed below, if the System determines the resting Post Only complex limit order locks or crosses the updated SBBO. For example, assume there are no orders for a specific strategy resting on the COB, the SNBBO is $3.00 by $3.15, and the SBBO is $2.95 by $3.15. Assume next that Complex Order 1 enters the COB to sell 10 contracts of that strategy at $3.14 and such order is posted to the COB. If Complex Order 2 then enters the COB to buy 10 contracts of that strategy at $3.14, but Complex Order 2 also contains the Post Only instruction, Complex Order 2 is rejected since it locks the resting contra order. Similarly, assume there are no orders for a specific strategy resting on the COB, the SNBBO is $3.00 by $3.15, and the SBBO is $2.95 by $3.20. If a two-leg Complex Order with the Post Only instruction enters the COB to buy 10 contracts of that strategy at $3.20, that Complex Order is rejected since it cannot leg in to the Simple Book and it locks the contra side SBBO. This proposed functionality is consistent with the purpose of the Post Only instruction and ensures a Post Only complex order will not remove liquidity from the Book. This is also consistent with the functionality and purpose of the Post Only order instruction on simple orders, and the same as C2 Rule 6.13(h)(3) and EDGX Options Rule 21.20(h)(2).

• If there is a zero NBO for any leg, the System replaces the zero with a price equal to one minimum increment above NBB to calculate the SNBBO, and complex orders with any buy legs do not Leg into the Simple Book. If there is a zero NBB, the System replaces the zero with a price equal to one minimum increment, and complex orders with any sell legs do not Leg into the Simple Book. If there is a zero NBB and zero NBO, the System replaces the zero NBB with a price equal to one minimum increment and replaces the zero NBO with a price equal to two minimum increments, and complex orders do not Leg into the Simple Book. The SBBO and SNBBO may not be calculated if the NBB or NBO is zero (as noted above, if the best bid or offer on the Exchange is not available, the System uses the NBB or NBO when calculating the SBBO). As discussed above, permissible execution prices are based on the SBBO. If the SBBO is not available, the System cannot determine permissible posting or execution pricing for a complex order (which are based on the SBBO), which could reduce execution opportunities for complex orders. If the System were to use the zero bid or offer when calculating the SBBO, it may also result in executions at erroneous prices (since there is no market indication for the price at which the leg should execute). For example, if a complex order has a buy leg in a series with no offer, there is no order in the leg markets against which this leg component could execute. This is the same as C2 Rule 6.13(h)(3) and EDGX Options Rule 21.20(h)(3) (except the proposed rule change incorporates the fact that the Exchange may apply a different minimum increment to a class for complex orders). This is also consistent with the proposed rule change that states complex order executions are not permitted if the price of a leg would be zero. Additionally, this is similar to the proposed rule change described above to improve the posting price of a complex order by one minimum increment if it would otherwise lock the SBBO. The proposed rule change is a reasonable process to ensure complex orders receive execution opportunities, even if there is no interest in the leg markets.[72]

Proposed Rule 5.33(i) states the System evaluates an incoming complex order upon receipt after the open of trading to determine whether it is a COA-eligible order or a do-not-COA order and thus whether it should be processed pursuant to proposed paragraph (d) or (e), respectively, routed to PAR for manual handling, or cancelled. The System also re-evaluates a complex order resting on the COB (including an order (or unexecuted portion) that did not execute pursuant to proposed paragraph (d) or (e) upon initial receipt) (1) at time the COB opens, (2) following a halt, and (3) during the trading day when the leg market price or quantity changes to determine whether the complex order can execute (pursuant to proposed paragraph (e)), should be repriced (pursuant to proposed paragraph (h)), should remain resting on the COB, or should be cancelled. Proposed paragraph (i) is the same as C2 Rule 6.13(i) and EDGX Options Rule 21.20(i). This evaluation process ensures that the System is monitoring and assessing the COB for incoming complex orders, and changes in market conditions or events

[71] *See also* C2 Rule 6.13(h) and EDGX Options Rule 21.20(h).

[72] Current Rule 6.13(b)(vi) states if a market order is received when the national best bid in a series is zero, if the Exchange best offer is less than or equal to $0.50, the Cboe Options system enters the market order into the book as a limit order with a price equal to the minimum trading increment for the series. Similar to the proposed rule change, this is an example of an exchange modifying an order price to provide execution opportunities for the order when there is a lack of contra-side interest when the order is received by the exchange.

that cause complex orders to reprice or execute, and conditions or events that result in the cancellation of complex orders on the COB. This ensures the integrity of the Exchange's System in handling complex orders and results in a fair and orderly market for complex orders on the Exchange.

Proposed Rule 5.33(j) states the System routes to PAR for manual handling or cancels or rejects a complex market order it receives when the underlying security is subject to a limit up-limit down state, as defined in the Limit Up-Limit Down Plan. If during a COA of a market order, the underlying security enters a Limit State or Straddle State, the System terminates the COA without trading and cancels or rejects all COA Responses. The Exchange only executes the stock leg of a stock-option order at a price permissible under the Limit Up-Limit Down Plan. If the stock-option order cannot execute, if a limit order, the System calculates the SBBO or SNBBO with a price for the stock leg that would be permissible under that Plan and posts it to the COB at that price (if eligible to rest), or if a market order, routes the stock-option order to PAR for manual handling, subject to a User's instructions. This is consistent with handling of simple market orders during a limit up-limit down state, and is substantively the same as C2 Rule 6.13(j) (except C2 does not offer stock-option orders) and EDGX Options Rule 21.20(j), except the C2 and EDGX Options do not provide for markets orders to route to PAR for manual handling, as those are electronic only exchanges.[73]

Proposed Rule 5.33(k) describes the impact of trading halts on the trading of complex orders. If a trading halt exists for the underlying security or a component of a complex strategy, trading in the complex strategy will be suspended, and the System queues a User's complex orders unless the User instructed the Exchange to cancel its complex orders upon a trading halt. The COB remains available for Users to enter and manage complex orders. Incoming complex orders that could otherwise execute or initiate a COA in the absence of a halt are placed on the COB or cancelled, subject to a User's instructions.[74] Incoming complex orders with a time in force of IOC will be cancelled or rejected.

If, during a COA, any component(s) and/or the underlying security of a COA-eligible order is halted, the COA ends early without trading and all COA Responses are cancelled or rejected. The System enters remaining complex orders on the COB or cancelled, subject to a User's instructions. When trading in the halted component(s) and/or underlying security of the complex order resumes, the System will re-open the COB pursuant to proposed paragraph (c) (as described above). The System queues any complex orders designated for a re-opening following a halt until the halt has ended, at which time they are eligible for execution in the COB opening process. This proposed rule change regarding the handling of complex orders during a trading halt is substantively the same as C2 Rule 6.13(k) and EDGX Options Rule 21.20(k).

Proposed Rule 5.33(l) contains provisions regarding the handling execution of stock-option orders.[75] The proposed rule change moves provisions from current Rule Interpretation and Policy .06 to proposed Rule 5.33(l) as follows[76]:

Rule provision	Current rule (current rulebook)	Proposed rule (shell rulebook)	Proposed substantive changes
A User may only submit a stock-option order (including a QCC Stock Order) if it complies with the Qualified Contingent Trade Exemption ("QCT Exemption") from Rule 611(a) of Regulation NMS. A User submitting a stock-option order represents that it complies with the QCT Exemption. To submit a stock-option order to the Exchange for execution, a User must enter into a brokerage agreement with one or more broker-dealers that are not affiliated with the Exchange, which broker-dealers the Exchange has identified as having connectivity to electronically communicate the stock components of stock-option orders to stock trading venues.	Rule 6.53C, Interpretation and Policy .06(a) and (g)(1)(C).	Rule 5.33, Interpretation and Policy .03.	The proposed rule change applies the same provision to all stock-option orders, including QCC with Stock Orders, as all stock-option orders must comply with the QCT Exemption. The proposed rule change deletes the requirement in current Rule 6.53C, Interpretation and Policy .06(a) that a TPH identify a designated give up on a stock-option order.[77] TPHs must identify a give-up on all orders submitted to the Exchange, which would include all stock-option orders, so the Exchange believes it is redundant to state this in the stock-option order rules.[78]
When a User submits to the System a stock-option order, it must designate a specific broker-dealer with which it has entered into a brokerage agreement pursuant to proposed Interpretation and Policy .03 (the "designated broker-dealer") to which the Exchange will electronically communicate the stock component of the stock-option order on behalf of the User.	Rule 6.53C, Interpretation and Policy .06(a) and (g)(1)(C).	Rule 5.33(l)(1)	The proposed rule change applies the same provision to all stock-option orders, including QCC with Stock Orders.
A stock-option order may execute against other stock-option orders (or COA responses, if applicable), but may not execute against orders in the Simple Book. A stock-option order may only execute if the price complies with proposed subparagraph (f)(2)(B) (as described above).	Rule 6.53C, Interpretation and Policy .06, introductory paragraph and (a).	Rule 5.33(l)(2)	None.

[73] *See* current Rule 6.53C(d)(ix) and Interpretation and Policy .06(f).

[74] This provision incorporates the fact that the Exchange has a trading floor. Therefore, if a User designates an order (by adding the Default or Direct to PAR Order Instruction, as described above) that is not eligible to rest on the COB as eligible to route to the PAR workstation for manual handling, if a User submits such a complex order during a halt, it would route to PAR, rather than be cancelled in accordance with the User's instructions. If the User had instead designated this order as Electronic Only, the order would be cancelled if submitted during a halt in accordance with the User's instructions.

[75] *See also* EDGX Options Rule 21.20(l) (which is the same as the proposed rule change). The Exchange notes C2 does not offer stock-option order functionality.

[76] Certain provisions from current Rule 6.53C, Interpretation and Policy .06 are included in other parts of proposed Rule 5.33, such as permissible minimum increments and execution prices, as described above.

Rule provision	Current rule (current rulebook)	Proposed rule (shell rulebook)	Proposed substantive changes
If a stock-option order can execute upon entry or following a COA, or if it can execute following evaluation while resting in the COB pursuant to paragraph (i), the System executes the option component (which may consist of one or more option legs) of a stock-option order against the option component of other stock-option orders resting in the COB or COA responses pursuant to the allocation algorithm applicable to the class pursuant to proposed subparagraph (d)(5)(A)(ii) above, as applicable, but does not immediately send the User a trade execution report, and then automatically communicates the stock component to the designated broker-dealer for execution at a stock trading venue.	Rule 6.53C, Interpretation and Policy .06(b) and (g)(2) [79].	Rule 5.33(l)(2)(A)	The proposed rule change prevents potential execution of the stock component of a qualified contingent transaction (''QCT'') where the stock component by waiting to communicate the stock component for execution until after the option component executes. This proposed execution process is the same process the Exchange currently uses to execute QCC with Stock Orders, which are a type of stock-option order (and thus the Exchange merely expands this process to all stock-option orders, as all stock-option orders must satisfy the same QCT Exemption). [80]
If the System receives an execution report for the stock component from the designated broker-dealer, the Exchange sends the User the trade execution report for the stock-option order, including execution information for the stock and option components. If the System receives a report from the designated broker-dealer that the stock component cannot execute, the Exchange nullifies the option component trade and notifies the User of the reason for the nullification.	Rule 6.53C, Interpretation and Policy .06(g)(3).	Rule 5.33(l)(2)(B)	This proposed execution process is the same process the Exchange currently uses to execute QCC with Stock Orders, which are a type of stock-option order (and thus the Exchange merely expands this process to all stock-option orders, as all stock-option orders must satisfy the same QCT Exemption). Currently, whenever a stock trading venue nullifies the stock leg of a QCT or whenever the stock leg cannot execute, the Exchange will nullify the option leg upon request of one of the parties to the transaction or on an Exchange Official's own motion in accordance with the Rules.[81] To qualify as a QCT, the execution of one component is contingent upon the execution of all other components at or near the same time.[82] Given this requirement, if the stock component does not execute at or near the same time as the option component, it is reasonable to expect a User that submitted a stock-option order to request such nullification.[83] If the stock component does not execute, rather than require the User that submitted the stock-option order to contact the Exchange to request the nullification of the option component execution pursuant to current Rule 6.25, Interpretation and Policy .04(c), the proposed rule eliminates this requirement for the submitting User to make such a request. Instead, the proposed rule change provides that the Exchange will automatically nullify the option transaction if the stock component does not execute. The Exchange believes such nullification without a request from the User is consistent with the definition of a QCT order. The proposed rule change merely automates an otherwise manual process for Users. [84]
If a stock-option order cannot execute, it rests in the COB (if eligible to rest) or routes to PAR for manual handling, subject to a User's instructions.	Rule 6.53C, Interpretation and Policy .06(b).	Rule 5.33(l)(2)	None.
Handling of QCC with Stock Orders	Rule 6.53C, Interpretation and Policy .06(g).	Rule 5.33(l)(3)	The Exchange notes that pursuant to current Rule 6.53 regarding QCC orders, a QCC order may have more than one option leg (*i.e.,* be comprised of a complex order). Because a QCC with Stock Order is defined as a QCC order submitted with a stock component, current Rule 6.53 (which includes the definition of a QCC with Stock Order) permits a QCC with Stock Order to be a Complex QCC with Stock Order. The proposed rule change merely explicitly states such an order is permitted.
Regulation SHO marking requirement	Rule 6.53C, Interpretation and Policy .06(e).	Rule 5.33(l)(4)(A)	None.
The Exchange will only execute the stock leg of a stock-option order at a price permissible under Regulation SHO. If a stock-option order cannot execute, for a limit order, the System calculates the SBBO or SNBBO with a price for the stock leg that would be permissible under Regulation SHO, and posts the stock-option order on the COB at that price (if eligible to rest), or if a market order, the System routes it to PAR for manual handling, subject to a User's instructions.	N/A	Rule 5.33(l)(4)(B)	While not explicitly stated in the current Rules, the Exchange will not execute the stock leg of a stock-option order at a price not permissible under Regulation SHO (current Rule 6.53C, Interpretation and Policy .06(a) states a stock-option order will not execute unless the stock leg is executable at a price necessary to achieve the desired net price). [85]

The Exchange believes the proposed provisions described above regarding complex order handling and executions provide a framework that is substantially the same as the framework in place on the Exchange today, as described above. The Exchange believes it will continue to enable the efficient trading of complex orders in a manner that is substantially similar to functionality available on Cboe Affiliated Exchanges. As described above, complex order executions are designed to work in concert with a priority of allocation that continues to respect the priority of allocations on the Simple Book while protecting orders Priority Customer orders in the Simple Book.

Proposed Interpretation and Policy .01 states Market-Makers are not required to quote on the COB. Complex strategies are not subject to any quoting requirements applicable to Market-Makers in the simple market for individual options series or classes. The Exchange does not take into account Market-Makers' volume executed in complex strategies when deterring whether Market-Makers meet their quoting obligations in the simple market for individual options. This codifies current Exchange practice and is the same as C2 Rule 6.13, Interpretation and Policy .01 and EDGX Rule 21.20, Interpretation and Policy .01.

The proposed rule change deletes current Rule 6.53C, Interpretation and Policy .01 regarding how the Exchange will announce determinations it may make pursuant to Rule 6.53C. Rule 1.5 in the shell Rulebook describes how the Exchange will announce determinations it may make pursuant to the Rules, and thus current Interpretation and Policy .01 is no longer necessary.

The proposed rule change deletes current Rule 6.53C, Interpretation and Policy .03 regarding the N-second timer for complex order transactions. The Exchange no longer has N-second timer functionality for simple or complex order transactions, making this provision obsolete.

The proposed rule change deletes current Rule 6.53C, Interpretations and Policies .04 and .06(b)(2), which describes how orders (including stock-option orders) resting on the COB may initiate a COA under certain conditions. This ''re-COA'' functionality will not be available on the Exchange following the technology migration. This is consistent with the Exchange's current authority to determine whether to apply re-COA functionality to a class. However, as described above, the System continuously evaluates orders resting on the COB for execution opportunities against incoming complex orders or orders in the leg markets.[86]

The proposed rule change moves the provision in current Rule 6.53C, Interpretation and Policy .05 that states a pattern or practice of submitting orders that cause a COA to conclude early will be deemed conduct inconsistent with just and equitable principles of trade and a violation of Rule 8.1 in the shell Rulebook (which will be equivalent to Rule 4.1 in the current Rulebook) to proposed Rule 5.33, Interpretation and Policy .02. The proposed rule change deletes the provision in Rule 6.53C, Interpretation and Policy .05 that redistributing the RFR message provided by the Exchange to persons not eligible to respond to such messages is prohibited, except in classes in which the Exchange allows all TPHs to respond to such messages. The Exchange believes redistribution of auction messages adds transparency to the market. The Exchange notes that Trading Permit Holders will continue to be prohibited from engaging in acts or practices inconsistent with just and equitable principles of trade.

The proposed rule change moves Rule 6.53B from the current Rulebook to Rule 5.41 in the shell Rulebook.[87] The proposed rule is virtually identical to the current rule, except the proposed rule change makes certain nonsubstantive changes, including to make the rule text more plain English, update cross-references, conform terminology to that used throughout the shell Rulebook, and add paragraph lettering and numbering. The Exchange notes it deletes the provision in current Rule 6.53B(a) that states S&P 500 variance trades may only trade electronically. The proposed rule change moves this Rule to Rule 5.41 in the shell Rulebook, which is in Chapter 5, Section C of the shell Rulebook, which section relates only to electronic trading. Because the proposed rule is in a section only about electronic trading, the Exchange believes including a provision that states these trades may only trade electronically would be redundant, and therefore does not include that provision.

[77] *See* Rule 6.21 in the current Rulebook (which rule the Exchange intends to move without any substantive changes to Rule 5.10 of the shell Rulebook in a separate rule filing).

[78] *See also* ISE Options 3, Sections 12(e) and 14.

[79] *See also* ISE Options 3, Section 14, Supplementary Material .02 (which states a ''trade'' of a stock-option order or stock-complex order will be automatically cancelled if market conditions prevent the execution of the stock or option leg(s) at the prices necessary to achieve the agreed upon net price); and Miami International Securities Exchange, LLC (''MIAX'') Rule 518, Interpretation and Policy .01(b) (pursuant to which the stock components will attempt execution prior to the option components, but ultimately require both the stock and option components to execute).

[80] *See* current Rule 6.53C, Interpretation and Policy .06(g).

[81] *See* current Rule 6.25, Interpretation and Policy .04(c).

[82] *See* Securities Exchange Act Release No. 54389 (August 31, 2006), 71 FR 52829, 52831 (September 7, 2006) (Order Granting an Exemption for Qualified Contingent Trades from Rule 611(a) of Regulation NMS Under the Securities Exchange Act of 1934) (''QCT Exemption Order''), which requires the execution of one component of the QCT to be contingent upon the execution of all other components at or near the same time to qualify for the exemption. In its Exemption Request, the Securities Industry Association stated that for contingent trades, the execution of one order is contingent upon the execution of the other order. SIA further stated that, by breaking up one or more components of a contingent trade and requiring that such components be separately executed, one or more parties may trade ''out of hedge.'' *See* Letter to Nancy M. Morris, Secretary, Commission, from Andrew Madoff, SIA Trading Committee, SIA, dated June 21, 2006 (''SIA Exemption Request''), at 3.

[83] *See* QCT Exemption Order at 52831. In the SIA Exemption Request, the SIA indicated parties to a contingent transaction are focused on the spread or ratio between the transaction prices for each of the component instruments, rather than on the absolute price of any single component instrument. The SIA also noted the economics of a contingent trade are based on the relationship between the prices of the security and related derivative or security. *See* SIA Exemption Request at 2.

[84] The Exchange believes this automatic nullification will reduce any compliance risk for the User associated with execution of a stock-option order and lack of execution of a stock order at or near the same time. In the SIA Exemption Request, the SIA stated that parties to a contingent trade will not execute one side of the trade without the other component or components being executed in full (or in ratio) and at the specified spread or ratio. *See* SIA Exemption Request at 2. While a broker-dealer could re-submit the stock component to a stock trading venue or execution after it initially fails to execute, there is a compliance risk that the time at which the stock component executes is not close enough to the time at which the option component executed. The Exchange conducts surveillance to ensure a User executes the stock component of a QCT, which will also apply to QCC with Stock Orders, if the option component executed. As a result, if the stock component does not execute when initially submitted to a stock trading venue by the designated broker-dealer, a User may be subject to compliance risk if it does not execute the stock component within a reasonable time period of the execution of the option component. The proposed rule change reduces this compliance risk for Users.

[85] Specifically, Rule 201 of Regulation SHO provides that when the short sale price test is triggered for an NMS stock, a trading center (such as the Exchange) must comply with Rule 201. Other options exchanges have similar marking requirements. *See also* MIAX Rule 518, Interpretation and Policy .01(b) (which requires execution price in accordance with Regulation SHO).

[86] Neither C2 nor EDGX Options permits complex orders to re-COA.

[87] The Exchange notes it does not currently allow S&P 500 variance trades; however, it may determine to make them available for trading in the future, in which case it would announce such determination pursuant to Rule 1.5 in the shell Rulebook.

The proposed rule change amends Rule 5.83 in the shell Rulebook to describe the complex orders types that the Exchange may make available for PAR routing for manual handling (and open outcry trading):

- *Order types:* limit and market orders.[88]
- *Order instructions:* AON, Attributable, Complex Only, MTP Modifier, Multi-Class Spread, Non-Attributable, Not Held, RTH Only, SPX Combo, and stock-option order.[89]
- *Times-in-Force:* Day and GTC.

Making these order types available for PAR routing is consistent with current Exchange authority under Rules 6.12A and 6.53 (which Rules identify which orders are eligible for PAR, and permit the Exchange to make order types available on a system-by-system basis, respectively). Currently, Rule 6.12A indicates attributable orders and market-maker trade prevention orders (similar to orders with an MTP Modifier) may not route to PAR. While attribution is only relevant with respect to electronic orders (as it involves a User's unique identifier to be displayed if resting on the Book), the Exchange believes a User may still want an order to be routed for manual handling if it cannot execute, as the Attributable designation has no impact on execution. A User may still designate an Attributable order as Electronic Only if the User does not want an Attributable order routed to PAR for manual handling (and thus be handled as it is today). Similarly, while the purpose of designating an MTP Modifier is to prevent certain electronic executions (and cannot be enforced in open outcry), the Exchange believes a User may still want an order with an MTP Modifier to be routed to PAR for manual handling if it cannot be processed electronically. The risk a User is intending to avoid with an MTP Modifier is generally not present on the trading floor. Again, a User may designate an order with an MTP Modifier as Electronic Only if the User does not want that order to be routed to PAR for manual handling (and thus be handled as it is today). The proposed rule changes provides Users with additional flexibility and control over the handling and executions of their orders, while also providing opportunities for orders to be handled in the same manner as they are today. Additionally, the Exchange believes listing these in the Rules will provide investors with additional transparency regarding which order types are eligible to route to PAR for manual handling.[90]

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[91] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[92] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[93] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, as described above, the general framework for the electronic processing of complex orders on the Exchange will remain the same following the technology migration. The Exchange believes that the general provisions regarding the trading of complex orders will continue to provide a clear framework for trading of complex orders, which will be in a manner consistent with that of C2 and EDGX Options, as described above. This consistency should promote a fair and orderly national options market system.

The proposed execution and priority rules will allow complex orders to interact with interest in the Simple Book and, conversely, interest on the Simple Book to interact with complex orders in an efficient and orderly manner. The proposed priority of execution of complex orders is consistent with general principles of customer priority and protects the leg markets, as it will ensure that executions of complex orders improve the SBBO if there is a Priority Customer representing any leg on the Simple Book. As discussed above, the proposed priority order is the same as that on EDGX Options.

The Exchange proposes that complex orders may be submitted as limit orders and market orders, and orders with a Time-in-Force of Day, GTC, GTD, IOC, or OPG, and with Order Instructions of All Sessions, AON, Book Only, Complex Only, MTP Modifiers, Post Only, RTH Only, QCC with Stock Order, or stock-option order. In particular, the Exchange believes that limit orders, GTD, IOC, DAY, GTC, and OPG orders all provide valuable limitations on execution price and time that help to protect Exchange participants and investors in both the Simple Book and the COB. As noted above, the Exchange currently makes most of these order types (including having similar criteria for being COA-eligible and providing an option to designate a complex order as do-not-COA) available for complex orders. Currently, complex orders may be submitted in the GTH and RTH trading sessions, and making the All Sessions and RTH Only instructions available will continue to permit Users to have the flexibility to submit complex orders into both trading sessions, in their discretion. The proposed rule change also clarifies that Attributable/Non-Attributable instructions are available for complex orders; however, these instructions merely apply to information that is displayed for the orders but do not impact how they execute. Because complex orders do not route (and the Exchange does not currently offer a Post Only instruction, which the Exchange proposes to make available for complex orders, as discussed below), all complex orders are currently the equivalent of Book Only, which is therefore consistent with current Exchange complex order functionality.

In particular, the Exchange notes that while the Complex Only Order (as further discussed below) may reduce execution opportunities for the entering Market-Maker, C2 and EDGX options each offer this functionality in connection with complex order functionality. The Exchange believes this is a reasonable limitation a Market-Maker may wish to include on its order in order to participate on the COB. In addition, the Exchange believes that offering participants the ability to utilize

[88] The Exchange current permits market and limit complex orders to be routed to PAR for manual handling.

[89] Rule 5.83(a) in the shell Rulebook currently lists Multi-Class Spreads and SPX Combos as available for PAR routing. Because those are multi-legged orders, the proposed rule change moves them to Rule 5.83(b), and adds subheadings to each of paragraph (a) and (b). These order instructions (other than Complex Only, which the Exchange does not currently offer) are current eligible to route to PAR.

[90] *See* Rules 6.12A(c) and 6.53 (in the current Rulebook) (which provide that certain order types in Rule 6.53 are eligible for routing to PAR, and that the Exchange may determine which order types in Rule 6.53 are available on a class and system (including PAR) basis); *see also* Rule 5.83 in the shell Rulebook.

[91] 15 U.S.C. 78f(b).

[92] 15 U.S.C. 78f(b)(5).

[93] *Id.*

MTP Modifiers for complex orders in a similar way to the way they are used on the Simple Book provides such participants with the ability to protect themselves from inadvertently automatic matching against their own interest.

The Post Only Order instruction on complex orders is designed to encourage market participants to add liquidity in the complex order market, which will benefit investors. By giving market participants the flexibility to manage their execution costs and the circumstances in which their complex orders are executed, the Exchange believes the proposed rule change would remove impediments to perfect the mechanism of a free and open market and a national market system and protect investors. The Exchange also believes that the proposed rule change will contribute to the protection of investors and the public interest by assuring compliance with rules related to locked and crossed markets.

Additionally, the Exchange notes that Post Only functionality is not new or unique functionality and is already available in a similar capacity. While the Post Only complex order type is not currently available in the market, the Exchange recently proposed to have a Post Only simple order type,[94] which functions in the same manner as the proposed Post Only complex order type. The purpose of a Post Only complex order is the same as the purpose of a Post Only simple order, and the Post Only Order instruction on complex orders ensures the submitter receives the benefit of a reduced fee when intending to add liquidity.

The proposed rule change benefits investors by providing transparency regarding how the System will handle and execute AON orders, which handling and execution are consistent with the size contingency of AON orders. The proposed rule change to require AON complex orders to COA and not permit them to rest in the COB or Leg into the Simple Book will protect investors, because it will provide AON complex orders with opportunities for execution and continue to protect orders on the Simple Book. As the Exchange noted above, there would be significant technical complexities associated with reprogramming priority within the System to permit AON complex orders to Leg into the Simple Book and provide AON orders with priority consistent with the standard priority principles described above. The Exchange notes that, in addition to EDGX Options, other options exchange do not permit AON complex orders to rest in the COB [95] or to leg into the simple book.[96] In addition, as described above, the proposed rule change protects resting Leg market interest because AON complex orders may not execute unless they improve the SBBO at the conclusion of a COA.

The Exchange believes the proposed complex orders types (in addition to those currently available on the Exchange) will provide investors with additional functionality that will provide them with more flexibility and control over the management of their complex orders and the manner and circumstances in which their complex orders may be executed, modified, or cancelled. As a result, this may provide for the protection of investors and contribute to market efficiency. This may encourage market participants to bring additional liquidity to the market, which benefits all investors. Additionally, this will provide Users with greater harmonization between the order handling instructions available among the Cboe Affiliated Exchanges.

The proposed rule change also benefits investors by adding transparency regarding which orders are eligible for electronic processing, and which orders are eligible for manual handling. The Exchange currently has authority pursuant to Rules 6.12A and 6.53 in the current Rulebook to determine which orders are eligible for electronic processing and PAR routing, and the proposed rule change is consistent with that authority.

If a complex order is not priced equal to, or better than, the SBBO or is not priced to improve other complex orders resting at the top of the COB, the Exchange does not believe that it is reasonable to anticipate that it would generate a meaningful number of COA Responses such that there would be price improvement of the complex order's limit price. Promoting the orderly initiation of COAs is essential to maintaining a fair and orderly market for complex orders; otherwise, the initiation of COAs that are unlikely to result in price improvement could affect the orderliness of the marketplace in general. The Exchange believes that this removes impediments to and perfects the mechanisms of a free and open market and a national market system by promoting the orderly initiation of COAs, and by limiting the likelihood of unnecessary COAs that are not expected to result in price improvement. The proposed circumstances in which an order may be eligible to COA are substantively the same as those in which an order may be eligible to COA on C2 and EDGX, as noted above.

The Exchange believes the proposed maximum 500 millisecond Response Time Interval promotes just and equitable principles of trade and removes impediments to a free and open market because it allows sufficient time for Trading Permit Holders participating in a COA to submit COA Responses and would encourage competition among participants, thereby enhancing the potential for price improvement for complex orders in the COA to the benefit of investors and public interest. The Exchange believes the proposed rule change is not unfairly discriminatory because it establishes a Response Time Interval applicable to all Exchange participants participating in a COA, which is the same maximum Response Time Interval on EDGX and C2, as noted above.

The proposed events that will conclude a COA early are reasonable and promote a fair and orderly market and national market system, because they will ensure that executions at the conclusion of a COA occur at permissible prices (and not outside the prices of complex order resting at the top of the COB or the SBBO, or at the SBBO if there is a Priority Customer order resting in any leg on the Simple Book). The proposed rule change will also benefit investors by continuing to provide clarity regarding what will cause a COA to conclude. These events would create circumstances under which a COA would not have been permitted to start, or that would cause the auction price no longer be consistent with the permissible prices at which executions at the conclusion of a COA may occur. Thus the Exchange believes it is appropriate to conclude a COA if those circumstances occur. The Exchange will no longer conclude a COA early due to the receipt of an opposite side order. The Exchange believes this promotes just and equitable principles of trade, because these orders may have the opportunity to trade against the COA'd order following the conclusion of the COA, which execution must still be at or better than the SBBO (or better than the SBBO if there is a Priority Customer order on any leg) and at or better than the best-priced complex orders on the COB. The Exchange believes this will protect investors, because it will

[94] *See* Rule 5.6(c) in the shell Rulebook.

[95] *See, e.g.,* ISE Options 3, Section 14(b)(3) (which requires AON complex orders to be submitted as IOC orders). While not specified in current Rules, this proposed change is consistent with current Exchange functionality (pursuant to the Exchange's authority in current Rule 6.53 to determine which order types are eligible for COB entry (an Exchange system)).

[96] *See, e.g.,* Phlx Rule 1098(e)(vi)(A).

provide more time for price improvement, and the unrelated order will have the opportunity to trade against the COA'd order in the same manner as all other contra-side interest.

The Exchange again notes that it has not proposed to limit the frequency of COAs for a complex strategy and could have multiple COAs occurring concurrently with respect to a particular complex strategy. The Exchange represents that it has systems capacity to process multiple overlapping COAs consistent with the proposal, including systems necessary to conduct surveillance of activity occurring in such auctions. Further, C2 and EDGX may both currently have multiple complex auctions in the same strategy run concurrently, as noted above. The Exchange does not anticipate overlapping auctions necessarily to be a common occurrence, however, after considerable review, believes that such behavior is more fair and reasonable with respect to Trading Permit Holders who submit orders to the COB because the alternative presents other issues to such Trading Permit Holders. Specifically, if the Exchange does not permit overlapping COAs, then a Trading Permit Holder who wishes to submit a COA-eligible order but has its order rejected because another COA is already underway in the complex strategy must either wait for such COA to conclude and re-submit the order to the Exchange (possibly constantly resubmitting the complex order to ensure it is received by the Exchange before another COA commences) or must send the order to another options exchange that accepts complex orders.

The proposed Legging restrictions protects investors and the public interest by ensuring that Market-Makers and other liquidity providers do not trade above their established risk tolerance levels, which is consistent with the purpose of current restrictions in place on the Exchange, as discussed above. The proposed Legging restrictions, as noted above, are the same as those offered on EDGX Options (while several are unique to the Exchange and exist today). Despite the enhanced execution opportunities provided by Legging, the Exchange believes it is reasonable and consistent with the Act to permit Market-Makers to submit orders designated as Complex Only Orders that will not leg into the Simple Book. This is analogous to other types of functionality offered by the Exchange that provides Trading Permit Holders the ability to direct the Exchange not to route their orders or remove liquidity from the Exchange. Similar to such analogous features, the Exchange believes that Market-Makers may utilize Complex Only Order functionality as part of their strategy to maintain additional control over their executions, in connection with their attempt to provide and not remove liquidity, or in connection with applicable fees for executions.

Evaluation of the executability of complex orders is central to the removal of impediments to, and the perfection of, the mechanisms of a free and open market and a national market system and, in general, the protection of investors and the public interest. The proposed evaluation process will ensure that the System will capture and act upon complex orders that are due for execution. The regular and event-driven evaluation process removes potential impediments to the mechanisms of the free and open market and the national market system by ensuring that complex orders are given the best possible chance at execution at the best price, evaluating the availability of complex orders to be handled in a number of ways as described in this proposal. Any potential impediments to the order handling and execution process respecting complex orders are substantially removed due to their continual and event-driven evaluation for subsequent action to be taken by the System. This protects investors and the public interest by ensuring that complex orders in the System are continually monitored and evaluated for potential action(s) to be taken on behalf of investors that submit their complex orders to the Exchange.

The proposed rule change to permit the Exchange to set an allowable value outside of the expected notional trade value for the legs of a stock-option order removes impediments to and perfects the mechanism of a free and open market and a national market system because it provides Users with functionality that allows stock-option strategies to trade outside of their specified net prices when the executable stock match price results in a small difference between the expected notional value of the trade and the actual trade value. Users generally prefer not to forgo an execution for their stock-option strategies when this occurs, as the residual amount is miniscule compared to the value of the trade. As a result of the proposed rule, Users will be able to receive an expeditious execution, and trade the stock and options components of a stock-option strategy in a moving market without introducing legging risk, instead of resubmitting their orders and potentially receiving a much worse price or missing an execution. The proposed Exchange determination of a value allowance outside of the expected notional value is the same as that on EDGX Options, as noted above, and similar to that of another options exchange.[97] The Exchange believes having the trade value allowance in a dollar amount is more straightforward and less confusing for investors than the calculation of a percentage. The Exchange also believes that determining the amount of the trade value allowance will simplify the implementation of this functionality and mitigate any potential investor confusion by setting just one Exchange-determined notional variance. Because the difference between the expected notional value of the trade and the actual trade value is inconsequential, especially as compared to the overall benefit to investors of an expeditious execution, the Exchange does not believe the proposed difference will have any significant impact on the Exchange's participants and, instead, may benefit participants overall. As stated, the Exchange would determine an allowance amount that would reasonably account for the average differences in notional trade values as well as the cost benefit to market participants between the differences in actual trade value versus expected notional trade value and the imposition of resubmitting their orders and potentially receiving a much worse price or missing an execution.

Based on the foregoing, the Exchange does not believe that the proposed complex order functionality raises any new or novel concepts under the Act, and is substantively the same as functionality available today on the Exchange or on C2 and/or EDGX Options, and instead is consistent with the goals of the Act to remove impediments to and to perfect the mechanism of a free and open market and a national market system, and to protect investors and the public interest. The proposed rule change is generally intended to align system functionality currently offered by the Exchange with functionality available on other Cboe Affiliated Exchanges in order to provide a consistent technology offering. A consistent technology offering, in turn, will simplify the technology implementation, changes, and maintenance by Users of the Exchange that are also participants on Cboe Affiliated Exchanges. The proposed rule change will provide Users with additional flexibility and increased functionality on the Exchange's System.

[97] *See also* ISE Rule Options 3, Section 14, Supplementary Material .03.

When the Exchange migrates to the same technology as that of the other Cboe Affiliated Exchanges, Users of the Exchange will have access to similar functionality on all Cboe Affiliated Exchanges. As such, the proposed rule change would foster cooperation and coordination with persons engaged in facilitating transactions in securities and would remove impediments to and perfect the mechanism of a free and open market and a national market system.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange reiterates that the proposed rule change is being proposed in the context of the technology integration of the Cboe Affiliated Exchanges. Thus, the Exchange believes this proposed rule change is necessary to permit fair competition among national securities exchanges. In addition, the Exchange believes the proposed rule change will benefit Exchange participants in that it will provide a consistent technology offering for Users by the Cboe Affiliated Exchanges.

The Exchange does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. The general framework and primary features of the Exchange's complex order functionality is not changing, and will continue to protect orders, including Priority Customer orders, resting in the Book. Therefore, the electronic processing of complex orders will occur in a substantially similar manner as it does today. The System's electronic processing of complex orders of all Users will apply in the same manner. Use of complex order functionality and the various complex order instructions will continue to be voluntary and within the discretion of Users.

The Exchange does not believe that the proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. As discussed above, the basis for the majority of the proposed rule changes in this filing are based on C2 Rule 6.13 and EDGX Options Rule 21.20, and thus have previously been filed with the Commission.

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

Because the foregoing proposed rule change does not:

A. Significantly affect the protection of investors or the public interest;

B. impose any significant burden on competition; and

C. 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) of the Act [98] and Rule 19b–4(f)(6) [99] 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 will 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–CBOE–2019–060 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–CBOE–2019–060. 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–CBOE–2019–060 and should be submitted on or before October 16, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[100]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–20711 Filed 9–24–19; 8:45 am]

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[98] 15 U.S.C. 78s(b)(3)(A).

[99] 17 CFR 240.19b–4(f)(6).

[100] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87031; File No. SR–NASDAQ–2019–073]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Concerning the Operation of the Nasdaq Opening, Halt and Closing Crosses

September 19, 2019.

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 September 5, 2019, The Nasdaq Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'')

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to clarify its rules concerning the operation of the Nasdaq Opening, Halt and Closing Crosses, and to make certain corrective changes to Rules 4702, 4703, 4752, 4753, 4754, and 4763.

The text of the proposed rule change is available on the Exchange's website at *http://nasdaq.cchwallstreet.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the 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 is proposing to amend Rules 4752, 4753 and 4754, concerning the operation of the Nasdaq Opening, Halt and Closing Crosses, respectively, to make them more efficient, and to make corrective and clarifying changes. The Exchange is also making a related change to Rule 4763(e)(2) concerning the repricing of short sale Orders that are Limit-on-Open (''LOO''),[3] Market-on-Open (''MOO''),[4] Limit-on-Close (''LOC''),[5] or Market-on-Close (''MOC'').[6] Last, the Exchange is making corrective changes to Rules 4702(b) and 4703(l).

New Rules 4752(d)(2)(G), 4753(b)(2)(E) and 4754(b)(2)(F)

Rules 4752(d)(2), 4753(b)(2) and 4754(b)(2) describe the steps followed in establishing the prices in the Nasdaq Opening, Halt and Closing Crosses, respectively. A Post-Only Order is an Order Type designed to have its price adjusted as needed to post to the Nasdaq Book in compliance with Rule 610(d) under Regulation NMS by avoiding the display of quotations that lock or cross any Protected Quotation[7] in a System Security[8] during Market Hours,[9] or to execute against locking or crossing quotations in circumstances where economically beneficial to the Participant[10] entering the Post-Only Order.[11] A Post-Only Order may participate in the Nasdaq Opening Cross, Nasdaq Halt Cross and/or the Nasdaq Closing Cross.[12]

The Exchange is adopting new rule text under Rules 4752(d)(2)(G), 4753(b)(2)(E) and 4754(b)(2)(F) that describes how the Exchange prices the Nasdaq Opening, Halt and Closing Crosses when the Cross would otherwise be priced by a partial execution of an Order deemed to have a price at one minimum increment away from a Post-Only Order pursuant to Rule 4703(l). Rule 4703(l) describes the Order Attribute that allows an Order to participate in the Nasdaq Opening, Halt or Closing Crosses,[13] including the process for pricing an Order that is locked or crossed at its non-displayed price by a Post-Only Order. Specifically, an Order to buy (sell) that is locked or crossed at its non-displayed price by a Post-Only Order on the Nasdaq Book shall be deemed to have a price at one minimum price increment[14] below (above) the price of the Post-Only Order for the purposes of the Cross price calculation.

Currently, if the Opening, Halt[15] or Closing Cross would otherwise occur at the ''deemed price'' of an Order that is locked or crossed at its non-displayed price by a Post-Only Order pursuant to Rule 4703(l), and that Order would not execute in full during the Cross, then Cross price is instead adjusted to the price of the Order's original ranked price. The new rule text clarifies the current approach to setting the Cross price in situations where there is a partial execution of an Order that is deemed to have a price at one minimum price increment away from a Post-Only Order. Consider an example where the NBBO is $10.00 × $10.01 and resting on the Nasdaq book are Order #1, a MOC Order to buy 500 shares, Order #2, a MOC Order to sell 300 shares, Order #3, a Non-Displayed Order to sell 100 shares at $10.01, and Order #4 a Non-Displayed Order to sell 300 shares at $10.00. If Order #4 is subsequently locked by Order #5, a Post-Only Order to buy 100 shares at $10.00, then for purposes of the Cross price calculation, Order #4 would be deemed to have a price of $10.01, where it is presented for execution ahead of Order #3, reflecting its price priority on the Nasdaq book.[16] Per Nasdaq's Cross calculation language,[17] $10.01 would be selected as the Cross price as it maximizes paired shares (*i.e.,* Orders #1 and #2 are executed in full and Order #4 is executed partially). But because Order #4 would not execute in full at this price, the Cross price is instead adjusted to $10.00. The Cross would execute 500 shares at a price of $10.00, with Order #1 and Order #2 receiving full executions, and Order #4 receiving a partial execution of 200 shares.

This approach to setting the Cross price is consistent with Nasdaq Cross price tiebreaker rules regarding unexecuted shares[18] and ensures that

[3] *See* Rule 4752(a)(3).

[4] *See* Rule 4752(a)(4).

[5] *See* Rule 4754(a)(4).

[6] *See* Rule 4754(a)(5).

[7] *See* Rule 4701(j).

[8] *See* Rule 4701(b).

[9] *See* Rule 4701(g).

[10] *See* Rule 4701(c).

[11] *See* Rule 4702(b)(4).

[12] *See* Rule 4702(b)(4)(C). The Exchange is proposing to eliminate text from the rule that states that only Post-Only Orders entered through OUCH and FLITE protocols may participate in the Nasdaq Opening and/or Closing Crosses. This rule text was mistakenly adopted when amendments were made to the rule. *See* Securities Exchange Act Release No. 75252 (June 22, 2015), 80 FR 36865 (June 26, 2015) (SR–NASDAQ–2015–024). Any of the Order entry protocols may be used to enter Post-Only Orders eligible to participate in the Nasdaq Opening and/or Closing Crosses.

[13] The Exchange is proposing to correct Rule 4703(l) by including the Nasdaq Halt Cross in the rule. As described in the proposal, the Nasdaq Halt Cross was erroneously omitted from the rule.

[14] *See* Rule 4701(k).

[15] *See supra* note 13.

[16] Order #4 has price priority over Order #3 because Order #3[sic] is deemed to be $10.01 for purposes of the Cross price calculation, but for purposes of execution priority it is ranked behind all orders priced at $10.

[17] *See* Rules 4752(d)(2)(A), 4753(b)(2)(A), and 4754(b)(2)(A).

[18] Rule 4754(b)(2)(C) concerns the tiebreaker criteria for selecting the Closing Cross price when paired shares are maximized and imbalance is minimized: ''shall occur at the entered price at which shares will remain unexecuted in the cross.'' Had Nasdaq selected a Cross price of $10.01, the participant behind Order #4 would perceive that its Order was traded through or was otherwise not represented in the Cross, which is inconsistent with the purpose of the tiebreaker language (*i.e.,* the Cross price is $10.01, but the shares remaining in the cross are priced is $10.00). The Order Imbalance Indicator provides the current state of interest in designated for participation in the Closing Cross, including the adjusted price of the Cross. *See* Rule

the original ranked price of the Order is reflected, since the remaining unexecuted shares of the Order are ranked in time priority behind all orders at the price at which the Order was posted on the Nasdaq Book and no other interest ranked at a less aggressive price would execute in the Cross.[19] Pricing such an Order to its original ranked price is consistent with the participant's expectations and the pricing of Nasdaq Crosses,[20] since the participant would otherwise perceive that its Order was traded through or not represented in the Cross. In the example above, a participant would not expect to receive an execution in the cross at $10.01, while leaving unexecuted shares of its sell Order on the Nasdaq Book at a more aggressive price of 10.00.

Changes to Rule 4763(e)(2)

Rule 4763 provides the Exchange's rules concerning the Short Sale Price Test of Rule 201 of Regulation SHO. If the Short Sale Price Test is triggered, paragraph (e) of Rule 4763 provides the process for re-pricing of Orders during the Short Sale Period, when the Short Sale Price Test is in effect. Rule 4703(l) states that, for purposes of the Nasdaq Opening or Closing Cross,[21] an Order to buy (sell) that is locked or crossed at its non-displayed price by a Post-Only Order on the Nasdaq Book shall be deemed to have a price at one minimum price increment below (above) the price of the Post-Only Order.

Currently, short sale LOO, MOO, LOC and MOC Orders are re-priced during the Short Sale Period to the Permitted Price, unless the NBBO spread is $.01 in which case such orders will be priced to the midpoint. As a consequence of the Cross price adjustment explained above, in rare cases short sale LOO, MOO, LOC and MOC Orders re-priced to the midpoint would be required for completion of the Nasdaq Opening and Closing Crosses but would not be able to execute at the Cross price due to the Short Sale Price Test, notwithstanding the fact that it had been already adjusted to the midpoint (*i.e.,* the short sale LOO, MOO, LOC and MOC Orders included in the price calculation but would not be executable at the Cross price). This would occur if, in a security subject to the Short Sale Price Test and a NBBO one minimum price increment wide, the Cross price would be adjusted to the National Best Bid due to the partial execution of a sell Order deemed to have a price at the National Best Offer pursuant to Rule 4703(l). Consider the same example given previously with two changes: The security is subject to a Short Sale Price Test, and Order #2 is now a MOC to sell short. Under the current rule, Order #2 would be repriced to $10.005, a Cross price of $10.01 would be selected, and, because Order #4 would receive a partial execution in the cross, the cross price would be adjusted to $10.00. The Cross would attempt to execute Order #1, Order #2, and Order #4 as in above, but because of the Short Sale Price Test, $10.00 is an impermissible execution price for Order #2, notwithstanding the fact that it had been already adjusted to the midpoint.[22]

To resolve this issue, Nasdaq is proposing to amend Rule 4763(e)(2) to add a condition stating that the re-pricing of short sale LOO, MOO, LOC and MOC Orders to the midpoint in lieu of the Permitted Price will not occur when a resting non-displayed Order is deemed to have a price at one minimum increment away from a Post-Only Order pursuant to Rule 4703(l), at the time of the Nasdaq Opening Cross or the Nasdaq Closing Cross. This change will prevent short sale LOO, MOO, LOC and MOC Orders subject to the Short Sale Price Test from being presented for execution at an ineligible price when the Nasdaq Opening and Closing Cross price is adjusted pursuant to proposed Rules 4752(d)(2)(G), 4753(b)(2)(E) and 4754(b)(2)(F). Thus under the proposed rule, if at the time of the Nasdaq Opening Cross or the Nasdaq Closing Cross the Short Sale Price Test is in effect and there is a resting non-displayed Order deemed to have a price at one minimum increment away from a Post-Only Order, pursuant to Rule 4703(l), short sale Orders that are LOO, MOO, LOC, or MOC will be re-priced to the Permitted Price instead of the midpoint. Re-pricing of short sale Orders in this manner ensures they are ranked behind [23] such non-displayed Orders, thereby preventing the inclusion of ineligible short sale Orders in the event the Cross price is adjusted,[24] or in some cases, preventing the adjustment from occurring at all.[25] Using the example above, at the time of the Closing Cross, Order #2 would be repriced to the Permitted Price of $10.01 instead of the midpoint, where it is now ranked behind Order #4 in execution priority.[26] As a result of this reordering, Order #4 would now receive a full execution, preventing the Cross price adjustment clause that would occur with a partial execution. The Cross would be priced at $10.01, and the System would execute Order #1 in full for 500 shares, Order #4 in full for 300 shares, and Order #2 for 200 shares.

The Exchange notes that this change in no way allows for execution of a short sale Order subject to the Short Sale Price Test at an impermissible price. Moreover, pricing such an Order to the Permitted Price is consistent with the participant's expectations of short sale executability and the pricing of Nasdaq Crosses, since the participant would not expect its short sale Orders to participate in the Cross if the Cross were to be priced to the National Best Bid during the Short Sale Price Test.

Last, the Exchange is correcting a citation in the rule concerning the description of the Pegging Order Attribute, which was in former Rule 4751(f)(4) but was moved to Rule 4703(d).[27]

Changes to Rules 4752(d)(3)(B), 4753(b)(3) and 4754(b)(3)(B)

The Exchange is proposing to make a corrective change to Rules 4752(d)(3)(B), 4753(b)(3) and 4754(b)(3)(B), which provide the processes followed when the Nasdaq Cross price is selected and fewer than all shares of Cross eligible Orders that are available in the Nasdaq Market Center would be executed. In 2017, the Exchange clarified Rules 4752, 4753 and 4754 to specify the execution priority of an Order that has been locked or crossed at its non-displayed price by a Post-Only Order and re-priced for

4754(a)(7)(A). Thus, adjustment of the Closing Cross price is reflected in the Order Imbalance Indicator.

[19] This occurs because the Order is meant to cede priority to all other Orders at its original price, but retain priority over all Orders at a less aggressive price.

[20] *See supra* note 18.

[21] Rule 4703(l) concerns the Order Attribute that permits an Order to participate in the Nasdaq Crosses. As described below, the rule currently only discusses the Nasdaq Opening and Closing Crosses, however, the rule should also include the Nasdaq Halt Cross. The Exchange is proposing to correct Rule 4703(l) and to make related changes to Order Types under Rule 4702(b).

[22] Although Order #2 has been converted to an Order with a midpoint pegging attribute, the System nevertheless attempts to execute Order #2 ahead of Order #4 because it remains a MOC Order.

[23] The Exchange notes that, although this proposal changes the ranking of short sale LOO, MOO, LOC and MOC Orders so that such Orders lose priority as described herein, these Orders are not disadvantaged in so doing because they would not execute at their original ranked price.

[24] Adjusting the price of these Orders would result in the short sale LOO, MOO, LOC and MOC Orders to not be included in the Cross price calculation.

[25] The adjustment will not occur at all because either the non-displayed Order executed in full, or the non-displayed Order executed in full and the short sale Order received a partial execution.

[26] Even though Order #2 is technically a MOC Order, it will be ranked behind Order #4 because it is no longer treated as a MOC Order but rather it is prioritized at the repriced price level.

[27] *See* Securities Exchange Act Release No. 75252 (June 22, 2015), 80 FR 36865 (June 26, 2015) (SR–NASDAQ–2015–024).

purposes of the Opening, Halt and Closing Crosses.[28] In making the clarifying changes, the Exchange amended Rules 4752(d)(3)(B), 4753(b)(3) and 4754(b)(3)(B) to add the following text: [29] ''An Order to buy (sell) that is locked or crossed at its non-displayed price by a Post-Only Order on the Nasdaq Book, and which has been deemed to have a price at one minimum price increment below (above) the price of the Post-Only Order, shall be ranked in time priority ahead of all orders one minimum price increment below (above) the price of the Post-Only Order but behind all orders at the price at which the Order was posted to the Nasdaq Book.'' [30] The text stating ''ahead of all orders one minimum price increment below (above) the price of the Post-Only Order'' is incorrect with respect to Orders covered by the Cross rules,[31] specifically midpoint Orders when the NBBO is one minimum price increment wide. In these cases, an Order to buy (sell) that is locked or crossed at its non-displayed price by a Post-Only Order on the Nasdaq Book, and which has been deemed to have a price at one minimum price increment below (above) the price of the Post-Only Order, is ranked in time priority behind all Orders at the price at which the Order was posted to the Nasdaq Book, without regard to all Orders that are one minimum price increment below (above) the price of the Post-Only Order. This is because the Order is meant to cede priority to all other Orders at its original price, but retains priority over all Orders at a less aggressive price. For example, consider a scenario in which the NBBO is $10.00 × $10.01 and resting on the Nasdaq Book are Order #1, a midpoint Order to sell at $10.005, and Order #2, a non-displayed Order to sell at $10.00. If Order #2 were to be subsequently locked at $10.00 by a Post Only Order to buy, then Order #2 would be deemed to have a price of $10.01 for the purposes of the Cross price calculation. However, if a cross price of $10.005 was selected, Order #2 would be presented for execution at its ranked price of $10.00—not at its deemed price of $10.01—ahead of the midpoint order ranked $10.005. Accordingly, the Exchange is deleting the inaccurate text from Rules 4752(d)(3)(B), 4753(b)(3) and 4754(b)(3)(B), which states that the locked or crossed Order would be ranked in time priority ahead of all orders one minimum price increment below (above) the price of the Post-Only Order but behind all orders at the price at which the Order was posted to the Nasdaq Book.

Changes to Rules 4702(b) and 4703(l)

As noted above, Rule 4703(l) concerns the Order Attribute that permits an Order to participate in the Nasdaq Crosses. Currently, the rule only discusses the Nasdaq Opening and Closing Crosses. This was an omission occurring when the Exchange adopted the rule in 2015.[32] Any resting Order on the Nasdaq Book that may participate in the Nasdaq Opening and Closing Crosses may also participate in a Nasdaq Halt Cross.[33] Accordingly, the Exchange is proposing to correct Rule 4703(l) by including the Nasdaq Halt Cross in the rule. The Exchange is proposing to make related changes to affected Order Types under Rule 4702(b) to now include participation in the Nasdaq Halt Cross as an Order Attribute. Last, the Exchange is amending Rule 4702(b)(4)(C) to correct text in the rule that currently states that the Post-Only Order may only participate in the Nasdaq Opening and Closing Crosses only if it is entered through an OUCH or FLITE port. The Exchange has never limited participation of Post-Only Orders in the Nasdaq Opening and Closing Crosses if they are entered through OUCH or FLITE ports

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[34] in general, and furthers the objectives of Section 6(b)(5) of the Act,[35] 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 making the Nasdaq Crosses operate more efficiently by preventing the inclusion of short sale Orders that would be unable to execute in a Nasdaq Cross, due to the Cross price selected. Moreover, new Rules 4752(d)(2)(G), 4753(b)(2)(E) and 4754(b)(2)(F) address how the Exchange sets the Nasdaq Opening, Halt and Closing Cross prices when there is a partial execution of an Order that is deemed to have a price at one minimum price increment away from a Post-Only Order, which is consistent with the Act because it ensures that the original ranked price of the Order is reflected. As noted above, the remaining unexecuted shares of the Order is ranked in time priority behind all Orders at the price at which the Order was posted on the Nasdaq Book and no other interest would execute at a less aggressive price. Thus, the new rule text allowing pricing such an Order to its original ranked price is consistent with Nasdaq Cross price tiebreaker rules regarding unexecuted shares, as well as the participant's expectations concerning execution in the Cross, since the participant would otherwise receive an execution at what would appear to be a partial execution of their Order at a price inferior to the Cross price. As noted above, such an execution would appear to the participant as though its Order was traded through or was otherwise not represented in the Cross.

The proposed change to Rule 4763(e)(2) to add a condition stating that the re-pricing of short sale Orders to the midpoint—in lieu of the Permitted Price—will not be permitted when a resting non-displayed Order is locked or crossed at its non-displayed price by a Post-Only Order on the Nasdaq Book at the time of the Nasdaq Opening Cross or the Nasdaq Closing Cross is consistent with the Act because it will ensure such short sale Orders are ranked behind any Orders adjusted pursuant to Rule 4703(l), which, for the reasons stated above, would remove impediments to and perfect the mechanism of a free and open market and a national market system. As noted above, this change is necessary to ensure that short sale Orders subject to the Short Sale Price Test are prevented from being included, but unable to be executed, when the Nasdaq Opening or Closing Cross price is adjusted pursuant to the new rules being added in Rules 4752(d)(2)(G), 4753(b)(2)(E) and 4754(b)(2)(F). The Exchange notes that this change in no way allows for execution of a short sale Order subject to the Short Sale Price Test an impermissible price. Consequently, the proposed change will

[28] *See* Securities Exchange Act Release No. 80425 (April 11, 2017), 82 FR 18196 (April 17, 2017) (SR–NASDAQ–2017–031).

[29] The change to Rule 4752(d)(3)(B) made it clear that the locking or crossing would occur during Early Market Hours.

[30] *See supra* note 28.

[31] Rule 4752(d)(3)(B) concerns LOO orders, Early Market Hours limit orders, OIO orders, SDAY limit orders, SGTC limit orders, GTMC limit orders, SHEX limit orders, displayed quotes and reserve interest priced more aggressively than the Nasdaq Opening Cross price based on limit price with time as the secondary priority. Rule 4753(b)(3) concerns Eligible Interest, which is any quotation or any order that has been entered into the system and designated with a time-in-force that would allow the order to be in force at the time of the Halt Cross. Rule 4754(b)(3)(B) concerns LOC orders, limit orders, IO orders, displayed quotes and reserve interest priced more aggressively than the Nasdaq Closing Cross price based on price with time as the secondary priority.

[32] *See supra* note 12.

[33] Thus, MOO, LOO, OIO, MOC, LOC and OI Orders are not affected, since they are only designated to operate in the Nasdaq Opening or Closing Cross. *See* Rule 4702(b).

[34] 15 U.S.C. 78f(b).

[35] 15 U.S.C. 78f(b)(5).

promote the efficient operation of the market.

The proposed changes to Rules 4752(d)(3)(B), 4753(b)(3) and 4754(b)(3)(B) delete inaccurate text from these rules concerning ranking of Orders in the Crosses that are locked or crossed at their non-displayed price by a Post-Only Order. The deletions from these rules reflect the current operation of these rules, which is consistent with the Act because the crossed or locked Order is meant to cede priority to all other Orders at its original price. The proposed changes to Rule 4703(l) corrects the rule to reflect that a member may also designate an Order to participate in the Nasdaq Halt Cross in addition to the Nasdaq Opening and Closing Crosses, which will reflect the current operation of the Exchange as described above. The Exchange is consequently updating Order Types under Rule 4702(b) that may also participate in a Nasdaq Halt Cross. The Exchange is also making a corrective change to Rule 4702(b)(4)(C) to correct text in the rule that currently states that the Post-Only Order may only participate in the Nasdaq Opening and Closing Crosses only if it is entered through an OUCH or FLITE port. The Exchange has never limited participation of Post-Only Orders in the Nasdaq Opening and Closing Crosses if they are entered through OUCH or FLITE ports. In sum, the proposed changes further perfect the operation of the Nasdaq Crosses, and protect investors by avoiding confusion that may be caused by inaccurate rules.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposed changes are not being done for competitive purposes, but rather to make the processing of the Nasdaq Opening and Closing Crosses more efficient by preventing short sale Orders from being included in the Nasdaq Opening and Closing Crosses, since these Orders may be unable to execute because of the Cross price selected if included therein. Moreover, the proposed changes correct inaccuracies in the rules, which do not affect competition whatsoever.

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) of the Act [36] and Rule 19b–4(f)(6) thereunder.[37]

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–NASDAQ–2019–073 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–2019–073. 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–NASDAQ–2019–073 and should be submitted on or before October 16, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[38]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–20710 Filed 9–24–19; 8:45 am]

BILLING CODE 8011–01–P

[36] 15 U.S.C. 78s(b)(3)(A).

[37] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[38] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87021; File No. 4–753]

Self-Regulatory Organizations; Long-Term Stock Exchange, Inc.; Notice of Filing of Proposed Minor Rule Violation Plan

September 19, 2019.

Pursuant to Section 19(d)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19d–1(c)(2) thereunder,[2] notice is hereby given that on August 23, 2019, Long-Term Stock Exchange, Inc. (''LTSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed minor rule violation plan (''MRVP'') with sanctions not exceeding $2,500 which would not be subject to the provisions of Rule 19d–

[1] 15 U.S.C. 78s(d)(1).

[2] 17 CFR 240.19d–1(c)(2).

1(c)(1) of the Act[3] requiring that a self-regulatory organization (''SRO'') promptly file notice with the Commission of any final disciplinary action taken with respect to any person or organization.[4] In accordance with Rule 19d-1(c)(2) under the Act, the Exchange proposed to designate certain specified rule violations as minor rule violations, and requested that it be relieved of the prompt reporting requirements regarding such violations, provided it gives notice of such violations to the Commission on a quarterly basis.

The Exchange proposes to include in its MRVP the procedures included in LTSE Rule 9.216(b) (''Procedure for Violation Under Plan Pursuant to Exchange Act Rule 19d–1(c)(2)'') and violations included in Rule 9.218 (''Violations Appropriate for Disposition Under Plan Pursuant to Exchange Act Rule 19d–1(c)(2)'').[5] According to the Exchange's proposed MRVP, under Rule 9.216(b), the Exchange may impose a fine (not to exceed $2,500) and/or a censure on any Member or its associated person with respect to any rule listed in LTSE Rule 9.218. If the Financial Industry Regulatory Authority (''FINRA'') Department of Enforcement or the Department of Market Regulation, on behalf of the Exchange, has reason to believe a violation has occurred and if the Member or its associated person does not dispute the violation, the Department of Enforcement or the Department of Market Regulation may prepare and request that the Member or associated person execute a minor rule violation plan letter accepting a finding of violation, consenting to the imposition of sanctions, and agreeing to waive such Member's or associated person's right to a hearing before a Hearing Panel or, if applicable, an Extended Hearing Panel, and any right of appeal to the LTSE Appeals Committee, the Board, the SEC, and the courts, or to otherwise challenge the validity of the letter, if the letter is accepted. The letter shall describe the act or practice engaged in or omitted, the rule, regulation, or statutory provision violated, and the sanction or sanctions to be imposed. Unless the letter states otherwise, the effective date of any sanction(s) imposed will be a date to be determined by LTSE Regulation staff. In the event the letter is not accepted by the Member or associated person, or is rejected by the Office of Disciplinary Affairs, the matter can proceed in accordance with the Exchange's disciplinary rules already approved by the Commission, which include hearing rights for formal disciplinary proceedings.[6]

The Exchange proposes that, as set forth in LTSE Rule 9.218, violations of the following rules would be appropriate for disposition under the MRVP: Rule 2.160(p) Continuing Education Requirements; Rule 4.511 (General Requirements related to books and records requirements); Rule 4.540 (Furnishing of Records); Rule 5.110 (Supervision); Rule 8.220 (Automated Submission of Trading Data Requested); Rule 11.151(a)(1) (Market Maker Two-sided Quote Obligation); Rule 11.290 (Short Sales); Rule 11.310 (Locking or Crossing Quotations in NMS Stocks); and Rule 11.420 (Order Audit Trail System Requirements).

Upon the Commission's declaration of effectiveness of the MRVP, the Exchange will provide to the Commission a quarterly report for any actions taken on minor rule violations under the MRVP. The quarterly report will include: The Exchange's internal file number for the case, the name of the individual and/or organization, the nature of the violation, the specific rule provision violated, the sanction imposed, the number of times the rule violation occurred, and the date of the disposition.

Based on compliance with the above, the Exchange hereby requests that the rule violations designated in LTSE Rule 9.218 be designated as minor rule violations subject to a minor rule violation reporting plan and that the Exchange be relieved of the current reporting requirements regarding such violations. In addition, going forward, to the extent that there are any changes to the rules applicable to the Exchange's MRVP, the Exchange hereby requests that the Commission deem such changes to be modifications to the Exchange's MRVP.

I. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed MRVP 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 No. 4–753 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 No. 4–753. 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 MRVP that are filed with the Commission, and all written communications relating to the proposed MRVP 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 proposed MRVP 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 No. 4–753, and should be submitted on or before October 16, 2019.

II. Date of Effectiveness of Proposed Minor Rule Violation Plan and Timing for Commission Action

Pursuant to Section 19(d)(1) of the Act and Rule 19d–1(c)(2) thereunder,[7] after

[3] 17 CFR 240.19d–1(c)(2).

[4] The Commission adopted amendments to paragraph (c) of Rule 19d–1 to allow SROs to submit for Commission approval plans for the abbreviated reporting of minor disciplinary infractions. *See* Securities Exchange Act Release No. 21013 (June 1, 1984), 49 FR 23828 (June 8, 1984). Any disciplinary action taken by an SRO against any person for violation of a rule of the SRO which has been designated as a minor rule violation pursuant to such a plan filed with and declared effective by the Commission shall not be considered ''final'' for purposes of Section 19(d)(1) of the Act if the sanction imposed consists of a fine not exceeding $2,500 and the sanctioned person has not sought an adjudication, including a hearing, or otherwise exhausted his administrative remedies.

[5] The Exchange received its grant of registration on May 10, 2019, which included approving the rules that govern the Exchange. Securities Exchange Act Release No. 85828 (May 10, 2019), 84 FR 21841 (May 15, 2019). Exhibit A includes the entirety of Rules 9.216(b) and 9.218. Terms not otherwise defined in this Notice are defined in the LTSE rules.

[6] *See, generally,* Chapter 9.

[7] 15 U.S.C. 78s(d)(1); 17 CFR 240.19d–1(c)(2).

October 16, 2019, the Commission may, by order, declare the Exchange's proposed MRVP effective if the plan is consistent with the public interest, the protection of investors, or otherwise in furtherance of the purposes of the Act. The Commission in its order may restrict the categories of violations to be designated as minor rule violations and may impose any other terms or conditions to the proposed MRVP, File No. 4–753, and to the period of its effectiveness, which the Commission deems necessary or appropriate in the public interest, for the protection of investors or otherwise in furtherance of the purposes of the Act.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[8]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–20679 Filed 9–24–19; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87025; File No. SR–NYSEAMER–2019–37]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Extend the Pilot Related to the Market-Wide Circuit Breaker in Rule 7.12E

September 19, 2019.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on September 17, 2019, NYSE American LLC (''NYSE American'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to extend the pilot related to the market-wide circuit breaker in Rule 7.12E. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

Rule 7.12E provides a methodology for determining when to halt trading in all stocks due to extraordinary market volatility (*i.e.,* market-wide circuit breakers). The market-wide circuit breaker (''MWCB'') mechanism under Rule 7.12E was approved by the Commission to operate on a pilot basis,[4] the term of which was to coincide with the pilot period for the Plan to Address Extraordinary Market Volatility Pursuant to Rule 608 of Regulation NMS (the ''LULD Plan''),[5] including any extensions to the pilot period for the LULD Plan.[6] The Commission recently approved an amendment to the LULD Plan for it to operate on a permanent, rather than pilot, basis.[7] In light of the proposal to make the LULD Plan permanent, the Exchange amended Rule 7.12E to untie the pilot's effectiveness from that of the LULD Plan and to extend the pilot's effectiveness to the close of business on October 18, 2019.[8]

The Exchange now proposes to amend Rule 7.12E to extend the pilot to the close of business on October 18, 2020. This filing does not propose any substantive or additional changes to Rule 7.12E. The Exchange will use the extension period to develop with the other SROs rules and procedures that would allow for the periodic testing of the performance of the MWCB mechanism, with industry member participation in such testing. The extension will also permit the exchanges to consider enhancements to the MWCB processes such as modifications to the Level 3 process.

The market-wide circuit breaker under Rule 7.12E provides an important, automatic mechanism that is invoked to promote stability and investor confidence during a period of significant stress when securities markets experience extreme broad-based declines. All U.S. equity exchanges and FINRA adopted uniform rules on a pilot basis relating to market-wide circuit breakers in 2012 (''MWCB Rules''), which are designed to slow the effects of extreme price movement through coordinated trading halts across securities markets when severe price declines reach levels that may exhaust market liquidity.[9] Market-wide circuit breakers provide for trading halts in all equities and options markets during a severe market decline as measured by a single-day decline in the S&P 500 Index.

Pursuant to Rule 7.12E, a market-wide trading halt will be triggered if the S&P 500 Index declines in price by specified percentages from the prior day's closing price of that index. Currently, the triggers are set at three circuit breaker thresholds: 7% (Level 1), 13% (Level 2), and 20% (Level 3). A market decline that triggers a Level 1 or Level 2 halt after 9:30 a.m. ET and before 3:25 p.m. ET would halt market-wide trading for 15 minutes, while a similar market decline at or after 3:25 p.m. ET would not halt market-wide trading. A market decline that triggers a Level 3 halt, at any time during the trading day, would halt market-wide trading until the primary listing market opens the next trading day.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b)

[8] 17 CFR 200.30–3(a)(44).

[1] 15 U.S.C.78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* Securities Exchange Act Release No. 67090 (May 31, 2012), 77 FR 33531 (June 6, 2012) (SR–NYSEAmex–2011–73).

[5] *See* Securities Exchange Act Release No. 67091 (May 31, 2012), 77 FR 33498 (June 6, 2012). The LULD Plan provides a mechanism to address extraordinary market volatility in individual securities.

[6] *See* Securities Exchange Act Release Nos. 67090 (May 31, 2012), 77 FR 33531 (June 6, 2012) (SR–NYSEAmex–2011–73) (Approval Order); and 68787 (January 31, 2013), 78 FR 8615 (February 6, 2013) (SR–NYSEMKT–2013–08) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change Delaying the Operative Date of a Rule Change to Exchange Rule 80B–Equities).

[7] *See* Securities Exchange Act Release No. 85623 (April 11, 2019), 84 FR 16086 (April 17, 2019).

[8] *See* Securities Exchange Act Release No. 85564 (April 9, 2019), 84 FR 15269 (April 15, 2019) (SR–NYSEAMER–2019–14).

[9] *See* Securities Exchange Act Release No. 67090 (May 31, 2012), 77 FR 33531 (June 6, 2012) (SR–BATS–2011–038; SR–BYX–2011–025; SR–BX–2011–068; SR–CBOE–2011–087; SR–C2–2011–024; SR–CHX–2011–30; SR–EDGA–2011–31; SR–EDGX–2011–30; SR–FINRA–2011–054; SR–ISE–2011–61; SR–NASDAQ–2011–131; SR–NSX–2011–11; SR–NYSE–2011–48; SR–NYSEAmex–2011–73; SR–NYSEArca–2011–68; SR–Phlx–2011–129) (''MWCB Approval Order'').

of the Act,[10] in general, and furthers the objectives of Section 6(b)(5) of the Act,[11] 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. The market-wide circuit breaker mechanism under Rule 7.12E is an important, automatic mechanism that is invoked to promote stability and investor confidence during a period of significant stress when securities markets experience extreme broad-based declines. Extending the market-wide circuit breaker pilot for an additional year would ensure the continued, uninterrupted operation of a consistent mechanism to halt trading across the U.S. markets while the Exchange, with the other SROs, consider and develop rules and procedures that would allow for the periodic testing of the performance of the MWCB mechanism, which would include industry member participation in such testing. The extension will also permit the exchanges to consider enhancements to the MWCB processes such as modifications to the Level 3 process.

The Exchange also believes that the proposed rule change promotes just and equitable principles of trade in that it promotes transparency and uniformity across markets concerning when and how to halt trading in all stocks as a result of extraordinary market volatility. Based on the foregoing, the Exchange believes the benefits to market participants from the MWCB under Rule 7.12E should continue on a pilot basis because the MWCB will promote fair and orderly markets, and protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act because the proposal would ensure the continued, uninterrupted operation of a consistent mechanism to halt trading across the U.S. markets while the Exchange, in conjunction with the other SROs, consider and develop rules and procedures that would allow for the periodic testing of the performance of the MWCB mechanism. Furthermore, as noted above, the extension will permit the exchanges to consider enhancements to the MWCB processes such as modifications to the Level 3 process.

Further, the Exchange understands that FINRA and other national securities exchanges will file proposals to extend their rules regarding the market-wide circuit breaker pilot. Thus, the proposed rule change will help to ensure consistency across market centers without implicating any competitive issues.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [12] and Rule 19b–4(f)(6) thereunder.[13]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [14] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act.

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEAMER–2019–37 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–NYSEAMER–2019–37. 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–NYSEAMER–2019–37 and should be submitted on or before October 16, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Jill M. Peterson,

Assistant Secretary.

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[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(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] 15 U.S.C. 78s(b)(2)(B).

[15] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87028; File No. SR–CBOE–2019–061]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Add a New Version of the Silexx Platform to Support FLEX Options Trading

September 19, 2019.

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 September 13, 2019, Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[3] and Rule 19b–4(f)(6) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') proposes to add a new version of the Silexx platform to support FLEX Options trading. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, 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

In 2016, the Exchange's parent company, Cboe Global Markets, Inc. (formerly named CBOE Holdings, Inc.) (''Cboe Global''), which is also the parent company of Cboe C2 Exchange, Inc. (''C2''), acquired Cboe EDGA Exchange, Inc. (''EDGA''), Cboe EDGX Exchange, Inc. (''EDGX'' or ''EDGX Options''), Cboe BZX Exchange, Inc. (''BZX'' or ''BZX Options''), and Cboe BYX Exchange, Inc. (''BYX'' and, together with Cboe Options, C2, EDGX, EDGA, and BZX, the ''Cboe Affiliated Exchanges''). Cboe Options intends to migrate its trading platform to the same system used by the Cboe Affiliated Exchanges, which the Exchange expects to complete on October 7, 2019.

In anticipation of migration, the Exchange proposes to add a new version of the Silexx platform in connection with the trading of FLEX Options. Silexx is a User-optional order entry and management trading platform. The current versions of the Silexx platform are designed so that a User may enter orders into the platform to send to the executing broker, including Trading Permit Holders (''TPHs''), of its choice with connectivity to the platform. The executing broker can then send orders to Cboe Options (if the broker-dealer is a TPH) or other U.S. exchanges (and trading centers) in accordance with the User's instructions. Users cannot directly route orders through any of the current versions of Silexx to an exchange or trading center nor is the platform integrated into or directly connected to Cboe Option's System. Additionally, the Exchange notes that it does not currently have an electronic broker or system that that supports FLEX Options trading on Cboe Options. Some firms have developed their own front-end systems to support FLEX trading,[5] and others use systems developed and provided by third-party vendors or brokers that support FLEX trading electronically. Moreover, in connection with migration, the Exchange intends to simplify the process pursuant to which FLEX Traders[6] may execute FLEX Orders on the Exchange, which will align the trading of FLEX Options with the trading on non-FLEX Options, which the Exchange believes may encourage more Users to submit FLEX Orders for execution, as Users are more familiar with this type of trading.

In anticipation of the changes to FLEX trading upon migration, the Exchange proposes to implement an additional version of the Silexx platform, Silexx FLEX. Silexx FLEX will exclusively support the trading of FLEX Options and allow for direct access to the Exchange. The Exchange notes that only authorized Users and associated persons of Users may establish connectivity to and directly access the Exchange, pursuant to Rule 5.5 (effective upon migration)[7], however, a User that is not authorized for direct access will be able to send orders through the Exchange's broker community who will have access to Silexx FLEX and can submit orders directly on the User's behalf.[8] The Exchange notes there will be a verification process for Users that wish to access Silexx FLEX to ensure that each User is authorized for direct Exchange access. Each verified User will require a username and password to authenticate their access. The Exchange notes that those authorized to directly access the Exchange must uphold supervisory duties over those associated with it to ensure that only authorized Users access the platform. In addition, the Exchange at this time does not propose to assess any fees in connection with the Silexx FLEX platform. Other than the above noted differences, the new Silexx platform will function in the same manner as the Silexx versions currently available to Users: It will be completely voluntary; FLEX orders entered through the platform will receive no preferential treatment as compared to FLEX Orders electronically

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

[5] Market participants are free to do so by accessing the Exchange's FLEX specs via the publicly accessible Application Programming Interface and using such information in order to support FLEX trading within their own technology, software, and front-end systems.

[6] A Trading Permit Holder may trade FLEX Options if the Exchange has approved the Trading Permit Holder to trade FLEX Options on the Exchange; such a Trading Permit Holder is referred to as a ''FLEX Trader''.

[7] The Exchange notes that in connection with this technology migration, the Exchange has a shell Rulebook that resides alongside its current Rulebook, which shell Rulebook will contain the Rules that will be in place upon completion of the Cboe Options technology migration. Rule 5.6 is currently in the shell Rulebook.

[8] The Exchange notes that Users may also send orders through a Silexx FLEX certified broker, once brokers begin electing to become certified. The Exchange has implemented a certification process which is open to any broker that supports FLEX trading and will allow Users without direct access to submit through an electronic broker certified with Silexx. The Exchange currently conducts similar certifications for any broker that wishes to connect to Cboe, and for other platform offerings (*e.g.* PULSe).

sent to Cboe Options in any other manner; FLEX Orders entered through the platform will be subject to current trading rules in the same manner as all other orders sent to the Exchange, which is the same as orders that are sent through the Exchange's System today; the Exchange's System will not distinguish between FLEX Orders sent from Silexx FLEX and orders sent in any other manner; and Cboe Silexx [9] will provide technical support, maintenance and user training for the new platform version upon the same terms and conditions for all Users.[10] The Exchange notes that it currently offers a similar front-end order entry system, the PULSe workstation, which also permits connectivity to Cboe Options. The Exchange notes that no changes are being made to the current Silexx platform versions or to the fees schedule in connection with the current versions.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[11] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [12] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [13] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers. Additionally, the Exchange also believes the proposed rule change is consistent with Section 6(b)(4) of the Act,[14] which requires that Exchange rules provide for the equitable allocation of reasonable dues, fees, and other charges among its Trading Permit Holders and other persons using its facilities.

The Exchange believes that offering the Silexx FLEX platform to market participants protects investors and is in the public interest because it will allow the Exchange to directly offer Users an order entry and management tool for FLEX trading in addition to the technology products it currently offers for non-FLEX trading, such as the other versions of the Silexx platform and the PULSe workstation. In addition, firms can create their own proprietary front-end FLEX Order entry technology or obtain systems with such functionality from third-party vendors.[15]

In particular, the Exchange believes that the proposed Silexx FLEX platform will facilitate transactions in FLEX Options and will remove impediments to and perfect the mechanism of a free and open market and national market system by offering to Users an order and management system with direct access to the Exchange for FLEX trading. The Exchange believes providing an alternative tool for FLEX Trading, in conjunction with the Exchange's planned changes to the FLEX trading process upon migration, may encourage more Users to submit FLEX Orders and responses to FLEX auctions (including price improvement auctions), which may lead to additional liquidity in the FLEX market, which ultimately benefits investors. Currently, the Exchange does not have an electronic broker or other system or platform that supports FLEX trading on the Exchange; Users must either build their own front-end systems or rely on outside brokers or vendors that support FLEX trading. As the Exchange anticipates an increase of FLEX trading due to the changes to be implemented upon migration, the Exchange believes that offering Silexx as a direct access platform for FLEX trading will facilitate transactions in these securities and, in general, protect investors. The Exchange believes the proposed platform will remove impediments to and perfect the mechanism of a free and open market and national market system because it will allow Users more control over the execution of their FLEX orders and to more efficiently trade in FLEX Options, as well as potentially reduce transaction costs associated with building out their own front-end FLEX systems or using outside vendors or brokers.

The Exchange believes the proposed rule change does not discriminate among market participants because use of the platform for FLEX trading is completely voluntary. Users can choose to enter FLEX Orders without the use of the platform. The Exchange is making the proposed version of the platform available as a convenience to market participants, who will continue to have the option to use any order entry and management system available in the marketplace to send FLEX Orders to the Exchange. As such, the platform is not an exclusive means available to market participants to send FLEX Orders to the Exchange but merely an alternative that will be offered by the Exchange. Like current Silexx platform versions, no orders sent through the Silexx FLEX platform to Cboe Options for execution will receive any preferential treatment or execute in any dissimilar manner from those FLEX Orders enters via another means. Additionally, the platform will be available to all Users, both those with authorized direct access and those without who will be able to call in their orders to an Exchange broker for execution through Silexx FLEX. As stated, the Exchange will license the platform to participants with authorized direct access pursuant to the same terms and conditions as the current versions of Silexx.

The Exchange believes that not charging a fee in connection with the proposed Silexx FLEX platform is reasonable and equitable. The Exchange notes that FLEX trading currently does not experience the same level of volume and liquidity as that of non-FLEX trading. The Exchange believes that offering the proposed Silexx FLEX platform is also not discriminatory because it will be made available at no cost to all FLEX Traders. The Exchange believes supplying market participants with more efficient functionality at no cost for FLEX trading may encourage participation in FLEX trading. Therefore, in order to incentivize growth and participation in FLEX trading, along with the overall changes to streamline FLEX trading that the Exchange will implement upon migration, the Exchange believes that it is reasonable, equitable and nondiscriminatory to allow for use of the Silexx FLEX platform at no cost at this time.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The

[9] Cboe Silexx is the wholly owned subsidiary of Cboe Options' parent company, Cboe Global Markets, Inc., which purchased Silexx in 2017.

[10] *See* Securities Exchange Act Release No. 82088 (November 15, 2017), 82 FR 55443 (November 21, 2017) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Describe Functionality of and Adopt Fees for a New Front-End Order Entry and Management Platform) (SR–CBOE–2017–068).

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(5).

[13] *Id.*

[14] 15 U.S.C. 78f(b)(4).

[15] *See supra* note 5.

proposed change will not impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because the Exchange will make the Silexx FLEX version of the platform available to market participants who are approved to trade FLEX Options on the Exchange on the same terms and conditions (save for its allowing for direct access and offering at no cost) as the current Silexx versions. As described in detail above, the use of the platform to trade in FLEX Options will be completely voluntary and market participants will continue to have the flexibility to use any FLEX Order entry and management that is proprietary or from third-party vendors, and/or market participants may choose any executing brokers to enter their FLEX Orders. The proposed platform is not an exclusive means of FLEX trading, and if market participants believe that other products, vendors, front-end builds, etc. available in the marketplace are more beneficial than the Silexx FLEX platform, they may simply use those products instead. Also, the Exchange notes that use of the platform will not provide market participants with any additional access to the Exchange than that which is available through the use of any other front-end order entry system supporting FLEX trading. FLEX Orders executed through the platform will not receive preferential treatment and the Exchange's System will not distinguish between orders sent from Silexx FLEX and orders sent in any other manner. The Exchange notes that similar platforms, other Silexx versions and PULSe workstations, are currently offered today. In addition to this, all market participants may use Silexx FLEX, both those with direct access and those without, by sending orders through the Exchange's broker community who will be able to submit orders directly though Silexx FLEX. Those approved for FLEX trading on the Exchange will be subject to the same terms and conditions as other Silexx versions (save for the offering of direct access), and no market participants will be assessed a fee to use Silexx FLEX.

The Exchange does not believe that the proposed change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because other market participants that support FLEX trading may continue to remain competitive for FLEX Order entry, including firms that build-out their own FLEX-supported front-end systems, and outside vendors and brokers that support electronic FLEX connectivity. As such, market participants approved for FLEX trading on the Exchange will be able to choose to execute, or continue to execute, their FLEX Orders through any of these means. The Exchange notes that all market participants are free to create their own proprietary front-end FLEX Order entry technology.[16] The Exchange also notes that Silexx FLEX will not have any preferential access to current or planned Cboe Options technology and will therefore compete on the same terms as any other firms that build-out their own FLEX-supported front-end systems and/or outside vendors and brokers that support electronic FLEX connectivity.

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

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[17] and subparagraph (f)(6) of Rule 19b–4 thereunder.[18]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act[19] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii)[20] permits the Commission to 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 it may implement the Silexx FLEX platform in connection with the technology migration on October 7, 2019. According to the Exchange, waiver of the operative delay will benefit investors by providing them with a platform that will support the trading of FLEX Options. The Commission believes that the proposed rule change raises no new or novel issues and that waiver of the operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the operative delay and designates the proposal operative upon filing.[21]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

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–CBOE–2019–061 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–CBOE–2019–061. 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

[16] *See supra* note 5.

[17] 15 U.S.C. 78s(b)(3)(A)(iii).

[18] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[19] 17 CFR 240.19b–4(f)(6).

[20] 17 CFR 240.19b–4(f)(6)(iii).

[21] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

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–CBOE–2019–061 and should be submitted on or before October 16, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[22]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–20707 Filed 9–24–19; 8:45 am]

BILLING CODE 8011–01–P

[22] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87023; File No. SR–NSCC–2019–002]

Self-Regulatory Organizations; National Securities Clearing Corporation; Notice of Filing of Partial Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Partial Amendment No. 1, To Amend Procedure VII with Respect to the Receipt of CNS Securities and Make Other Changes

September 19, 2019.

I. Introduction

On July 22, 2019, National Securities Clearing Corporation (''NSCC'') filed with the Securities and Exchange Commission (''Commission'') proposed rule change SR–NSCC–2019–002, pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder.[2] The proposed rule change was published for comment in the **Federal Register** on August 8, 2019.[3] On September 16, 2019, NSCC filed Partial Amendment No. 1 to the proposed rule change to postpone the implementation date of the proposed rule change.[4] The Commission did not receive any comment letters on the proposed rule change. The Commission is publishing this notice to solicit comment on Partial Amendment No. 1 from interested persons and to approve the proposed rule change, as modified by Partial Amendment No. 1 (hereinafter, ''Proposed Rule Change''), on an accelerated basis.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

II. Description of the Proposed Rule Change

The proposed rule change would amend Procedure VII (CNS Accounting Operation) of NSCC's Rules & Procedures (''Rules'')[5] with respect to the receipt of securities from NSCC's Continuous Net Settlement (''CNS'') System.[6] Specifically, these amendments would reflect a change in the allocation algorithm used during the night cycle used by NSCC's CNS System. The proposed rule change would also make technical changes to the Rules.

A. Background

NSCC's CNS System is an automated accounting and securities settlement system that centralizes and nets the settlement of compared and recorded securities transactions and maintains an orderly flow of security and money balances. The settlement processing cycle spans two business days, with a night cycle that begins at approximately 8:30 p.m. Eastern Time (''ET'') on the day prior to settlement date and runs until approximately 10 p.m. ET, and a day cycle that begins at approximately 6:30 a.m. ET on settlement date and runs until approximately 3:10 p.m. ET. The night cycle and day cycle settlement processes are essentially the same, except that the night cycle settlement process runs in batches and the day cycle settlement process runs continuously.

Transactions that do not get processed for settlement during the night cycle are carried into the following day cycle for settlement processing.

CNS relies on an interface with the Depository Trust Company (''DTC''), an affiliate of NSCC, for the book-entry movement of securities. Procedure VII (CNS Accounting Operation) describes the receipt and delivery of CNS Securities. CNS long (buy) positions are allocated to Members as the securities are received by NSCC (*i.e.,* CNS long positions are transferred from the NSCC account at DTC to the accounts of NSCC Members at DTC) in accordance with the CNS System algorithm.

Currently, NSCC employs an algorithm to determine the order in which Members with long allocations receive positions from CNS; however, Members can submit priority requests that override NSCC's algorithm when they have special needs to receive securities owed to them (*e.g.,* the security is undergoing a corporate action or the Member has an urgent customer delivery).[7] The priority requests can be submitted for the night cycle, the day cycle, or both. The current priority groups are as follows—

First, long positions in a CNS Reorganization Sub-Account established pursuant to paragraph H.4 of Procedure VII of the Rules;[8]

Second, long positions against which Buy-In Intent[9] notices are due to expire that day but which were not filled the previous day;

Third, long positions against which Buy-In Intent notices are due to expire the following day;

Fourth, (i) long positions in a receiving ID Net Subscriber's agency account established at a Qualified Securities Depository,[10] and (ii) long positions against the component securities of index receipts;

Fifth, in descending sequence, priority levels as specified by Standing Priority Requests and as modified by Priority Overrides.

[3] Securities Exchange Act Release No. 86556 (August 2, 2019), 84 FR 39037 (August 8, 2019) (SR–NSCC–2019–002) (''Notice'').

[4] NSCC submitted a courtesy copy of Partial Amendment No. 1 to the proposed rule change through the Commission's electronic public comment letter mechanism. Accordingly, Partial Amendment No. 1 to the proposed rule change has been publicly available on the Commission's website since September 16, 2019: *https://www.sec.gov/comments/sr-nscc-2019-002/srnscc2019002-6132116-192236.pdf.*

[5] Capitalized terms not defined herein are defined in the Rules, *available at http://www.dtcc.com/~/media/Files/Downloads/legal/rules/nscc_rules.pdf.*

[6] The CNS System and its operation are described in Rule 11 (CNS System) and Procedure VII (CNS Accounting Operation) of the Rules. *Id.*

[7] Specifically, under Procedure VII, subsection E (Influencing Receipts from CNS), Members can request that they receive priority for some or all issues on a standing or override basis.

[8] *Supra* note 5.

[9] Section 7 of Rule 11 (CNS System) and subsection J of Procedure VII (CNS Accounting Operation) of the Rules provide that in the event a Member has a Long Position in a CNS Security, the Member may demand immediate delivery thereof by submitting to NSCC a Buy-In Intent notice in such form and within such times as determined by NSCC. *Supra* note 5.

[10] ID Net Service and its operation are described in Rule 65 (ID Net Service) and Procedure XVI (ID Net Service) of the Rules. *Supra* note 5.

Currently, when more than one long position in a given CNS Security exists within the same priority group, the positions are allocated based on their age (*i.e.,* the ''oldest'' position is allocated first). In addition, when more than one long position in a given CNS Security exists within the same priority group and all of those have been long the same number of consecutive days (*i.e.,* within the same age group), the allocation rank is determined by a computer generated random number. The allocation algorithm currently used for the night and day cycles is the same but is computed separately.

B. Proposed Changes to Allocation Algorithm

Under the current algorithm, approximately 50 percent of the CNS transactions are processed for settlement during the night cycle. In order to improve processing efficiency and maximize the number of CNS transactions that would get processed for settlement during the night cycle, NSCC is proposing a modification to the allocation algorithm used during the night cycle.[11] NSCC anticipates that the proposal would increase the percentage of CNS transactions processed for settlement during the night cycle to approximately 65 percent.[12] NSCC is not proposing changes to the allocation algorithm used during the day cycle.

As described above, the current allocation sequence for day cycle and night cycle is as follows: Priority groups, age of positions, and random number within an age group. Under the proposal, NSCC would change the allocation algorithm so that age of positions and random number within an age group would no longer be considered as factors when allocating CNS long positions within the same priority group during the night cycle. Instead, allocation of CNS long positions within the same priority group during the night cycle would be determined by the DTC settlement optimization algorithm. [13]

NSCC represents that eliminating the age of positions and random number within an age group from being considered as factors when allocating CNS long positions within the same priority group during the night cycle would help maximize the number of transactions processed for settlement during the night cycle.[14] Specifically, according to NSCC, removing the requirement to process transactions for settlement during the night cycle in an order based on the age of positions and random number within an age group would help the DTC settlement optimization algorithm perform more effectively in identifying the optimal order by which transactions are processed for settlement, which, in turn, would help maximize the number of transactions processed for settlement during the night cycle.[15]

NSCC is proposing to add a clause to subsection C.4 of Procedure VII (CNS Accounting Operation) to make it clear that there would be differences in the allocation algorithm used for receipts from CNS between the day cycle and the night cycle processes. NSCC is also proposing to add a parenthetical regarding subsection E of Procedure VII for ease of reference. To reflect the proposed elimination of random number within an age group as a factor when allocating CNS long positions within the same priority group during the night cycle, NSCC is proposing to modify the first paragraph of subsection E of Procedure VII by deleting the references to an algorithm which changes daily.

NSCC is also proposing to revise subsection E.4 of Procedure VII to reflect the proposed changes to the allocation algorithm used during the night cycle by adding (i) ''and, for the day cycle only,'' to the first paragraph in subsection E.4 and (ii) ''For the day cycle only,'' to the third and fourth paragraphs of subsection E.4. According to NSCC, these changes are being proposed to state that age of positions and random number within an age group would only be considered as factors when allocating CNS long positions during the day cycle.[16]

In addition, NSCC is proposing to modify the last paragraph of subsection E.4 of Procedure VII to clarify that the allocation algorithm used for the night and day cycles is computed separately to allow for the use of different allocation factors in those respective cycles.[17]

NSCC is proposing technical changes by replacing references to ''evening cycle'' with ''night cycle'' in subsections A, C.3, E.1, E.2, E.4, E.5, and H.5 of Procedure VII. Similarly, NSCC is proposing to replace references to (i) ''evening allocation'' with ''night allocation'' in subsections C.3, C.4, and J.1 of Procedure VII, (ii) ''evening and day delivery cycles'' with ''night and day delivery cycles'' in subsection E.4 of Procedure VII and (iii) ''evening allocation cycle'' with ''night cycle'' in Section I of Addendum G. These changes are being proposed to ensure consistency in terminology usage in the Rules.[18] NSCC is also proposing technical changes to correct cross references in subsections E.3 and E.4(a) of Procedure VII.

C. Description of Partial Amendment No. 1

In Partial Amendment No. 1, NSCC proposes to amend the implementation timeframe of the proposal.[19] In its original filing with the Commission, NSCC previously stated that the proposed rule change would be effective by September 26, 2019. Pursuant to Partial Amendment No. 1, the Proposed Rule Change would be effective by December 6, 2019.

III. Discussion and Commission Findings

Section 19(b)(2)(C) of the Act [20] 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 rules and regulations thereunder applicable to such organization. After carefully considering the Proposed Rule Change, the Commission finds that the Proposed Rule Change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to DTC. In particular, the Commission finds that the Proposed Rule Change is consistent with Section 17A(b)(3)(F) of the Act.[21]

Section 17A(b)(3)(F) of the Act requires, in part, that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions.[22] The Commission believes that the proposed changes to the allocation algorithm used during the night cycle are designed to promote prompt and accurate clearance and settlement of securities transactions. Removing the requirement to process transactions for settlement during the night cycle in an order based on the age of positions and random number within an age group should enhance the effectiveness of the

[11] *See* Notice, *supra* note 3, at 39038–39.

[12] *Id.*

[13] On July 22, 2019, DTC submitted a proposed rule change to implement a new algorithm to optimize its settlement processing of transactions during the night cycle (''DTC settlement optimization algorithm''). The proposal is designed to maximize the number of transactions processed for settlement during the night cycle. *See* Securities Exchange Act Release No. 86554 (August 2, 2019), 84 FR 39025 (August 8, 2019) (SR–DTC–2019–005).

[14] *See* Notice, *supra* note 3, at 39038–39.

[15] *Id.*

[16] *Id.*

[17] *Id.*

[18] *Id.*

[19] Partial Amendment No. 1, *supra* note 4.

[20] 15 U.S.C. 78s(b)(2)(C).

[21] 15 U.S.C. 78q–1(b)(3)(F).

[22] *Id.*

DTC settlement optimization algorithm in identifying the optimal order to process transactions for settlement. Being able to effectively identify the optimal order to process transactions for settlement should help maximize the number of transactions processed for settlement during the night cycle. Therefore, the Commission believes that the proposed changes to the allocation algorithm used during the night cycle are designed to promote the prompt and accurate clearance and settlement of securities transactions, consistent with Section 17A(b)(3)(F) of the Act.[23]

The Commission also believes that the proposal to make technical changes is designed to promote prompt and accurate clearance and settlement of securities transactions. The proposed technical changes would help ensure consistency in terminology usage and correct cross references in the Rules, both of which would ensure the Rules are clear and accurate. The Commission believes that using consist terminology and correct cross references would avoid any confusion by Members and allow Members to accurately understand NSCC's clearance and settlement services. In turn, the Commission believes that the proposal is designed to promote prompt and accurate clearance and settlement of securities transactions by NSCC. As such, the Commission believes the proposal to make technical changes is consistent with Section 17A(b)(3)(F) of the Act.[24]

IV. Solicitation of Comments on Partial Amendment No. 1 to the Proposed Rule Change

Interested persons are invited to submit written data, views and arguments concerning whether Partial Amendment No. 1 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–NSCC–2019–002 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–NSCC–2019–002. 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 NSCC and on DTCC's website (*http://dtcc.com/legal/sec-rule-filings.aspx*). 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–NSCC–2019–002 and should be submitted on or before October 16, 2019.

V. Accelerated Approval of the Proposed Rule Change, as Modified as Partial Amendment No. 1

The Commission finds good cause, pursuant to Section 19(b)(2) of the Act,[25] to approve the proposed rule change prior to the 30th day after the date of publication of Partial Amendment No. 1 in the **Federal Register**. As noted above, Partial Amendment No. 1 delays the implementation timeframe of the proposal from September 26, 2019 to December 6, 2019.[26] The Commission believes that the Partial Amendment is consistent with the Act because it does not raise any regulatory issues and would provide more time before the proposal would go into effect.

For the reasons discussed above, the Commission finds that Partial Amendment No. 1 is reasonably designed to protect investors and the public interest, and consistent with the requirements of the Act. Accordingly, the Commission finds good cause, pursuant to Section 19(b)(2) of the Act,[27] to approve the proposed rule change, as modified by Partial Amendment No. 1, on an accelerated basis.

VI. Conclusion

On the basis of the foregoing, the Commission finds that the proposed rule change, as modified by Partial Amendment No. 1, is consistent with the requirements of the Act and, in particular, with the requirements of Section 17A of the Act[28] and the rules and regulations promulgated thereunder.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act[29] that proposed rule change SR–NSCC–2019–002, as modified by Amendment No. 1, be, and hereby is, approved on an accelerated basis.[30]

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[31]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–20695 Filed 9–24–19; 8:45 am]

BILLING CODE 8011–01–P

[23] *Id.*

[24] *Id.*

[25] 15 U.S.C. 78s(b)(2).

[26] Partial Amendment No. 1, *supra* note 4.

[27] 15 U.S.C. 78s(b)(2).

[28] 15 U.S.C. 78q–1.

[29] 15 U.S.C. 78s(b)(2).

[30] In approving the proposed rule change, the Commission considered the proposals' impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[31] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87014; File No. SR–BOX–2019–27]

Self-Regulatory Organizations; BOX Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Fee Schedule on the BOX Options Market LLC ("BOX") Facility To Establish BOX Connectivity Fees for Participants and Non-Participants Who Connect to the BOX Network

September 19, 2019.

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 September 5, 2019, BOX Exchange LLC (the "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange filed the proposed rule change

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

pursuant to Section 19(b)(3)(A)(ii) of the Act,[3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposal effective upon filing with 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 the Substance of the Proposed Rule Change

The Exchange is filing with the Securities and Exchange Commission (''Commission'') a proposed rule change to amend the Fee Schedule on the BOX Options Market LLC (''BOX'') facility. The text of the proposed rule change is available from the principal office of the Exchange, at the Commission's Public Reference Room and also on the Exchange's internet website at *http://boxexchange.com.*

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 amend Section VI. (Technology Fees) of the BOX Fee Schedule to establish BOX Connectivity Fees for Participants and non-Participants who connect to the BOX network. Connectivity fees will be based upon the amount of bandwidth that will be used by the Participant or non-Participant. Further, BOX Participants or non-Participants connected as of the last trading day of each calendar month will be charged the applicable Connectivity Fee for that month. The Connectivity Fees will be as follows:

Connection type	Monthly fees
Non-10 Gb Connection	$1,000 per connection.
10 Gb Connection	$5,000 per connection.

The Exchange also proposes to amend certain language and numbering in Section VI.A to reflect the changes discussed above. Specifically, the Exchange proposes to add the title ''Third Party Connectivity Fees'' under Section VI.A. Further, the Exchange proposes to add Section VI.A.2, which details the proposed BOX Connectivity Fees discussed above. Finally the Exchange is proposing to remove Section VI.C. High Speed Vendor Feed (''HSVF''), and reclassify the HSVF as a Port Fee.

The Exchange initially filed the proposed fees on July 19, 2018, designating the proposed fees effective July 1, 2018. The first proposed rule change was published for comment in the **Federal Register** on August 2, 2018.[5] The Commission received one comment letter on the proposal.[6] The proposed fees remained in effect until they were temporarily suspended pursuant to a suspension order (the ''Suspension Order'') issued by the Division of Trading and Markets, which also instituted proceedings to determine whether to approve or disapprove the proposed rule change.[7] The Commission subsequently received one further comment letter on the proposed rule change, supporting the decision to suspend and institute proceedings on the proposed fee change.[8]

In response to the Suspension Order, the Exchange timely filed a Notice of Intention to Petition for Review [9] and Petition for Review to vacate the Division's Order,[10] which stayed the Division's suspension of the filing. On November 16, 2018 the Commission granted the Exchange's Petition for Review but discontinued the automatic stay.[11] The Exchange then filed a statement to reiterate the arguments set for in its petition for review and to supplement that petition with additional information.[12]

The Exchange subsequently refiled its fee proposal on November 30th, 2018. The proposed fees were noticed and again temporarily suspended pursuant to a suspension order issued by the Division of Trading and Markets, which also instituted proceedings to determine whether to approve or disapprove the proposed rule change.[13] The Commission received two comment letters supporting the decision to suspend and institute proceedings on the proposed fee change.[14]

The Exchange again refiled its fee proposal on February 13, 2019. The proposed fees were noticed and again temporarily suspended pursuant to a suspension order issued by the Division of Trading and Markets, which also instituted proceedings to determine whether to approve or disapprove the proposed rule change.[15] The Commission received four comment letters supporting the decision to suspend and institute proceedings on the proposed fee change.[16]

On March 29, 2019, the Commission issued its Order Disapproving each

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

[5] *See* Securities Exchange Act Release No. 83728 (July 27, 2018), 83 FR 37853 (August 2, 2018) (SR–BOX–2018–24).

[6] *See* Letter from Tyler Gellasch, Executive Director, The Healthy Markets Association, to Brent J. Fields, Secretary, Commission, dated August 23, 2018 (''Healthy Markets Letter'').

[7] *See* Securities Exchange Act Release No. 34–84168 (September 17, 2018).

[8] *See* Letter from Theodore R. Lazo, Managing Director and Associate General Counsel, and Ellen Greene, Managing Director, Financial Services Operations, Securities Industry and Financial Markets Association, dated October 15, 2018.

[9] *See* Letter from Amir Tayrani, Partner, Gibson, Dunn & Crutcher LLP, dated September 19, 2018.

[10] *See* Petition for Review of Order Temporarily Suspending BOX Exchange LLC's Proposal to Amend the Fee Schedule on BOX Market LLC, dated September 26, 2018.

[11] *See* Securities Exchange Act Release No. 84614. Order Granting Petition for Review and Scheduling Filing of Statements, dated November 16, 2018. Separately, the Securities Industry and Financial Markets Association filed an application under Section 19(d) of the Exchange Act challenging the Exchange's proposed fees as alleged prohibitions or limitations on access. *See In re Securities Industry and Financial Markets Association,* Admin. Proc. File No. 3–18680 (Aug. 24, 2018). The Commission thereafter remanded that denial-of-access proceeding to the Exchange while ''express[ing] no view regarding the merits'' and emphasizing that it was ''not set[ting] aside the challenged rule change[ ].'' *In re Applications of SIFMA & Bloomberg,* Exchange Act Rel. No. 84433, at 2 (Oct. 16, 2018) (''Remand Order''), *available at https://www.sec.gov/litigation/opinions/2018/34-84433.pdf.* The Division's Suspension Order is inconsistent with the Commission's intent in the Remand Order to leave the challenged fees in place during the pendency of the remand proceedings and singles out the Exchange for disparate treatment because it means that the Exchange—unlike every other exchange whose rule changes were the subject of the Remand Order—is not permitted to continue charging the challenged fees during the remand proceedings.

[12] *See* Letter from Amir Tayrani, Partner, Gibson, Dunn & Crutcher LLP, dated December 10, 2018.

[13] *See* Securities Exchange Act Release No. 84823 (December 14, 2018), 83 FR 65381 (December 20, 2018) (SR–BOX–2018–37).

[14] *See* Letters from Tyler Gellasch, Executive Director, The Healthy Markets Association (''Second Healthy Markets Letter''), and Chester Spatt, Pamela R. and Kenneth B. Dunn Professor of Finance, Tepper School of Business, Carnegie Mellon University (''Chester Spatt Letter''), to Brent J. Fields, Secretary, Commission, dated January 2, 2019.

[15] *See* Securities Exchange Act Release No. 85201 (February 26, 2019), 84 FR 7146 (March 1, 2019)(SR–BOX–2019–04).

[16] *See* Letters from Theodore R. Lazo, Managing Director and Associate General Counsel, SIFMA (''Second SIFMA Comment Letter''), Tyler Gellasch, Executive Director, Healthy Markets Association (''Third Healthy Markets Letter''), Stefano Durdic, Former Owner of R2G Services, LLC, and Anand Prakash.

iteration of the BOX Proposal (''BOX Order''). In the BOX Order, the Commission highlighted a number of deficiencies it found in three separate rule filings by BOX to establish BOX's connectivity fees that prevented the Commission from finding that BOX's proposed connectivity fees were consistent with the Act.

On May 21, 2019 the Division of Trading and Markets released new Guidance on SRO Rule Filings Relating to Fees. The Exchange then refiled the proposed fees on June 26, 2019 to incorporate the new guidance released by the Commission.

The Commission received two comment letters on BOX's June 26, 2019 Proposal.[17] The Third SIFMA Comment Letter did not request that the Commission suspend BOX's Proposal, but rather requested that the Commission ''carefully consider whether BOX provided sufficient evidence to satisfy the applicable statutory standards.'' The Fourth Healthy Markets Letter walks through the procedural history of the BOX and MIAX filings and urges the Commission to propose reforms with regard to immediately effective rule filings.

The Exchange is again re-filing the fee proposal (''the Proposal'') to further bolster its cost-based discussion to support its claim that the Proposal is fair and reasonable because they will permit recovery of BOX costs and will not result in excessive pricing or supracompetitive profit. The Exchange believes that the proposed fees are consistent with the Act because they (i) are reasonable, equitably allocated, not unfairly discriminatory, and not an undue burden on competition; (ii) comply with the BOX Order and the Guidance; (iii) are, as demonstrated by this Proposal and supported by evidence (including data and analysis), constrained by significant competitive forces; and (iv) are, as demonstrated in this Proposal and supported by specific information (including quantitative information), fair and reasonable because they will permit recovery of BOX's costs and will not result in excessive pricing or supracompetitive profit. Accordingly, the Exchange believes that the Commission should find that the proposed fees are consistent with the Act. The proposed rule change is immediately effective upon filing with the Commission pursuant to Section 19(b)(3)(A) of the Act.

As discussed herein, the Exchange believes that it is reasonable and appropriate to begin charging for physical connectivity fees to partially offset the costs associated with maintaining and enhancing a state-of-the-art exchange network infrastructure in the US options industry. There are significant costs associated with various projects and initiatives to improve overall network performance and stability, as well as costs paid to the third-party data centers for space rental, power used, etc.

BOX has always offered physical connectivity to Participants and non-Participants to access the BOX's trading platforms, market data, test systems and disaster recovery facilities. These physical connections consist of 10Gb and non-10Gb connections, where the 10Gb connection provides for faster processing of messages sent to it in comparison to the non-10Gb connection. Since launching in 2012, BOX has not charged for physical connectivity and has instead relied on transaction fees as the basis of revenue. However, in recent years transaction fees have continually decreased across the options industry. At the same time these transactions fees were decreasing, the options exchanges, except for BOX, began charging physical connectivity fees to market participants. As such, BOX began to find itself at a significant competitive disadvantage, and had no choice but to begin charging Participants and non-Participants fees for connecting directly to the BOX network (which BOX has taken considerable measures to maintain and enhance for the benefit of those Participants and non-Participants) in order to remain competitive with the other options exchanges in the industry.

As discussed in the Exchange's recent Petition for Review of the Commission's Order Disapproving BOX's three filings, not allowing BOX to charge such connectivity fees arbitrarily and inequitably treats BOX differently from each of the other exchanges that submitted prior immediately effective connectivity fee filings that were not suspended or disapproved by the Commission.[18] The Exchange notes that all other options exchanges currently charge for similar physical connectivity.[19]

2. Statutory Basis

The Exchange believes that the proposal is consistent with the requirements of Section 6(b) of the Act, in general, and Section 6(b)(4) and 6(b)(5) of the Act,[20] in particular, in that it provides for the equitable allocation of reasonable dues, fees, and other charges among BOX Participants and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

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.'' [21]

The Exchange believes that the proposed fees in general constitute an equitable allocation of fees, and are not unfairly discriminatory, because they allow BOX to recover costs associated with offering access through the network connections. The proposed fees are also expected to offset the costs both the Exchange and BOX incur in maintaining and implementing ongoing improvements to the trading systems, including connectivity costs, costs incurred on software and hardware enhancements and resources dedicated

[17] *See* Letter from Theodore R. Lazo, Managing Director and Associate General Counsel, SIFMA, dated August 5, 2019 (''Third SIFMA Comment Letter'') and Letter from Tyler Gellasch, Executive Director, Healthy Markets Association, dated August 5, 2019 (''Fourth Healthy Markets Letter'').

[18] *See* Securities Exchange Act Release No. 85927. Order Granting Petition for Review and Scheduling Filing of Statements, dated May 23, 2019.

[19] Nasdaq PHLX LLC (''Phlx''), The Nasdaq Stock Market LLC (''Nasdaq''), NYSE Arca, Inc. (''Arca''), NYSE American LLC (''NYSE American''), Nasdaq ISE, LLC (''ISE''), Cboe Exchange, Inc. (''Cboe''), Cboe BZX Exchange, Inc. (''CboeBZX''), Cboe EDGX Exchange, Inc. (''CboeEDGX'') and Cboe C2 Exchange, Inc. (''C2'') all offer a type of 10Gb and non-10Gb connectivity alternative to their participants. See Phlx, and ISE Rules, General Equity and Options Rules, General 8, Section 1(b). Phlx and ISE each charge a monthly fee of $2,500 for each 1Gb connection, $10,000 for each 10Gb connection and $15,000 for each 10Gb Ultra connection, which is the equivalent of the Exchange's 10Gb ULL connection. See also Nasdaq Price List—Trading Connectivity. Nasdaq charges a monthly fee of $7,500 for each 10Gb direct connection to Nasdaq and $2,500 for each direct connection that supports up to 1Gb. See also NYSE American Fee Schedule, Section V.B, and Arca Fees and Charges, Co-Location Fees. NYSE American and Arca each charge a monthly fee of $5,000 for each 1Gb circuit, $14,000 for each 10Gb circuit and $22,000 for each 10Gb LX circuit, which is the equivalent of the Exchange's 10Gb ULL connection. See also Cboe, CboeBZX, CboeEDGX and C2 Fee Schedules. Cboe charges monthly quoting and order entry bandwidth packet fees. Specifically, Cboe charges $1,600 for the 1st through 5th packet, $800 for the 6th through 8th packet, $400 for the 9th through 13th packet and $200 for the 14th packet and each additional packet. CboeBZX, CboeEDGX and C2 each charge a monthly fee of $2,500 for each 1Gb connection and $7,500 for each 10Gb connection.

[20] 15 U.S.C. 78f(b)(4) and (5).

[21] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496 (June 29, 2005).

to software development, quality assurance, and technology support.

The Exchange believes that its proposal is consistent with Section 6(b)(4) of the Act, in that the proposed fee changes are fair, equitable and not unreasonably discriminatory, because the fees for the connectivity alternatives available on BOX, as proposed, are constrained by significant competitive forces. The U.S. options markets are highly competitive (there are currently 16 options markets) and a reliance on competitive markets is an appropriate means to ensure equitable and reasonable prices.

The Exchange acknowledges that there is no regulatory requirement that any market participant connect to BOX, or that any participant connect at any specific connection speed. The rule structure for options exchanges are, in fact, fundamentally different from those of equities exchanges. In particular, options market participants are not forced to connect to (and purchase market data from) all options exchanges, as shown by the number of Participants of BOX as compared to the much greater number of participants at other options exchanges. Not only does BOX have less than half the number of participants as certain other options exchanges, but there are also a number of BOX Participants that do not connect directly to BOX. Further, of the number of Participants that connect directly to BOX, many such Participants do not purchase market data from BOX. In addition, of the market makers that are connected to BOX, it is the individual needs of the market maker that require whether they need one connection or multiple connections to BOX. BOX has market maker Participants that only purchase one connection (10Gb) and BOX has market maker Participants that purchase multiple connections. It is all driven by the business needs of the market maker. Market makers that are consolidators that target resting order flow tend to purchase more connectivity that market makers that simply quote all symbols on BOX. Even though non-Participants purchase and resell 10Gb and non-10Gb connections to both Participants and non-Participants, no market makers currently connect to BOX indirectly through such resellers.

In SIFMA's comment letter, they argue that all broker-dealers are required to connect to all exchanges which is not true in the options markets. The options markets have evolved differently than the equities markets both in terms of market structure and functionality. For example, there are many order types that are available in the equities markets that are not utilized in the options markets, which relate to mid-point pricing and pegged pricing which require connection to the SIPs and each of the equities exchanges in order to properly execute those orders in compliance with best execution obligations. In addition, in the options markets there is a single SIP (OPRA) versus two SIPs in the equities markets, resulting in few hops and thus alleviating the need to connect directly to all the options exchanges. Additionally, in the options markets, the linkage routing and trade through protection are handled by the exchanges, not by the individual participants. Thus not connecting to an options exchange or disconnecting from an options exchange does not potentially subject a broker-dealer to violate order protection requirements as suggested by SIFMA. The Exchange recognizes that the decision of whether to connect to BOX is separate and distinct from the decision of whether and how to trade on BOX. The Exchange acknowledges that many firms may choose to connect to BOX, but ultimately not trade on it, based on their particular business needs.

To assist prospective Participants or firms considering connecting to BOX, the Exchange provides information about BOX's available connectivity alternatives.[22] The decision of which type of connectivity to purchase, or whether to purchase connectivity at all for a particular exchange, is based on the business needs of the firm. Section 2.4 of the BOX Connectivity Guide details the bandwidth requirements depending on the type of traffic each firm requires. Simple Order routing requires 128 kbps of bandwidth, which could be achieved with a non-10Gb connection, while receiving the five best limits in all classes for the HSVF requires a 10Gb connection not purchase such data feed products. Accordingly, purchasing market data is a business decision/choice, and thus the pricing for it is constrained by competition.

Contrary to SIFMA's argument, there is competition for connectivity to BOX. BOX competes with ten (10) non-Participants who resell BOX connectivity or market data. These are resellers of BOX connectivity—they are not arrangements between broker dealers to share connectivity costs. Those non-Participants resell that connectivity to multiple market participants over that same connection, including both Participants and non-Participants of BOX. When connectivity is re-sold by a third-party, BOX does not receive any connectivity revenue from that sale. It is entirely between the third-party and the purchaser, thus constraining the ability of BOX to set its connectivity pricing as indirect connectivity is a substitute for direct connectivity. There are currently ten (10) non-Participants that purchase connectivity to BOX. Those non-Participants resell that connectivity or market data to approximately twenty-seven (27) customers, some of whom are agency broker-dealers that have tens of customers of their own. Some of those twenty-seven (27) customers also purchase connectivity directly from BOX. Accordingly, indirect connectivity is a viable alternative that is already being used by non-Participants of BOX, constraining the price that BOX is able to charge for connectivity.

The Exchange is comprised of 51 BOX Participants. Of those 51 Participants, 13 Participants have purchased 10Gb or non-10Gb connections or some combination of multiple various connections. Furthermore, every Participant who has purchased at least one connection also trades on BOX with the exception of one new Participant who is currently in the on-boarding process. The remaining Participants who have not purchased any connectivity to BOX are still able to trade on BOX indirectly through other Participants or non-Participant service bureaus that are connected. These remaining Participants who have not purchased connectivity are not forced or compelled to purchase connectivity, and they retain all of the other benefits of membership with the Exchange. Accordingly, Participants and non-Participants have the choice to purchase connectivity and are not compelled to do so in any way.

The Exchange believes that the proposed fees are fair, equitable and not unreasonably discriminatory because the connectivity pricing is associated with relative usage or the various market participants and does not impose a barrier to entry to smaller participants. Accordingly, BOX offers two direct connectivity alternatives and various indirect connectivity (via third party) alternatives, as described above. BOX recognizes that there are various business models and varying sizes of market participants conducting business on BOX. The non-10Gb direct connectivity alternatives[23] are all

[22] *See* BOX Connectivity Guide at *https://boxoptions.com/assets/NET-BX-001E-BOX-Network-Connection-Specifications-v2.7.pdf.*

[23] Non-10Gb connectivity alternatives are comprised of protocol types that are at or under 1Gb bandwidth. The protocol types are: Gigabit

Continued

comprised of bandwidth of equal to or less than 1Gb and are purchased by market participants that require less bandwidth. As stated above, Section 2.4 of the BOX Connectivity Guide details the bandwidth requirements depending on the type of traffic each firm requires. While non-10Gb connections can fully support the sending of orders and the consumption of BOX's HSVF Data Feed,[24] these connections use less exchange resources and network infrastructure. In contrast, market participants that purchase 10Gb connections utilize the most bandwidth, and those are the participants that consume the most resources from the network. The 10Gb connection offers optimized connectivity for latency sensitive participants and is faster in round trip time for connection oriented traffic to BOX than the non-10Gb connection. This lower latency is achieved through more advanced network equipment, such as advanced hardware and switching components, which translates to increased costs to BOX. Market participants that are less latency sensitive can purchase non-10Gb direct connections and quote in all products on BOX and consume the HSVF Market Data Feed, and such non-10Gb direct connections are priced lower than the 10Gb connections, offering smaller sized market makers a lower cost alternative.

A 10Gb connection uses at least ten times the network infrastructure as the non-10Gb connections and BOX has to scale the systems by the amount and size of all connections regardless of how they are used.[25] Accordingly, the Exchange believes that the allocation of the proposed fees ($1,000 per non-10Gb connection and $5,000 per 10Gb connection) are reasonable based on the network resources consumed by the market participants—lower bandwidth consuming market participants pay the least, and highest bandwidth consuming market participants pay the most, particularly since higher bandwidth consumption translates to higher costs to BOX.

Separately, the Exchange is not aware of any reason why market participants could not simply drop their connections and cease being BOX Participants if the Exchange were to establish unreasonable and uncompetitive price increases for its connectivity alternatives. Market participants choose to connect to a particular exchange and because it is a choice, BOX must set reasonable connectivity pricing, otherwise prospective participants would not connect and existing participants would disconnect or connect through a third-party reseller of connectivity. No options market participant is required by rule, regulation, or competitive forces to be a BOX Participant.[26] Several market participants choose not to be BOX Participants and choose not to access BOX, and several market participants also access BOX indirectly through another market participant. If all market participants were required to be Participants of each exchange and connect directly to the exchange, all exchanges would have over 200 Participants, in line with Cboe's total membership.

The Exchange believes that its proposal is consistent with Section 6(b)(4) of the Act because the proposed fees allow the BOX to recover a portion of the costs incurred by BOX associated with maintaining and enhancing a state-of-the-art exchange network infrastructure in the US options industry. Additionally, there are significant costs associated with various projects and initiatives to improve overall network performance and stability, as well as costs paid to the third-party data centers for space rental, power used, etc.

The Exchange notes that unlike its competitors, BOX does not own its own data center and therefore cannot control data center costs. While some of the data center expenses are fixed, much of the expenses are not fixed, and thus increases as the number of physical connections increase. For example, new non-10Gb and 10Gb connections require the purchase of additional hardware to support those connections. Further, as the total number of all connections increase, BOX needs to increase their data center footprint and consume more power, resulting in increased costs charged by their third-party data center provider.

Further, as discussed herein, because the costs of operating a data center are significant and not economically feasible for BOX, BOX does not operate its own data centers, and instead contracts with a third-party data center provider. The Exchange notes that larger, dominant exchange operators own/operate their data centers, which offers them greater control over their data center costs. Because those exchanges own and operate their data centers as profit centers, BOX is subject to additional costs. Connectivity fees, which are charged for accessing the BOX's data center network infrastructure, are directly related to the network and offset such costs.

As discussed herein, the Exchange now believes that it is reasonable and appropriate to begin charging for physical connectivity fees to partially offset the costs associated with maintaining and enhancing a state-of-the-art exchange network infrastructure in the US options industry. There are significant costs associated with various projects and initiatives to improve overall network performance and stability, as well as costs paid to the third-party data centers for space rental, power used, etc. As discussed above, the Exchange notes that unlike other options exchanges, BOX does not own and operate its own data center and therefore cannot control data center costs. As detailed herein, BOX has incurred substantial costs associated with maintaining and enhancing the BOX network. These costs, coupled with BOX's historically low transaction fees, place BOX at a competitive disadvantage against other options exchanges who charge connectivity fees to market participants. BOX has no choice but to begin charging Participants and non-Participants fees for connecting directly to the network which BOX has taken considerable measures to maintain and enhance for the benefit of those Participants and non-Participants in order to remain competitive with the other options exchanges in the industry.

As the Exchange explained to the Division, the existence of robust competition between exchanges to attract order flow requires exchanges to keep prices for all of their joint services—including connectivity to the exchanges' networks at a pro-competitive level.[27] This conclusion is substantiated by the report prepared by Professor Janusz A. Ordover and Gustavo Bamberger addressing the theory of ''Platform Competition'' and its application to the pricing of exchanges' services, including

Ethernet, Ethernet, Fast Ethernet, Fiber Channel, OC–3, Singlemode Fiber, ISDN, POTS and T1.

[24] The Exchange notes that, unlike MIAX, BOX's HSVF Data Feed does not require a 10Gb physical connection. On BOX, the HSVF Data Feed cab be consumed through a non-10Gb connection. On MIAX, the 1Gb connection cannot support the consumption of the top of market data feed or the depth data feed product—both require a 10Gb connection.

[25] The Exchange's network infrastructure requirements are based on the premise of all connections operating at full capacity,

[26] Cboe Exchange Inc. has over 200 members, Nasdaq ISE, LLC has approximately 100 members, and NYSE American LLC has over 80 members. In comparison, the BOX has 51 Participants.

[27] Letter from Lisa J. Fall, BOX, to Brent J. Fields, Secretary, Securities and Exchange Commission (Feb. 19, 2019), *https://www.sec.gov/comments/sr-box-2018-24/srbox201824-4945872-178516.pdf.*

connectivity services.[28] In the report, Ordover and Bamberger explain that ''the provision of connectivity services . . . is inextricably linked to the provision of trading services, so that, as a matter of economics, it is not possible to appropriately evaluate the pricing of connectivity services in isolation from the pricing of trading and other 'joint' services offered by'' an exchange. Ordover and Bamberger state that ''connectivity services are an 'input' into trading'' and that ''excessive pricing of such services would raise the costs of trading on [an exchange] relative to its rivals and thus discourage trading on'' that exchange.

Although the Ordover/Bamberger Statement focuses on the pricing of connectivity services by Nasdaq-affiliated equities exchanges, its ''overarching conclusion . . . that the pricing of connectivity services should not be analyzed in isolation'' applies with equal force to the proposed fees. Because BOX is engaged with rigorous competition with other exchanges to attract order flow to its platform, BOX is constrained in its ability to price its joint services—including connectivity services—at supracompetitive levels. That competition ensures that BOX's connectivity fees are set at levels consistent with the requirements of the Exchange Act.

As detailed in the Exchange's and BOX Market's [29] 2018 audited financial statements which are publicly available as part of the Exchange's Form 1 Amendment, BOX only has two sources of revenue that it can control: Transaction fees and non-transactions fees.[30] Accordingly, BOX must cover all of its expenses from these two sources of revenue.

The Proposed Fees are fair and reasonable because they will not result in excessive pricing or supracompetitive profit, when comparing the total annual expense of the Exchange and BOX associated with providing the network connectivity services versus the total projected annual revenue of the Exchange [31] and BOX associated with providing the network connectivity services. For 2018, the annual expense for BOX and the Exchange associated with providing the network connectivity services was approximately $8.9 million.[32] This amount is comprised of both direct and indirect expenses. The direct expense (which relates 100% to the network infrastructure, associated data center processing equipment required to support various connections, network monitoring systems and associated software required to support the various forms of connectivity) was approximately $6.4 million.[33]

The indirect expense (which includes expense from such areas as trading operations, software development, business development, information technology, marketing, human resources, legal and regulatory, finance and accounting) that the Exchange and BOX allocate to the maintenance and support of network connectivity services was approximately $2.5 million.[34] This indirect expense amount of $2.5 million represents approximately 10% of the total annual expenses of BOX and the Exchange for 2018. Total projected annualized revenue associated with selling the network connectivity services (reflecting the proposed fees on a fully-annualized basis, using July 2019 data) for BOX is projected to be approximately $4.6 million. This projected revenue amount of $4.6 million represents approximately 13% of total net revenue of BOX and Exchange for 2018 of approximately $35.5 million. The Exchange believes that an indirect expense allocation of 10% of total expense (less direct expense) to network connectivity services is fair and reasonable, as total projected network connectivity revenue represents approximately 13% of total net revenue for 2018. That is, direct expense of $6.4 million plus indirect expense of $2.5 million fairly reflects the total annual expense associated with providing the network connectivity services, both from the perspective of similar revenue and expense percentages (connectivity to total), as well as matching connectivity resources to connectivity expenses. The Exchange believes that this is a conservative allocation of indirect expense. Accordingly, the total projected connectivity revenue for BOX, reflective of the proposed fees, on an annualized basis, of $4.6 million, is almost half of the total annual actual BOX and Exchange connectivity expense (direct and indirect) for 2018 of $8.9 million. Further, even the direct expense associated with providing network connectivity ($6.4 million) exceeds expected revenue from connectivity.

The Exchange projects comparable network connectivity revenue and expense for 2019 for BOX. Accordingly, the Proposed Fees are fair and reasonable because they do not result in excessive pricing or supracompetitive profit, when comparing the actual network connectivity costs to the Exchange and BOX versus the projected network connectivity annual revenue. Additional information on overall revenue and expense can be found in the Exchange's and BOX's 2018 audited financial results, which is publicly available as part of the Exchange's Form 1 filed with the Commission.

The Exchange again notes that other exchanges have similar connectivity alternatives for their participants, including similar low-latency connectivity. For example, Nasdaq PHLX LLC (''Phlx''), NYSE Arca, Inc. (''Arca''), NYSE American LLC (''NYSE American'') and Nasdaq ISE, LLC (''ISE'') all offer a 1Gb, 10Gb and 10Gb low latency ethernet connectivity alternatives to each of their participants.[35] The Exchange further notes that Phlx, ISE, Arca and NYSE American each charge higher rates for such similar connectivity to primary and secondary facilities.[36]

[28] *See* Attachment to Letter from Lisa J. Fall, *supra* note 27 (''Ordover/Bamberger Statement'').

[29] BOX Exchange LLC (''Exchange'') and BOX Options Market LLC (''BOX'') are two different entities. The Exchange is a national securities exchange registered with the SEC under Section 6 of the Securities Exchange Act of 1934. The Exchange fulfills the regulatory functions and responsibilities and oversees BOX, the equity options market. Expenses associated with network connectivity services are born by both the Exchange and BOX.

[30] Options Price Authority Reporting (''OPRA'') income is not controlled by BOX.

[31] Revenues for the Exchange are limited to the Options Regulatory Fee (''ORF'') and fines and disgorgements.

[32] A more detailed breakdown of the annual operational expense in 2018 includes over $2.8 million for space rental, power used, connections, etc. at the Exchange's data centers, over $1.1 million for data center support and management of third party vendors, over $700,000 in technological improvements to the data center infrastructure, over $1.4 million for resources for technical and operational services for the Exchange's data centers and $400,000 in market data connectivity fees. Of note, regarding market data connectivity fees, this is the cost associated with BOX consuming connectivity/content from the equities markets in order to operate the Exchange, causing BOX to effectively pay its competitors for this connectivity.

[33] Direct connectivity expenses are a portion of the following line items in the BOX and Exchange Form 1 Financial Statements: Technical and Operational, Other and Communications and Data Processing.

[34] Indirect expenses for connectivity are a portion of the following line items in the BOX and Exchange Form 1 Financial Statements: Employee Costs, Depreciation and Amortization, Consulting, Financial and Administrative, and Other.

[35] *See* Phlx and ISE Rules, General Equity and Options Rules, General 8, Section 1(b). Phlx and ISE each charge a monthly fee of $2,500 for each 1Gb connection, $10,000 for each 10Gb connection and $15,000 for each 10Gb Ultra connection, which the equivalent of the Exchange's 10Gb ULL connection. *See also* NYSE American Fee Schedule, Section V.B, and Arca Fees and Charges, Co-Location Fees. NYSE American and Arca each charge a monthly fee of $5,000 for each 1Gb circuit, $14,000 for each 10Gb circuit and $22,000 for each 10Gb LX circuit, which the equivalent of the Exchange's 10Gb ULL connection.

[36] *Id.*

Finally, the Exchange believes redefining the HSVF Connection Fee as a Port Fee is reasonable, equitable and not unfairly discriminatory. This classification is more accurate because an HSVF subscription is not enabled through a physical connection to the Exchange. Although market participant must be credentialed by BOX to receive the HSVF, anyone can become credentialed by submitting the required documentation.[37] The Exchange does not propose to alter the amount of the existing HSVF fee; subscribers to the HSVF will continue to pay $1,500 per month. As with the Connectivity Fees, BOX's HSVF Port Fee is in line with industry practice.[38]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

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, the Exchange has received no official complaints from Participants that purchase the Exchange's connectivity that the Exchange's fees or the Proposed Fees are negatively impacting or would negatively impact their abilities to compete with other market participants or that they are placed at a disadvantage.[39] The Exchange believes that the Proposed Fees do not place certain market participants at a relative disadvantage to other market participants because the connectivity pricing is associated with relative usage of the various market participants and does not impose a barrier to entry to smaller participants. As described above, the less expensive non-10Gb direct connection is generally purchased by market participants that utilize less bandwidth. The market participants that purchase 10Gb connections utilize the most bandwidth, and those are the participants that consume the most resources from the network. Accordingly, the Proposed Fees 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 reflect the network resources consumed by the various size of market participants—lowest bandwidth consuming members pay the least, and highest bandwidth consuming members pays the most, particularly since higher bandwidth consumption translates to higher costs to BOX.

Inter-Market Competition

The Exchange believes the Proposed Fees do not place an undue burden on competition on other SROs that is not necessary or appropriate. In particular, options market participants are not forced to connect to (and purchase market data from) all options exchanges, as shown by the number of Participants of BOX as compared to the much greater number of members at other options exchanges (as described above). Not only does BOX have less than half the number of Participants as certain other options exchanges, but there are also a number of the Exchange's Participants that do not connect directly to BOX. Additionally, the Exchange notes other exchanges have similar connectivity alternatives for their participants, including similar low-latency connectivity, but with much higher rates to connect.[40] The Exchange is also unaware of any assertion that its existing fee levels or the Proposed Fees would somehow unduly impair its competition with other options exchanges. To the contrary, if the fees charged are deemed too high by market participants, they can simply disconnect.

Unilateral action by the Exchange in establishing fees for services provided to its Participants and others using its facilities will not have an impact on competition. As a small exchange in the already highly competitive environment for options trading, the Exchange does not have the market power necessary to set prices for services that are unreasonable or unfairly discriminatory in violation of the Exchange Act. The Exchange's proposed fees, as described herein, are comparable to and generally lower than fees charged by other options exchanges for the same or similar services. Lastly, the Exchange believes the proposed change will not impose a burden on intramarket competition as the proposed fees are applicable to all Participants and others using its facilities that connect to BOX.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Exchange Act[41] and Rule 19b–4(f)(2) thereunder,[42] because it establishes or changes a due, or fee.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend the rule change if it appears to the Commission that the action is necessary or appropriate in the public interest, for the protection of investors, or would otherwise further 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 Comment

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–BOX–2019–27 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–BOX–2019–27. 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

[37] *See Trading Interface Specification*, BOX Options, *https://boxoptions.com/technology/trading-interface-specifications/*

[38] See Cboe Data Services, LLC (CDS) Fee Schedule § VI (charging $500 per month for up to five users to access the Enhanced Controlled Data Distribution Program).

[39] The Exchange notes that it did receive one complaint from a non-Participant third party that, prior to the proposed fees, received connectivity for free and resold it to other market participants. This non-Participant ceased connectivity to the Exchange in January 2019.

[40] *See supra* note 19.

[41] 15 U.S.C. 78s(b)(3)(A)(ii).

[42] 17 CFR 240.19b–4(f)(2).

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 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–BOX–2019–27, and should be submitted on or before October 16, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[43]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–20706 Filed 9–24–19; 8:45 am]

BILLING CODE 8011–01–P

[43] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87022; File No. SR–DTC–2019–005]

Self-Regulatory Organizations; The Depository Trust Company; Notice of Filing of Partial Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Partial Amendment No. 1, To Amend the Settlement Guide To Implement a New Algorithm for Transactions Processed in the Night Cycle

September 19, 2019.

I. Introduction

On July 22, 2019, the Depository Trust Company (''DTC'') filed with the Securities and Exchange Commission (''Commission'') proposed rule change SR–DTC–2019–005, pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') and Rule 19b–4 thereunder.[1] The proposed rule change was published for comment in the **Federal Register** on August 8, 2019.[2] On September 16, 2019, DTC filed Partial Amendment No. 1 to the proposed rule change to postpone the implementation date of the proposed rule change.[3] The Commission did not receive any comment letters on the proposed rule change. The Commission is publishing this notice to solicit comment on Partial Amendment No. 1 from interested persons and to approve the proposed rule change, as modified by Partial Amendment No. 1 (hereinafter, ''Proposed Rule Change''), on an accelerated basis.

[1] 15 U.S.C. 78s(b)(1) and 17 CFR 240.19b–4.

II. Description of the Proposed Rule Change[4]

DTC proposes to amend the Settlement Guide to implement a new processing algorithm for book-entry Deliveries[5] and Payment Orders[6] processed in the DTC night cycle (''Night Cycle'').[7] Specifically, DTC proposes to make enhancements to its processing of transactions in the Night Cycle.

Currently, other than a limited look-ahead process as described below, DTC does not employ a processing mechanism that is designed to proactively optimize the percentage of available transactions that are processed for settlement on settlement date. DTC proposes to implement a process that would facilitate a higher percentage of available transactions being processed for settlement during the Night Cycle.[8]

Specifically, pursuant to the Proposed Rule Change, DTC would introduce an algorithm that would test multiple scenarios that would incorporate all transactions available for processing at the start of the Night Cycle as a single batch (''Night Batch Process''), to determine the order of processing of those transactions that allows for the optimal percentage of the transactions to satisfy risk and position controls (*i.e.,* the Collateral Monitor and Net Debit Cap controls),[9] and therefore be processed for settlement in the Night Cycle. Consistent with DTC's existing processing environment, the scenarios used would only involve processing of the transactions on a bilateral basis (*i.e.,* no netting of Deliveries).[10] Once the optimal order of processing has been identified, the results reflecting this optimal processing order would be incorporated into DTC's core processing environment on a transaction-by-transaction basis, and member output would be produced using existing DTC output facilities. Delivery instructions provided to DTC after the Night Batch Process has begun would be submitted for daytime processing. According to DTC, the Proposed Rule Change would facilitate more efficient processing of Deliveries and Payment Orders in the Night Cycle and increase the percentage of transactions that have been processed for settlement prior to the start of regular daytime processing.[11]

[2] Securities Exchange Act Release No. 86554 (August 2, 2019), 84 FR 39025 (August 8, 2019) (SR–DTC–2019–005) (''Notice'').

[3] DTC submitted a courtesy copy of Partial Amendment No. 1 to the proposed rule change through the Commission's electronic public comment letter mechanism. Accordingly, Partial Amendment No. 1 to the proposed rule change has been publicly available on the Commission's website since September 16, 2019: *https://www.sec.gov/comments/sr-dtc-2019-005/srdtc2019005-6132114-192254.pdf*

[4] Capitalized terms not defined herein are defined in the Rules, By-Laws and Organization Certificate of DTC (''Rules''), *available at www.dtcc.com/~/media/Files/Downloads/legal/rules/dtc_rules.pdf,* and the DTC Settlement Service Guide (''Settlement Guide''), *available at http://www.dtcc.com/~/media/Files/Downloads/legal/service-guides/Settlement.pdf.*

[5] Pursuant to Rule 1, the term ''Delivery'' as used with respect to a Security held in the form of a Security Entitlement on the books of DTC, means debiting the Security from an Account of the Deliverer and crediting the Security to an Account of the Receiver. *See* Rules, *supra* note 4.

[6] Pursuant to the Settlement Guide, ''Payment Order'' means a transaction in which a Participant charges another Participant for changes in value for outstanding stock loans or option contract premiums. *See* Settlement Guide, *supra* note 4, at 5.

[7] The Night Cycle starts at approximately 8:30 p.m. ET on the Business Day prior to settlement date and runs until approximately 10:00 p.m. ET each Business Day. Transactions that cannot satisfy DTC's controls at the time they are introduced to DTC will recycle throughout the day and be continuously reattempted until approximately 3:10 p.m. for valued transactions, and 6:35 p.m. for free transactions. *See* Notice, *supra* note 2, at 39026.

[8] DTC stated that 50 percent of transactions available for processing at the start of the Night Cycle are processed for settlement during the Night Cycle. DTC anticipates that the proposal would increase the percentage of transactions processed for settlement during the Night Cycle to approximately 65 percent. *See* Notice, *supra* note 2, at 39026.

[9] In managing its credit risk, DTC uses the Collateral Monitor and Net Debit Cap. These two controls work together to protect the DTC settlement system in the event of Participant default. The Collateral Monitor requires net debit settlement obligations, as they accrue intraday, to be fully collateralized; the Net Debit Cap limits the amount of any Participant's net debit settlement obligation to an amount that can be satisfied with DTC liquidity resources (the Participants Fund and the committed line of credit from a consortium of lenders). *See* Settlement Guide, *supra* note 4, at 64–67.

[10] The Proposed Rule Change relates only to the processing order of Deliveries and does not impact DTC's funds settlement process, by which associated funds debits and credits in the Participant's settlement account are netted intraday to calculate, at any time, a net debit balance or net credit balance, resulting in an end-of-day settlement obligation or right to receive payment.

[11] *See* Notice, *supra* note 2, at 39026.

Elimination of Obsolete Functions

Currently, Participants can use a profile in the Inventory Management System (''IMS'') that allows them to define the order in which their transactions get submitted for processing during the Night Cycle.[12] The submission ordering allows Participants to control the order in which different transaction types are submitted into DTC's core processing system. The recycle ordering allows Participants to control how DTC attempts to process recycling, or pending, transactions. Similar to the submission ordering, Participants can also prioritize transactions by transaction types under recycle ordering. Additionally, Participants can instruct DTC to (i) attempt transactions in the defined order but complete any transaction that can be completed, (ii) only complete transactions in the defined order, or (iii) not complete any transactions until instructed to do so. Because the proposed Night Batch Process would attempt to maximize settlement regardless of transaction type, the IMS profile would become obsolete with respect to transactions processed in the Night Cycle and would not be utilized for processing of transactions in the Night Batch Process.

DTC's look-ahead process (''Look-Ahead Process'') runs throughout the processing day at fifteen-minute intervals and selects pairs of transactions that when processed simultaneously will not violate the involved Participants' Net Debit Cap, Collateral Monitor, and other risk management system controls.[13]

The Look-Ahead Process reduces transaction blockage for Securities by identifying a receive transaction pending due to a Net Debit Cap insufficiency, and determines whether the processing of an offsetting delivery transaction pending because of a quantity deficiency in the same Security would permit both transactions to be completed in compliance with DTC's risk management system controls.[14] DTC's processing system calculates the net effect to the Collateral Monitor and Net Debit Cap controls for all three Participants involved, and if the net effect will not result in a deficit in the Collateral Monitor or Net Debit Cap for any of the three Participants, the system processes the transactions simultaneously.[15] Because the Night Batch Process would provide an algorithm to maximize settlement for all transactions processed in the Night Cycle, the Look-Ahead Process would become obsolete for Night Cycle processing and would not be utilized for processing of transactions in the Night Batch Process.

Description of Partial Amendment No. 1

In Partial Amendment No. 1, DTC proposes to amend the implementation timeframe of the proposal.[16] In its original filing with the Commission, DTC previously stated that the proposed rule change would be effective by September 26, 2019. Pursuant to Partial Amendment No. 1, the Proposed Rule Change would be effective by December 6, 2019.

III. Discussion and Commission Findings

Section 19(b)(2)(C) of the Act [17] 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 rules and regulations thereunder applicable to such organization. After carefully considering the Proposed Rule Change, the Commission finds that the Proposed Rule Change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to DTC. In particular, the Commission finds that the Proposed Rule Change is consistent with Section 17A(b)(3)(F) of the Act.[18]

Section 17A(b)(3)(F) of the Act requires, in part, that the rules of a clearing agency be designed ''to assure the safeguarding of securities and funds which are in the custody or control of the clearing agency or for which it is responsible.'' [19] The Proposed Rule Change would implement a new processing algorithm for book-entry Deliveries and Payment Orders processed in the Night Cycle. Specifically, DTC would test the entire batch of transactions available for processing at the start of the Night Batch Process to determine the optimal order to process transactions in the Night Cycle, such that they may satisfy risk and position controls, which would help maximize the number of transactions processed for settlement during the Night Cycle.

Helping to identify the optimal order to process transactions for settlement would help maximize the number of transactions processed for settlement during the Night Cycle. Therefore, the Commission believes that the Proposed Rule Change would promote the prompt and accurate clearance and settlement of securities transactions, consistent with Section 17A(b)(3)(F) of the Act.

IV. Solicitation of Comments on Partial Amendment No. 1 to the Proposed Rule Change

Interested persons are invited to submit written data, views and arguments concerning whether Partial Amendment No. 1 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–DTC–2019–005 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–DTC–2019–005. 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 DTC and on DTCC's website (*http://dtcc.com/legal/sec-rule-filings.aspx*). All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal

[12] *See* Securities Exchange Act Release No. 52450 (September 15, 2005), 70 FR 55641 (September 22, 2005) (File No. SR–DTC–2005–07) and Securities Exchange Act Release No. 50944 (December 29, 2004), 70 FR 1927 (January 11, 2005) (File No. SR–DTC–2004–10).

[13] *See* Settlement Guide, *supra* note 4, at 43.

[14] *Id.*

[15] *Id.*

[16] Partial Amendment No. 1, *supra* note 3.

[17] 15 U.S.C. 78s(b)(2)(C).

[18] 15 U.S.C. 78q–1(b)(3)(F)

[19] *Id.*

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–DTC–2019–005 and should be submitted on or before October 16, 2019.

V. Accelerated Approval of the Proposed Rule Change, as Modified as Partial Amendment No. 1

The Commission finds good cause, pursuant to Section 19(b)(2) of the Act,[20] to approve the proposed rule change prior to the 30th day after the date of publication of Partial Amendment No. 1 in the **Federal Register**. As noted above, Partial Amendment No. 1 delays the implementation timeframe of the proposal from September 26, 2019 to December 6, 2019.[21] The Commission believes that the Partial Amendment is consistent with the Act because it does not raise any regulatory issues and would provide more time before the proposal would go into effect.

For the reasons discussed above, the Commission finds that Partial Amendment No. 1 is reasonably designed to protect investors and the public interest, and consistent with the requirements of the Act. Accordingly, the Commission finds good cause, pursuant to Section 19(b)(2) of the Act,[22] to approve the proposed rule change, as modified by Partial Amendment No. 1, on an accelerated basis.

VI. Conclusion

On the basis of the foregoing, the Commission finds that the proposed rule change, as modified by Partial Amendment No. 1, is consistent with the requirements of the Act and, in particular, with the requirements of Section 17A of the Act[23] and the rules and regulations promulgated thereunder.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act[24] that proposed rule change SR–DTC–2019–005, as modified by Amendment No. 1, be, and hereby is, approved on an accelerated basis.[25]

[20] 15 U.S.C. 78s(b)(2).

[21] Partial Amendment No. 1, *supra* note 3.

[22] 15 U.S.C. 78s(b)(2).

[23] 15 U.S.C. 78q–1.

[24] 15 U.S.C. 78s(b)(2).

[25] In approving the proposed rule change, the Commission considered the proposals' impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[26]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–20702 Filed 9–24–19; 8:45 am]

BILLING CODE 8011–01–P

[26] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87017; File No. SR–NYSEARCA–2019–66]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Extend the Pilot Related to the Market-Wide Circuit Breaker in Rule 7.12–E

September 19, 2019.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on September 17, 2019, NYSE Arca, Inc. (''NYSE Arca'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to extend the pilot related to the market-wide circuit breaker in Rule 7.12–E. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

Rule 7.12–E provides a methodology for determining when to halt trading in all stocks due to extraordinary market volatility (*i.e.,* market-wide circuit breakers). The market-wide circuit breaker (''MWCB'') mechanism under Rule 7.12–E was approved by the Commission to operate on a pilot basis,[4] the term of which was to coincide with the pilot period for the Plan to Address Extraordinary Market Volatility Pursuant to Rule 608 of Regulation NMS (the ''LULD Plan''),[5] including any extensions to the pilot period for the LULD Plan.[6] The Commission recently approved an amendment to the LULD Plan for it to operate on a permanent, rather than pilot, basis.[7] In light of the proposal to make the LULD Plan permanent, the Exchange amended Rule 7.12–E to untie the pilot's effectiveness from that of the LULD Plan and to extend the pilot's effectiveness to the close of business on October 18, 2019.[8]

The Exchange now proposes to amend Rule 7.12–E to extend the pilot to the close of business on October 18, 2020. This filing does not propose any substantive or additional changes to Rule 7.12–E. The Exchange will use the extension period to develop with the other SROs rules and procedures that would allow for the periodic testing of the performance of the MWCB mechanism, with industry member participation in such testing. The extension will also permit the exchanges to consider enhancements to the MWCB processes such as modifications to the Level 3 process.

The market-wide circuit breaker under Rule 7.12–E provides an

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* Securities Exchange Act Release No. 67090 (May 31, 2012), 77 FR 33531 (June 6, 2012) (SR–NYSEArca –2011–68).

[5] *See* Securities Exchange Act Release No. 67091 (May 31, 2012), 77 FR 33498 (June 6, 2012). The LULD Plan provides a mechanism to address extraordinary market volatility in individual securities.

[6] *See* Securities Exchange Act Release Nos. 67090 (May 31, 2012), 77 FR 33531 (June 6, 2012) (SR–NYSEArca –2011–68) (Approval Order); and 68785 (January 31, 2013), 78 FR 8646 (February 6, 2013) (SR–NYSEArca –2013–06) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change Delaying the Operative Date of a Rule Change to Exchange Rule 7.12).

[7] *See* Securities Exchange Act Release No. 85623 (April 11, 2019), 84 FR 16086 (April 17, 2019).

[8] *See* Securities Exchange Act Release No. 85561 (April 9, 2019), 84 FR 15262 (April 15, 2019) (SR–NYSEArca –2019–23).

important, automatic mechanism that is invoked to promote stability and investor confidence during a period of significant stress when securities markets experience extreme broad-based declines. All U.S. equity exchanges and FINRA adopted uniform rules on a pilot basis relating to market-wide circuit breakers in 2012 (''MWCB Rules''), which are designed to slow the effects of extreme price movement through coordinated trading halts across securities markets when severe price declines reach levels that may exhaust market liquidity.[9] Market-wide circuit breakers provide for trading halts in all equities and options markets during a severe market decline as measured by a single-day decline in the S&P 500 Index.

Pursuant to Rule 7.12–E, a market-wide trading halt will be triggered if the S&P 500 Index declines in price by specified percentages from the prior day's closing price of that index. Currently, the triggers are set at three circuit breaker thresholds: 7% (Level 1), 13% (Level 2), and 20% (Level 3). A market decline that triggers a Level 1 or Level 2 halt after 9:30 a.m. ET and before 3:25 p.m. ET would halt market-wide trading for 15 minutes, while a similar market decline at or after 3:25 p.m. ET would not halt market-wide trading. A market decline that triggers a Level 3 halt, at any time during the trading day, would halt market-wide trading until the primary listing market opens the next trading day.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[10] in general, and furthers the objectives of Section 6(b)(5) of the Act,[11] 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. The market-wide circuit breaker mechanism under Rule 7.12–E is an important, automatic mechanism that is invoked to promote stability and investor confidence during a period of significant stress when securities markets experience extreme broad-based declines. Extending the market-wide circuit breaker pilot for an additional year would ensure the continued, uninterrupted operation of a consistent mechanism to halt trading across the U.S. markets while the Exchange, with the other SROs, consider and develop rules and procedures that would allow for the periodic testing of the performance of the MWCB mechanism, which would include industry member participation in such testing. The extension will also permit the exchanges to consider enhancements to the MWCB processes such as modifications to the Level 3 process.

The Exchange also believes that the proposed rule change promotes just and equitable principles of trade in that it promotes transparency and uniformity across markets concerning when and how to halt trading in all stocks as a result of extraordinary market volatility. Based on the foregoing, the Exchange believes the benefits to market participants from the MWCB under Rule 7.12–E should continue on a pilot basis because the MWCB will promote fair and orderly markets, and protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act because the proposal would ensure the continued, uninterrupted operation of a consistent mechanism to halt trading across the U.S. markets while the Exchange, in conjunction with the other SROs, consider and develop rules and procedures that would allow for the periodic testing of the performance of the MWCB mechanism. Furthermore, as noted above, the extension will permit the exchanges to consider enhancements to the MWCB processes such as modifications to the Level 3 process.

Further, the Exchange understands that FINRA and other national securities exchanges will file proposals to extend their rules regarding the market-wide circuit breaker pilot. Thus, the proposed rule change will help to ensure consistency across market centers without implicating any competitive issues.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[12] and Rule 19b–4(f)(6)(iii) thereunder.[13]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[14] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEARCA–2019–66 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–NYSEARCA–2019–66. This file number should be included on the

[9] *See* Securities Exchange Act Release No. 67090 (May 31, 2012), 77 FR 33531 (June 6, 2012) (SR–BATS–2011–038; SR–BYX–2011–025; SR–BX–2011–068; SR–CBOE–2011–087; SR–C2–2011–024; SR–CHX–2011–30; SR–EDGA–2011–31; SR–EDGX–2011–30; SR–FINRA–2011–054; SR–ISE–2011–61; SR–NASDAQ–2011–131; SR–NSX–2011–11; SR–NYSE–2011–48; SR–NYSEAmex –2011–73; SR–NYSEArca –2011–68; SR–Phlx–2011–129) (''MWCB Approval Order'').

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(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] 15 U.S.C. 78s(b)(2)(B).

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–NYSEARCA–2019–66 and should be submitted on or before October 16, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–20694 Filed 9–24–19; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87024; File No. SR–CBOE–2019–059]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Certain Rules Relating To Market-Makers Upon Migration to the Trading System Used by Cboe Affiliated Exchanges

September 19, 2019.

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 September 6, 2019, Cboe Exchange, Inc. filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') proposes to amend and move certain current Rules in connection with Market-Makers from the Exchange's currently effective Rulebook (''current Rulebook'') to the shell structure for the Exchange's Rulebook that will become effective upon the migration of the Exchange's trading platform to the same system used by the Cboe Affiliated Exchanges (as defined below) (''shell Rulebook''). The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, 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

In 2016, the Exchange's parent company, Cboe Global Markets, Inc. (formerly named CBOE Holdings, Inc.) (''Cboe Global''), which is also the parent company of Cboe C2 Exchange, Inc. (''C2''), acquired Cboe EDGA Exchange, Inc. (''EDGA''), Cboe EDGX Exchange, Inc. (''EDGX'' or ''EDGX Options''), Cboe BZX Exchange, Inc. (''BZX'' or ''BZX Options''), and Cboe BYX Exchange, Inc. (''BYX'' and, together with Cboe Options, C2, EDGX, EDGA, and BZX, the ''Cboe Affiliated Exchanges''). The Cboe Affiliated Exchanges are working to align certain system functionality, retaining only intended differences between the Cboe Affiliated Exchanges, in the context of a technology migration. The Exchange intends to migrate its trading platform to the same system used by the Cboe Affiliated Exchanges, which the Exchange expects to complete on October 7, 2019. The Exchange believes offering similar functionality to the extent practicable will reduce potential confusion for market participants.

In connection with this technology migration, the Exchange has a shell Rulebook that resides alongside its current Rulebook, which shell Rulebook will contain the Rules that will be in place upon completion of the Cboe Options technology migration.

The Exchange now proposes to update and amend its rules under Chapter 8 (Market-Makers, Trading Crowds and Modified Trading Systems). Specifically, the Exchange proposes to amend its rules regarding Market-Maker registration, class appointments, and obligations (applicable to Market-Makers generally and the various Market-Maker types, *i.e.* Designated Primary Market-Makers (''DPMs''), Primary Market-Makers (''PMMs''), and Lead Market-Makers (''LMMs'')) to conform to the corresponding Market-Makers rules of its affiliated options exchanges, C2, EDGX Options, and BZX Options (the ''Affiliated Options Exchanges'').[3] The Exchange proposes these amendments to reflect the current Market-Maker functionality and general rule language of that of the Affiliated Options Exchanges to the extent necessary to retain intended differences unique to Cboe Options market-model, functionality and/or rule text. In conforming its Rule to that of is Affiliated Options Exchanges' rules, the Exchange proposes few substantive changes, which include proposed changes to the FLEX appointment process, updates to Market-Maker class appointments and obligations to such appointments to apply across Global Trading Hours (''GTH'') and Regular Trading Hours (''RTH''), updates to the

[15] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Exchange notes that the Affiliated Options Exchanges recently updated and harmonized their Market-Maker rules. The recent updates to BZX Option's Market-Maker rules will be implemented on or around October 1, 2019, and this filing refers to these updates. *See* Securities Exchange Act Release No. 85845 (May 13, 2019), 84 FR 22541 (May 17, 2019) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Delay the Operative Date of Rule Change Pursuant to SR–CboeBZX–2019–025) (SR–CboeBZX–2019–043).

appointment cost structure, amendments to certain obligation provisions, including the bid/ask requirement, the series excluded from continuous quoting obligations and adding a ''good-standing'' rule, and updates to some of the rules in connection with DPMs, including segregation of accounts for DPM-related transactions accounts from a firms other accounts, the DPM net liquidating requirements, requirement to have two DPM designees, Exchange review of DPMs, as well as On-Floor terminations (which is also in connection with LMMs) and designations of classes in connection with DPMs and LMMs.

The Exchange also proposes to make non-substantive changes to simplify, clarify, and generally update its Market-Maker rules by consolidating various provisions and rules (including select rules not covered under current Chapter 8 but pertain to Market-Maker requirements), simplifying rule language (*e.g.* revising run-ons and unnecessary clauses), updating the rule text to read in plain English, deleting duplicative and obsolete rule provisions, reformatting provision sequencing, numbering, and lettering, and revising headings. The Exchange also updates cross-references to rules not yet in the shell Rulebook but that will be in the shell Rulebook and implemented upon migration. The tables below list each rule under current Chapter 8, along with the few additional rules related to Market-Makers that the Exchange proposes to consolidate with the Market-Maker rules, the proposed rule in the shell Rulebook to which the current rule will be moved, the corresponding rule of one or more of the Affiliated Options Exchanges to which the propose change conforms (if applicable), whether the proposed change is substantive or non-substantive, and finally, a description of the proposed rule change. The Exchange notes that all current provisions proposed to move to the corresponding proposed provisions in the shell Rulebook will also be deleted from the current rules upon migration.

Market-Maker Registration (Proposed Chapter 3, Section C)

The proposed rule change moves current Chapter 8 rules related to registration (including approvals, eligibility, termination, etc.) and general Market-Maker functions, from the current Rulebook to Chapter 3, Section C (TPH Trading Functions) of the shell Rulebook as follows:

Current rule	Proposed rule	Corresponding other Exchange rule	Substantive change	Description of change
Rule 8.1 (Market-Maker Defined).	Rule 3.52 (Market-Makers).	C2 Rule 8.1, EDGX Options Rule 22.2, BZX Options Rule 22.2.	N	Conforms language to that of the Affiliated Options Exchanges' rules. Language defining Market-Makers deleted; duplicative of the definition already in Rule 1.1.
Rule 8.2 (Registration of Market-Makers).	Rule 3.52 (Market-Makers).	C2 Rule 8.1, EDGX Options Rule 22.2, BZX Options Rule 22.2.	Y: see further discussion below..	Conforms registration process provisions to that of the Affiliated Options Exchanges' rules.
Rule 8.13 (Preferred Market-Makers).	Rule 3.56 (PMMs)	N/A	N	Moves Rule 8.13(a) and (b), and Interpretation and Policy .01(a) to proposed rule, deleted Interpretation and Policy .01(b) regarding PMM participation entitlements,[4] and renumbers provisions, changes headings, and updates cross-references. Removes receipt of PMM order through complex order book (''COB'')/or complex order auctions as such complex entitlements are infrequently allocated, if at all, and, in addition to this, complex orders traded on the COB or COA will not have PMM allocation in the migrated system.
Rule 8.15 (Lead Market-Makers).	Rule 3.55 (LMMs)	N/A	N	Moves current Rule 8.15(a) and Interpretation and Policy .01 to proposed rule and renumbers provisions, changes headings, and updates cross-references. Moves current Rule 6.1A(iii)(A) to proposed rule, which states that the Exchange may approve one or more market-Makers to act as LMMs in each class during GTH for one-month terms.
Rule 6.1A (Global Trading Hours), paragraph (e)(iii)(A).				
Rule 8.81 (DPM Designees).	Rule 3.54 (DPM Designees).	N/A	Y: see further discussion below.	Deletes current 8.1(d) which provides that each DPM must have two designees that are nominees of the DPM, requirement is an unnecessary expense to DPMs. Renumbers provisions and updates cross-references and updates language to read in plain English.
Rule 8.83 (Approval to Act as DPM).	Rule 3.53 (DPMs)	N/A	N	Modifies the term ''appointment'' to ''designation'' to clarify the distinction between a Market-Maker approved to act as a DPM and its appointment to options classes (and updates this term throughout the proposed Market-Maker rules). Updates the term ''allocation'' of ''securities'' to ''appointment'' of classes, which is consistent with the terms used throughout Market-Maker rules (this update is made throughout the proposed Market-Maker rules). Removes language in connection with the ''Hybrid Trading System'' and ''Hybrid classes'' (and makes same update throughout the proposed Market-Maker rules.)[5] Renumbers provisions (including adding Interpretations and Policies to the rule text) and updates cross-references and updates language to read in plain English.
Rule 8.88 (Review of DPM Operations and Performance).	Rule 3.53 (DPMs)	N/A	N	Renumbers provisions and updates cross-references and headings and updates language to read in plain English.
Rule 8.89 (Transfer of DPM Appointments).	Rule 3.53 (DPMs)	N/A	N	Moves to proposed rule to consolidate rules regarding Exchange approval, transfer review, and termination/limitation of status as DPM. Renumbers provisions and updates cross-references and headings and updates language to read in plain English. Updates certain terms to delineate between Exchange designation as a DPM and DPM appointment to a class (makes this change where applicable throughout the rules).

[4] The proposed rule change deletes Interpretation and Policy .01(b) because the Exchange already moved/consolidated participation entitlements and rates into shell Rulebook in Rule 5.32. See Securities Exchange Act Release No. 86374 (July 15, 2019), 84 FR 34963 (July 19, 2019) Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to System Connectivity and Order Entry and Allocation Upon the Migration of the Exchange's Trading Platform to the Same System Used by the Cboe Affiliated Exchanges) (SR–CBOE–2019–033). The Exchange notes that SR–CBOE–2019–003 inadvertently failed to remove Rule 8.13.01(b) when it consolidated into the shell Rulebook. The filing deleted the following provisions: Rule 8.13(c) (regarding entitlement rates for PMMs); Rule 8.15(c)–(d) (regarding participation entitlements for LMMs); Rule 8.87 (in its entirety, regarding participation entitlements for DPMs).

[5] As noted, on October 7, 2019 the Exchange's trading platform will be migrated to the same system used by the Cboe Affiliated Exchanges. The Exchange's trading system will still exist as a hybrid system but will no longer be referred to as the ''Hybrid Trading System.'' Instead, it will be defined as the ''System,'' pursuant to Rule 1.1 in the shell Rulebook, to mean ''the Exchange's hybrid trading platform that integrates electronic and open outcry trading of option contracts on the Exchange.'' The Exchange notes that the term ''Hybrid class'' is no longer relevant because as of 2018, all classes listed for trading on the Exchange now trade on the same platform (prior to that, certain classes traded on the Exchange's Hybrid 3.0 platform, while most classes traded on the Exchange's Hybrid platform), making the distinction obsolete.

Current rule	Proposed rule	Corresponding other Exchange rule	Substantive change	Description of change
Rule 8.90 (Termination, Conditioning, or Limiting Approval to Act as a DPM).	Rule 3.53 (DPMs)	N/A	N	Moves to proposed rule to consolidate rules regarding Exchange approval, transfer review, and termination/limitation of status as DPM. Renumbers provisions and updates cross-references and headings, and updates language to read in plain English.
Rule 24A.9 (FLEX Market-Maker Appointments and Obligations).	Rule 3.57 (FLEX Market-Makers).	N/A	Y: see below for further detail.	Moves current Rule 24A.9(a) to proposed rule Changes current ''FLEX Qualified Market-Makers'' to ''FLEX Market-Makers'' to harmonize language under the Market-Maker type rules to the extent possible. Removes current Rule 24A.9(b) regarding FLEX Appointed Market-Makers because the Exchange currently does not have any FLEX Appointed Market-Makers nor a participation entitlement established. To the extent the Exchange determines in the future to appoint FLEX Market-Makers as FLEX Appointed Market-Makers (or similar role) and establish a participation entitlement, the Exchange will submit a separate rule filing.

The majority of these rules are virtually identical (other than renumbering or reorganizing paragraphs, updating cross-references and headings, updating language to read in plain English, and making the types of non-substantive changes as described above), and are merely moving from the current Rulebook to the shell Rulebook. The Exchange intends to move the current rules indicated above to proposed Chapter 3, Section C (TPH Trading Functions) of the shell Rulebook in order to consolidate into one location the rules that provide for the application, approval, and removal processes for its various Market-Maker types. As indicated in the table above, the proposed change does not substantively alter the Market-Maker registration requirement provisions (current Rule 8.1(b) and Rule 8.2) but rather proposes to consolidate its current Market-Maker registration provisions into proposed Rule 3.52, which conforms its paragraphs and language to mirror that of the Affiliated Options Exchanges' corresponding rules (to the extent Affiliated Options Exchanges' have corresponding rules).

The Exchange notes that the proposed Rule 3.52 permits the Exchange to impose limits to the number of Trading Permit Holders (''THPs'') that may become Market-Makers based on a non-exhaustive list of objective factors, including system constraints and capacity restrictions. This is consistent with the corresponding rules of the Affiliated Options Exchanges.[6]

The proposed rule change removes the requirement that, at a minimum, the Exchange conduct a review of a DPM's operations or performance on an annual basis. This gives the Exchange more flexibility regarding when a full review or evaluation is warranted given the firm characteristics and infrastructure of DPM firms do not tend to change and the Exchange has various surveillances in place that, if they were to identify a lapse or failure in a DPM's compliance with its obligations, proposed Rule 3.53 allows the Exchange to initiate a review of a DPM's operations or performance at any time, as it currently may.

Proposed Rules 3.53 and 3.55 amend language under current Rule 8.83(g) and 8.15.01(c), respectively, which provide that a class in which an Off-Floor DPM and/or Off-Floor LMM has been appointed, the Exchange in its discretion may also appoint an On-Floor LMM, and, if the Exchange in its discretion determines to reallocate a class in which an Off-Floor DPM and/or Off-Floor LMM has been appointed, the On-Floor LMM appointment will automatically terminate. The proposed rules update these rules to remove automatic termination and allow for the Exchange to terminate the On-Floor LMM appointment in its discretion because the performance of an Off-Floor DPM and/or Off-Floor LMM is not connected or indicative of the performance of an On-Floor LMM that may be high performing, therefore, automatic termination would be unnecessary and disruptive to the On-Floor LMM's appointment and obligations.

The proposed rule change updates the FLEX Market-Maker approval and appointment process under proposed Rule 3.57(b). The proposed change removes the language in current Rule 24A.9(a) that provides for Exchange designation of two or more FLEX Market-Makers to each FLEX Index Option of a given class, and two or more FLEX Market-Makers to each FLEX Equity Option of a given class. The proposed change removes these provisions, as they are no longer necessary in the enhancement and maintenance of the Exchange's Market-Maker program or for FLEX classes. Instead, proposed Rule3.57(c) updates the language of current Rule 24A.9(a) in connection with FLEX appointments and Non-FLEX appointments. The current rule conditions a FLEX Market-Maker's appointment in a FLEX Index Option class or a FLEX Equity Option class on maintaining an appointment in one or more Non-FLEX Index Option classes or one or more Non-FLEX Equity Option classes, as applicable. Such Non-FLEX Option class appointment(s) need not be in a class(es) that has the same underlying index or security as the appointed FLEX Option. The proposed change updates the appointment process so that a Market-Maker approved for FLEX market-making will automatically receive an appointment in the same FLEX options class(es) as its Non-FLEX class appointments selected in relation to its general Market-Making responsibilities pursuant to proposed Rule 5.50. The proposed rule does not alter the obligations of a FLEX Market-Maker, as they will continue to be required to maintain an appointment in a Non-FLEX class. The proposed rule change simplifies the FLEX appointment process, but will continue to provide that each FLEX class will have appointed Market-Makers to provide liquidity in that class, in addition to all other market participants.

The proposed rule change deletes current Rule 8.83(b) which provides that each DPM shall have at least two DPM Designees who are nominees of the DPM. The Exchange has determined that for a DPM to maintain Trading Permits for two nominees is an unnecessary expense to a member organization designated to act as a DPM. Current Rule 3.8 requires that each member organization have at least one nominee (which, upon migration, will be referred to as a ''Responsible Person'' for TPH organizations that hold electronic Trading Permits).[7] The Exchange implemented Rule 8.83(b) in 1999 in order to ensure that a DPM is responsible for ensuring there is always a nominee available, if, for example, a nominee were to depart from the

[6] *See* C2 Rule 8.1; EDGX Options Rule 22.2; and BZX Options Rule 22.2.

[7] The Exchange will implement a rule change to current Rule 3.8 in anticipation of migration that will require a designation of a nominee only for floor-based Trading Permits. TPH organizations that hold electronic permits will be required to designate a ''Responsible Person'', who must be affiliated with the TPH. The Exchange notes that it updates this reference where applicable in the proposed rules herein this filing.

organization.[8] The Exchange notes the infrequency in which a DPM necessitated or could not provide for a ''back-up'' DPM over the last two decades and, therefore, that the benefit or protection potentially provided by this rule is far outweighed by the expense a DPM must incur to maintain two nominees. A DPM, like all member organizations, will continue to be required to maintain at least one nominee (or Responsible Person) and may choose to maintain multiple nominees (or Responsible Persons).

Market-Maker Appointments and Obligations (Proposed Chapter 5, Section D)

The proposed rule change also moves current Chapter 8 rules related to Market-Maker appointments to classes and Market-Maker obligations from the current Rulebook to Chapter 5, Section D (Market-Maker Appointments and Obligations) of the shell Rulebook as follows:

Current rule	Proposed rule	Corresponding other exchange rule	Substantive change	Description of change
Rule 8.3 (Appointment of Market-Makers).	Rule 5.50 (Market-Maker Appointments).	C2 Rule 8.2, EDGX Options Rule 22.3, BZX Options Rule 22.3.	Y: see below for further detail.	Conforms to the Affiliated Options Exchanges' corresponding rules regarding appointments to the extent necessary to adhere to existing Exchange rule text, maintain provisions specific to Cboe Options, and to account for details/descriptions included in the Exchange's Rules but not in the applicable Affiliated Options Exchanges' rules. Incorporates GTH appointment costs. Removes provisions in connection with Trading Permits as they relate to appointment costs, which is consistent with the fee schedule and Exchange functionality to be implemented upon migration. Deletes obsolete provisions and language regarding Exchange-appointed classes as the Exchange does not currently appoint and Market-Makers already choose appointments. Removes current language that refers to the creation of Virtual Trading Crowds (''VTCs'') The Exchange previously maintained two different assignment types for appointment costs, VTC and Physical Trading Crowd (''PTC'')[9] and PTC appointments have long been eliminated, therefore, there is no longer a need to discern VTC appointments; all appointments assign appointment costs in the same manner. Deletes language that allows the Exchange to group classes and make appointments to those groupings because the Exchange does not invoke these provisions and Market-Makers already select their own appointments. Deletes redundant language and provisions proposed or currently elsewhere in the rules, updates cross-references, paragraph numbering, headings, and language to read in plain English.
Rule 6.1A (Global Trading Hours), paragraph (e) (Appointments).				
Rule 8.7 (Obligations of Market-Makers).	Rule 5.51 (Market-Maker Obligations).	C2 Rule 8.5, EDGX Options Rule 22.5, BZX Options Rule 22.5.	N	Moves current Rule 8.7(a) and (b) and Interpretation and Policy .09 to proposed rule and conforms to the Affiliated Options Exchanges' rules to the extent necessary to adhere to existing Exchange rule text, maintain provisions specific to Cboe Options rules, and to account for details/descriptions included in the Exchange's Rules but not in the applicable rules of the Affiliated Options Exchanges. Removes provisions redundant of and/or already encompassed by a Market-Maker's obligation to engage in dealing to maintain fair and orderly markets. Proposed Rule 5.51(e), which provides that if the Exchange finds any substantial or continued failure by a Market-Maker to engage in a course of dealings, the Market-Maker will be subject to disciplinary action or suspension or revocation of its registration or its appointment(s), is based on and consistent with the Affiliated Exchanges' rules, as well as the Exchange's current authority to take disciplinary action for Market-Maker failure to meet its Market-Maker obligations (e.g. continuous quoting requirements).
Rule 8.7 (Obligations of Market-Makers).	Rule 5.52 (Market-Maker Quotes).	C2 Rule 8.6, EDGX Options Rule 22.6, BZX Options Rule 22.6.	Y: see below for further details.	Moves current Rule 8.7(c) and (d), as well as Interpretations and Policies .03, .05, .06, .09, .10, and .11 to proposed rule. Conforms proposed quoting obligation provisions to Affiliated Options Exchanges' quoting obligation rules (including for GTH) to the extent necessary to adhere to existing Exchange rule text, maintains provisions specific to the Exchange and to account for details/descriptions included in the Exchange's Rules but not in the applicable Affiliated Options Exchanges' rules. Moves the definition of ''continuous quoting obligations'' from current Rule 1.1 for consistency and consolidation; this includes the current two-sided quote requirement language which is incorporated into proposed Rule 5.52(c). Deletes Rule 6.1A(e)(iv), as this was related separate trading session appointments and Hybrid classes, neither will be applicable upon migration. Proposed rule does not substantively alter current obligations but rather removes redundancies and makes the quoting obligation rules easier to follow by consolidating current provisions and streamlining language (which includes removing the lengthy and potentially confusing examples under current 8.7(d)(iii); the Exchange instead currently disseminates notices with such examples, explanations, answers to FAQ, and Exchange contact information). Deletes obsolete and redundant language/provisions, updates cross-references, paragraph lettering, headings, and language to read in plain English.
Rule 1.1 (definition of ''continuous quoting obligations'').				
Rule 6.1A (Global Trading Hours), paragraph (e)(iv).				
N/A	Rule 5.53 (Good-Standing for Market-Makers).	C2 Rule 8.4, EDGX Options Rule 22.4, BZX Options Rule 22.4.	Y: see below for further details.	Proposed rule conforms to Market-Maker good standing rules of the Affiliated Options Exchanges.

[8] *See* Securities and Exchange Act No. 41325 (April 22, 1999), 64 FR 23691 (May 3, 1999) (Notice of Filing of Proposed Rule Change by the Chicago Board Options Exchange, Inc. To Update and Reorganize Its Rules Relating to Designated Primary Market-Makers) (SR–CBOE–98–54).

[9] *See* Securities Exchange Act Release No. 51371 (March 15, 2005), 70 FR 13557 (March 21, 2005) (Notice of Filing of Proposed Rule Change by the Chicago Board Options Exchange, Incorporated To Amend CBOE Rule 8.4 To Remove the Physical Trading Crowd Appointment Alternative for Remote Market-Makers and To Create an ''A+'' Tier Consisting of the Two Most Actively-Traded Products on the Exchange) (SR–CBOE–2005–23).

[10] The Exchange intends to move Interpretation and Policy .01 and .01(c) to proposed Rule 4.14 of the shell Rulebook at a later date in anticipation of migration.

[11] The Exchange intends to move Interpretation and Policy .01 and .01(c) to proposed Rule 4.14 of the shell Rulebook at a later date in anticipation of migration.

Current rule	Proposed rule	Corresponding other exchange rule	Substantive change	Description of change
Rule 8.13 (Preferred Market-Makers).	Rule 5.56 (PMMs) ..	C2 Rule 8.6, EDGX Options 22.6, BZX Options 22.6.	Y: update of the time-to-expiration language for certain series excluded is the only substantive change made; described below.	Moves current 8.13(b)–(d) and Interpretations and Policies .01(a) through .04 to proposed rule. Codifies that PMM obligations are applicable only during Regular Trading Hours, which is currently the manner in which they apply. Updates the language in current Rule 8.13 to clarify that receipt of PMM orders is the point in time when a PMM receives an entitlement (i.e. after being preferred on an order), this is currently that manner in which receipt functions. Conforms time-to-expiration-language for series excluded to the Affiliated Options time-to-expiration (i.e. from 9 months to 270 days). Renumbers provisions, changes headings, and updates cross-references and language to read in plain English.
Rule 8.14 (Hybrid Trading System Platforms & Market-Maker Participants).	Rule 5.50 (Market-Maker Appointments) paragraph (l).	Consistent with EDGX Options Rule 22.2(c)*.	Y: see below for further details.	Moves current Rule 8.14 to proposed paragraph (l).[10] Removes current Rule 8.14(a) as it is no longer necessary because all classes now trade on the System (Hybrid Trading System). Removes conditions in current paragraph (b) for Exchange designation of classes without a DPM/LMM and updates rule language to reflect this change.
Rule 8.15 (Lead Market-Makers).	Rule 5.55 (LMMs) ..	N/A	N	Moves current 8.15(b)–(d) and Interpretations and Policies .02—.04 to proposed rule, deletes certain provisions redundant of Market-Maker obligations under proposed Rule 5.52 (current Rule 8.7, to which a LMM must already comply). Codifies that LMM obligations are applicable only during Regular Trading Hours, which is the current manner in which LMM obligations already apply. Renumbers provisions and updates cross-references and headings, and language to read in plain English. Moves current Rule 6.1A(iii)(B) to Rule 6.1A to proposed 5.55(b).
Rule 6.1A (Global Trading Hours), paragraph (iii)(B).				
Rule 8.84 (Conditions on the Allocations of Securities to DPMs).	Rule 5.50 (Market-Maker Appointments).	N/A	N	Moves current rule to proposed 5.50(k), Interpretation and Policy .02 to 5.50(i)(5), and deletes current Interpretation and Policy .01(b) because it is redundant of an existing provision in current Rule 8.95 with which current Rule 8.84 is being consolidated with in proposed Rule 5.50. Renumbers provisions and updates cross-references and headings, and language to read in plain English.
Rule 8.85 DPM Obligations.	Rule 5.54 (DPMs) ..	N/A	Y: see below for further details.	Moves current rule, including Interpretations and Policies, to proposed rule. Codifies that DPM obligations are applicable only during Regular Trading Hours, which is the current manner in which DPM obligations already apply. Removes segregation of account requirements for DPM-related transactions. Deletes current 8.85(a)(ii) which states obligations redundant of those in 8.85(a)(i). Deletes Rule 8.85(a)(iii) which is redundant of Market-Maker obligations under proposed rule 5.52 (current Rule 8.7, to which a DPM must already comply). Changes ''Exchange committee to ''Exchange'' as the Exchange, rather than a specific committee, requires DPM Designees. Renumbers provisions and updates cross-references and headings and language to read in plain English
Rule 8.95 (Allocation of Securities and Location of Trading Crowds and DPMs).	Rule 5.50 (Market-Maker Appointments).	N/A	N	Deletes Interpretation and Policy .04 which would be redundant of Rule 8.84, also being consolidated into proposed Rule 5.50. Deletes current 8.95(j) and Interpretation and Policy .03, which is obsolete as it refers to classes open for trading prior to 1987. Renumbers provisions and updates headings and cross-references and language to read in plain English.
Rule 21.19 (Obligations of Market-Makers (Treasury Bonds and Notes)).	N/A	C2 Rule 8.6, EDGX Options Rule 22.6, BZX Options Rule 22.6.	N	Deletes current rule (which covers bid/ask requirements for government securities) to align with proposed no bid/ask requirement, which is consistent with the Affiliated Options Exchanges. In addition, the Exchange delisted government securities in 2011, therefore, Market-Maker obligations in such classes are no longer relevant.
Rule 22.14 (Maximum Bid-Ask Differentials; Market-Maker Appointments & Obligations).	N/A	N/A	N	Deletes current rule (which covers bid/ask requirements for binary options) to align with proposed no bid/ask requirement, which is consistent with the Affiliated Options Exchanges. In addition, the Exchange delisted binary options in 2015, therefore, Market-Maker obligations in such classes are no longer relevant.
29.17 (Market-Maker Appointments & Obligations).	N/A	N/A	N	Deletes current rule, which provides for certain Market-Making obligations in relation to Credit Option classes as the Exchange delisted Credit Options in 2014, therefore, this provision is no longer relevant to the current or proposed Market-Maker program.
Rule 24A.9 (FLEX Market-Maker Appointments and Obligations).	Rule 5.57 (FLEX Market-Makers).	N/A	N	Moves current Rule 21A.9(d) and (e) to proposed rule. Removes current Rule 21A.9(c) regarding FLEX Appointed Market-Maker obligations because the Exchange currently does not have any FLEX Appointed Market-Makers. To the extent the Exchange determines in the future to have FLEX Appointed Market-Makers in place, the Exchange will submit a separate rule filing. Updates cross-references, heading, and language to read in plain English.
Rule 8.7 (Obligations of Market-Makers).	Rule 5.51 (Market-Maker Obligations).	C2 Rule 8.5, EDGX Options Rule 22.5, BZX Options Rule 22.5.	N	Moves current Rule 8.7(a) and (b) and Interpretation and Policy .09 to proposed rule and conforms to the Affiliated Options Exchanges' rules to the extent necessary to adhere to existing Exchange rule text, maintain provisions specific to Cboe Options rules, and to account for details/descriptions included in the Exchange's Rules but not in the applicable rules of the Affiliated Options Exchanges. Removes provisions redundant of and/or already encompassed by a Market-Maker's obligation to engage in dealing to maintain fair and orderly markets. Proposed Rule 5.51(e), which provides that if the Exchange finds any substantial or continued failure by a Market-Maker to engage in a course of dealings, the Market-Maker will be subject to disciplinary action or suspension or revocation of its registration or its appointment(s), is based on and consistent with the Affiliated Exchanges' rules, as well as the Exchange's current authority to take disciplinary action for Market-Maker failure to meet its Market-Maker obligations (e.g. continuous quoting requirements).

Current rule	Proposed rule	Corresponding other exchange rule	Substantive change	Description of change
Rule 8.7 (Obligations of Market-Makers).	Rule 5.52 (Market-Maker Quotes).	C2 Rule 8.6, EDGX Options Rule 22.6, BZX Options Rule 22.6.	Y: see below for further details.	Moves current Rule 8.7(c) and (d), as well as Interpretations and Policies .03, .05, .06, .09, .10, and .11 to proposed rule. Conforms proposed quoting obligation provisions to Affiliated Options Exchanges' quoting obligation rules (including for GTH) to the extent necessary to adhere to existing Exchange rule text, maintains provisions specific to the Exchange and to account for details/descriptions included in the Exchange's Rules but not in the applicable the Affiliated Options Exchanges' rules. Moves the definition of ''continuous quoting obligations'' from current Rule 1.1 for consistency and consolidation; this includes the current two-sided quote requirement language which is incorporated into proposed Rule 5.52(c). Deletes Rule 6.1A(e)(iv), as this was related separate trading session appointments and Hybrid classes, neither will be applicable upon migration. Proposed rule does not substantively alter current obligations but rather removes redundancies and makes the quoting obligation rules easier to follow by consolidating current provisions and streamlining language (which includes removing the lengthy and potentially confusing examples under current 8.7(d)(iii); the Exchange instead currently disseminates notices with such examples, explanations, answers to FAQ, and Exchange contact information). Deletes obsolete and redundant language/provisions, updates cross-references, paragraph lettering, headings, and language to read in plain English.
Rule 1.1 (definition of ''continuous quoting obligations'').				
Rule 6.1A (Global Trading Hours), paragraph (e)(iv).				
N/A	Rule 5.53 (Good-Standing for Market-Makers).	C2 Rule 8.4, EDGX Options Rule 22.4, BZX Options Rule 22.4.	Y: see below for further details.	Proposed rule conforms to Market-Maker good standing rules of the Affiliated Options Exchanges.
Rule 8.13 (Preferred Market-Makers).	Rule 5.56 (PMMs)	C2 Rule 8.6, EDGX Options 22.6, BZX Options 22.6.	Y: update of the time-to-expiration language for certain series excluded is the only substantive change made; described below..	Moves current 8.13(b)–(d) and Interpretations and Policies .01(a) through .04 to proposed rule. Codifies that PMM obligations are applicable only during Regular Trading Hours, which is currently the manner in which they apply. Updates the language in current Rule 8.13 to clarify that receipt of PMM orders is the point in time when a PMM receives an entitlement (i.e. after being preferred on an order), this is currently that manner in which receipt functions. Conforms time-to-expiration-language for series excluded to the Affiliated Options time-to-expiration (i.e. from 9 months to 270 days). Renumbers provisions, changes headings, and updates cross-references and language to read in plain English.
Rule 8.14 (Hybrid Trading System Platforms & Market-Maker Participants).	Rule 5.50 (Market-Maker Appointments) paragraph (l).	Consistent with EDGX Options Rule 22.2(c)*.	Y: see below for further details.	Moves current Rule 8.14 to proposed paragraph (l).[11] Removes current Rule 8.14(a) as it is no longer necessary because all classes now trade on the System (Hybrid Trading System). Removes conditions in current paragraph (b) for Exchange designation of classes without a DPM/LMM and updates rule language to reflect this change.
Rule 8.15 (Lead Market-Makers).	Rule 5.55 (LMMs)	N/A	N	Moves current 8.15(b)–(d) and Interpretations and Policies .02—.04 to proposed rule, deletes certain provisions redundant of Market-Maker obligations under proposed Rule 5.52 (current Rule 8.7, to which a LMM must already comply).Codifies that LMM obligations are applicable only during Regular Trading Hours, which is the current manner in which LMM obligations already apply. Renumbers provisions and updates cross-references and headings, and language to read in plain English. Moves current Rule 6.1A(iii)(B) to Rule 6.1A to proposed 5.55(b).
Rule 6.1A (Global Trading Hours), paragraph (iii)(B).				
Rule 8.84 (Conditions on the Allocations of Securities to DPMs).	Rule 5.50 (Market-Maker Appointments).	N/A	N	Moves current rule to proposed 5.50(k), Interpretation and Policy .02 to 5.50(i)(5), and deletes current Interpretation and Policy .01(b) because it is redundant of an existing provision in current Rule 8.95 with which current Rule 8.84 is being consolidated with in proposed Rule 5.50. Renumbers provisions and updates cross-references and headings, and language to read in plain English.
Rule 8.85 DPM Obligations.	Rule 5.54 (DPMs)	N/A	Y: see below for further details.	Moves current rule, including Interpretations and Policies, to proposed rule. Codifies that DPM obligations are applicable only during Regular Trading Hours, which is the current manner in which DPM obligations already apply. Removes segregation of account requirements for DPM-related transactions. Deletes current 8.85(a)(ii) which states obligations redundant of those in 8.85(a)(i). Deletes Rule 8.85(a)(iii) which is redundant of Market-Maker obligations under proposed rule 5.52 (current Rule 8.7, to which a DPM must already comply). Changes ''Exchange committee to ''Exchange'' as the Exchange, rather than a specific committee, requires DPM Designees. Renumbers provisions and updates cross-references and headings and language to read in plain English
Rule 8.95 (Allocation of Securities and Location of Trading Crowds and DPMs).	Rule 5.50 (Market-Maker Appointments).	N/A	N	Deletes Interpretation and Policy .04 which would be redundant of Rule 8.84, also being consolidated into proposed Rule 5.50. Deletes current 8.95(j) and Interpretation and Policy .03, which is obsolete as it refers to classes open for trading prior to 1987. Renumbers provisions and updates headings and cross-references and language to read in plain English.
Rule 21.19 (Obligations of Market-Makers (Treasury Bonds and Notes)).	N/A	C2 Rule 8.6, EDGX Options Rule 22.6, BZX Options Rule 22.6.	N	Deletes current rule (which covers bid/ask requirements for government securities) to align with proposed no bid/ask requirement, which is consistent with the Affiliated Options Exchanges. In addition, the Exchange delisted government securities in 2011, therefore, Market-Maker obligations in such classes are no longer relevant.
Rule 22.14 (Maximum Bid-Ask Differentials; Market-Maker Appointments & Obligations).	N/A	N/A	N	Deletes current rule (which covers bid/ask requirements for binary options) to align with proposed no bid/ask requirement, which is consistent with the Affiliated Options Exchanges. In addition, the Exchange delisted binary options in 2015, therefore, Market-Maker obligations in such classes are no longer relevant.
29.17 (Market-Maker Appointments & Obligations).	N/A	N/A	N	Deletes current rule, which provides for certain Market-Making obligations in relation to Credit Option classes as the Exchange delisted Credit Options in 2014, therefore, this provision is no longer relevant to the current or proposed Market-Maker program.

Current rule	Proposed rule	Corresponding other exchange rule	Substantive change	Description of change
Rule 24A.9 (FLEX Market-Maker Appointments and Obligations).	Rule 5.57 (FLEX Market-Makers).	N/A	N	Moves current Rule 21A.9(d) and (e) to proposed rule. Removes current Rule 21A.9(c) regarding FLEX Appointed Market-Maker obligations because the Exchange currently does not have any FLEX Appointed Market-Makers. To the extent the Exchange determines in the future to have FLEX Appointed Market-Makers in place, the Exchange will submit a separate rule filing. Updates cross-references, heading, and language to read in plain English.

As indicated above, many of the proposed rules are virtually identical (other than updating the rule text to plain English, updating cross-references, revising headings renumbering provisions, and, where applicable, deleting duplicative provisions as a result of consolidation, and making other types of non-substantive changes described above) and are merely moving from the current Rulebook to the shell Rulebook.

Proposed Rule 5.50 (Market-Maker Appointments)

Proposed Rule 5.50 consolidates rules under current Chapter 8 in connection with class appointments, which includes appointment costs and class appointments to DPMs and Trading Crowds. Below describes in more detail the substantive changes proposed:

Proposed Rule 5.50(a) provides that a registered Market-Maker may select class appointments to make markets in those classes during all trading sessions, *i.e.* Regular Trading Hours (''RTH'') [12] and Global Trading Hours (''GTH'') [13]. Particularly, this proposed change removes current language, which provides that a Market-Maker may select class appointments in one or more trading sessions in order to harmonize its rules and processes with the Affiliate Options Exchanges, which allow for a Market-Maker selected class appointment that apply to classes during all trading sessions.[14] In other words, if a Market-Maker selects an appointment in Cboe Volatility Index (''VIX'') options, which series are open for trading during GTH and RTH, that appointment would apply during both trading sessions (and thus, the Market-Maker would have an appointment to make markets in VIX during both GTH and RTH). As a result, a Market-Maker continuous quoting obligations set forth in proposed Rule 5.52(d) (current Rule 8.7(d)) would apply to the class for an entire trading day. A Market-Maker with appointments in either GTH or RTH is required to provide continuous quotes in at least 60% of the series [15] for 90% of the time it is quoting in those classes.[16] The Exchange notes that a Market-Maker's continuous obligations will continue to function in this manner, therefore, the extension of obligations to appointed classes to trading sessions will have a de minimis, if any, impact on a Market-Maker's continuous quoting obligations, as they may continue to choose when to actively quote and have their obligations to their appointed classes apply.

Proposed 5.50(b) states that a Market-Maker may enter an appointment request via an Exchange-approved electronic interface with the Exchange's systems by 2:30 a.m.[17] for ''All Sessions'' [18] classes, that is an option class the Exchange lists for trading during both GTH and RTH., which appointment becomes effective on the open of the Global Trading session, or by 9:00 a.m. for classes traded during Regular Trading Hours, which appointment becomes effective on the open of the Regular Trading session. Market-Makers already request appointments via an Exchange-approved electronic interface, therefore this proposed rule merely codifies the existing request process.[19] This is consistent with the corresponding rules of the Affiliated Options Exchanges,[20] but is amended to provide Market-Makers with flexibility regarding appointments between its two trading sessions, which are different in scope than those of the Affiliate Options Exchanges.

The proposed rule change (proposed Rule 5.50(g)(1)) also deletes language in current Rule 8.3(c)(iv) that allows for only 1.0 appointment cost and one tier appointment per Trading Permit, as well as rule language relevant to this limitation. In anticipation of migration, the Exchange intends to update and simplify its fee schedule, and a Market-Maker firm will need only one Market-Making Trading Permit, regardless of the number of classes in which it chooses to have appointments.[21] Upon migration, a Market-Maker firm will only be required to have one permit and will be charged for one or more ''Appointment Units'' (which will scale from 1 ''unit'' to more than 5 ''units''), depending on which classes they elect appointments. Appointment Units will replace the standard 1.0 appointment cost, but function in the same manner. Appointment weights (which, in the proposed rule, replaces the term ''appointment costs'', but these terms are equivalent) for each appointed class will be summed for each Market-Maker in order to determine the total appointment units, to which fees will be assessed. This is the current manner in which the tier costs per class appointment are summed to meet the 1.0 appointment cost, the only difference will be that if a Market-Maker exceeds this ''unit'' then their fees will be assessed under the ''unit'' that corresponds to the total of their appointment weights, as opposed to holding another Trading Permit because it exceeded the 1.0 ''unit''. The proposed rule also updates some of the appointment costs (and updates this term to reflect ''appointment weights'' in line with the fees schedule for migration) in order to align with the rebalanced Appointment Units upon migration. The proposed change is intended to provide for a more straightforward and efficient administration of the appointment unit process as it will remove the more burdensome process in obtaining Trading Permits and replace it with a simple, scaled appointment unit regime (which is reflective of the same scaled regimes Market-Makers are accustomed to within the Exchange's fees schedule). The Exchange believes that by making the appointment unit process less burdensome for Market-Makers, the proposed rule may potentially incentivize more market-making across classes.

The proposed rule change removes the condition in current Rule 8.14(b) that the Exchange may only designate classes to not have a DPM or LMM if

[12] From 8.30 a.m. CT to 3:15 p.m. CT.

[13] From 2:00 a.m. CT to 8:15 a.m. CT.

[14] *See* C2 Rule 8.2; EDGX Options Rule 22.3; and BZX Options Rule 22.3. The Exchange notes that GTH session on the Affiliated Options Exchanges occurs from 7:30 a.m. CT to 8:15 a.m. CT.

[15] Proposed Rule 5.52(d) (current Rule 8.7(d).

[16] Proposed Rule 5.52(d) (current Rule 1.1).

[17] All times are Eastern Time pursuant to Rule 1.6 in shell Rulebook.

[18] *See* Rule 1.1 in the shell Rulebook.

[19] *See* Cboe Release No. C2019071600 (2019), available at *http://cdn.cboe.com/resources/release_notes/2019/Quarterly-Rebalance-of-Option-Class-Tiers-and-Online-Appointment-System-Q2–2019.pdf*

[20] *See* C2 Rule 8.2; EDGX Options Rule 22.3; and BZX Options Rule 22.3.

[21] *See* Exchange Notice C2019081900 (August 19, 2019). Also, the Exchange intends to propose this change to the Fees Schedule in a separate rule filing.

there are at least four Market-Makers quoting in the class that are subject to the continuous quoting obligations. When the Exchange implemented this condition, there were a limited number of classes trading on the Hybrid System and this condition was designed, at that time, to enhance the Exchange's Market-Making program in the select classes trading on Hybrid, which was relatively new to the Exchange. As discussed above, all classes now trade on the System (*i.e.* Hybrid), and Market-Makers select their own appointments which adequately cover all classes of options necessitating market-making liquidity. In addition to this, proposed Rule 5.52(g) (current Rule 8.7(d)(iv)) allows for the Exchange to call on a Market-Maker to submit a single quote or maintain continuous quotes in one or more series of a Market-Maker's appointed class whenever, in the judgment of the Exchange, it is necessary to do so in the interest of maintaining a fair and orderly market. The Exchange believes these rules provide for sufficient liquidity in classes trading on the Exchange. Also, the proposed change is consistent with the rules of EDGX Options, which currently has a DPM program and lists many of the same classes. Pursuant to EDGX Options rules, it may choose to appoint one DPM per class, yet its rules do not obligate it to do so, nor do they require for a requisite number of Market-Makers when EDGX does not choose to appoint a DPM to a class.[22]

Proposed Rules Regarding Market-Maker Obligations

The Exchange notes that the proposed rules in connection with Market-Marker obligations (presented in the table above) largely make non-substantive changes to update and simplify the rules by reorganizing and consolidating provisions, simplifying language, updating language to plain English and removing redundancies. For example, and as indicated in the table above, proposed Rule 5.51 only makes non-substantive changes to the rule governing a Market-Maker's general obligations (current Rule 8.7, in part), most of which remove redundant provisions that are already covered under the umbrella of a Market-Maker's obligation to engage in dealing to maintain fair and orderly markets. The proposed rules make only a few substantive changes to Market-Maker's obligations. The following provides an overview of the proposed substantive changes being made to the obligations for Market-Maker and Market-Maker types (which are described in further detail in the sections below):

- Adds exceptions under proposed Rule 5.52(a) to the current requirement (under current Rule 8.51)[23] that a Market-Maker's quotes must be firm. These are consistent with the exceptions to the firm quote requirement for Market-Makers on the Affiliated Options Exchanges.
- Amends language throughout proposed Rule 5.52 to reflect that a Market-Maker's current continuous quoting requirements (*i.e.,* 90% of the time a Market-Maker is quoting in its appointed classes) in 60% of the series of the Market-Maker's appointed classes will now apply to all trading sessions (GTH and RTH). As indicated in the table above, the 90% continuous quoting requirement in 60% of appointed classes is currently the quoting requirement for Market-Makers. The proposed rule change does not alter this continuous electronic quoting obligation but merely incorporates the definition of continuous electronic quotes into this proposed rule, as opposed to having this term defined elsewhere in the Rules, as it is currently. The Exchange notes that DPMs, PMMs, and LMMs will also continue to have the same electronic quoting requirements which will continue to apply only during RTH, as they currently do.
- Updates the series excluded from a Market-Maker's continuous quoting obligations under proposed 5.52(d)(2), including: Amending the exclusion of ''9-month'' series to ''270-day series'' (and makes this proposed change where applicable throughout the rules); and adding that any intra-day add-on series on the day during which such series are added for trading and any Quarterly Options series are excluded from the continuous quoting obligation. The Exchange notes that it does not propose to add these series to be excluded from PMM, DPM, and LMM obligations.
- Removes the quote width requirements (current Rule 8.7(d)(i)(A) and (ii)(A), Rule 21.19, and Rule 22.14). This is consistent with the Market-Maker quoting requirements on the Affiliated Options Exchanges.
- Adds proposed Rule 5.53 which governs good standing for Market-Makers and is consistent with rules of the Affiliated Options Exchanges.
- Removes the requirement under proposed Rule 5.54 that DPMs must segregate in a manner prescribed by the Exchange (*i.e.* segregated accounts) transaction made in a DPM capacity from other transactions/activity.

Proposed Rule 5.52 (Market-Maker Quotes)

Proposed Rule 5.52 consolidates overall the Market-Maker quoting obligations and amends obligations to 1) include quoting obligations under the Affiliated Options Exchanges' rules, and 2) update current quoting obligations to be consistent, the extent possible to maintain Exchange specific requirements, with the quoting obligations of the Affiliated Options Exchanges. The Exchange notes that, as proposed, a Market-Maker's obligations will be substantially similar to its current obligations.

Proposed Rule 5.52(a) provides for the firm quote obligation for Market-Makers pursuant to Rule 602 of Regulation NMS, to which Market-Makers must already comply pursuant to current Rule 8.51 (Firm Disseminated Market Quotes).[24] Proposed Rule 5.52(a) mirrors the firm quoting provision for Market-Makers under the rules of the Affiliated Options Exchanges, and adds exceptions to firm quotes that are the same as the exceptions under corresponding rules of the Affiliated Options Exchanges.[25] These proposed exceptions to a Market Maker's firm quote include system malfunction, unusual market conditions, and quotes during the pre-open.

Proposed Rule 5.52(d)(2), regarding continuous electronic quoting requirements incorporates obligations to appointed classes to the entire trading day (*i.e.,* GTH and RTH, which is described in detail above) by removing or updating language that refers to ''Regular Trading Hours'' and ''per trading session'' and its amends its list of series of excluded from a Market-Maker's continuous quoting obligation to incorporates the exclusion of any intra-day add-on series on the day during which such series are added for trading and any Quarterly Options series. This exclusion is consistent with corresponding rules of the Affiliated Options Exchanges.[26] As stated above,

[22] *See* EDGX Options Rule 22.2(c).

[23] The Exchange notes that current Rule 8.51, which governs Firm Disseminated Market Quotes will be maintained as is, and continue to apply to Market-Makers, but will be moved to the shell Rulebook at a later date.

[24] See supra note 25.

[25] *See* C2 Rule 8.6; EDGX Options Rule 22.6; BZX Options Rule 22.6.

[26] *Id; see also* Securities Exchange Act Release No. 71129 (December 18, 2013), 78 FR 77736 (December 18, 2013) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Modify BATS Options Market Maker Continuous Quoting Obligation Rules) (SR–BATS–2013–062), which adopted exclusions, including Quarterly Options series, to Market Maker's quoting obligations and noted that such exclusions were ''consistent with the rules of several other options exchanges'' and ''did not diminish the quoting

proposed Rule 5.52(d)(2) also amends the current quoting exclusion of any series with an expiration of nine months or greater to an expiration of greater than 270 days, which is consistent with the time-to-expiration language for the same exclusion under the Affiliated Options Exchanges' rules. The Exchange notes that Market Makers generally already monitor expirations by a defined count of 270 days, as opposed to a nine month count in which the number of days continuously varies. Therefore, this proposed change aligns the Exchange's rules with current industry practice already in place on the Affiliated Options Exchanges. The Exchange also applied this change in the PMM obligation rule (the only other location in the Market-Maker rules which refers to 9-month series), proposed Rule 5.56.

The proposed rule change also removes the quote width requirements under current Rule 8.7(d)(i)(A) and (d)(ii)(A)), as well as reference to such determined quote widths throughout the proposed rules, including those for SPX, Interpretation and Policy .08 regarding bid/ask determinations for indexes, and current Rule 24A.9(e). This is consistent with the corresponding rules of the Affiliated Options Exchanges [27] and the manner in which Market-Makers on those exchanges are required to quote many of the same classes as Market-Makers on the Exchange. The Exchange notes that currently the quote width requirement for generally all classes is $10, however, Market-Makers consistently maintain two-sided quotes that are much tighter than the required width. Indeed, even if markets are experiencing period of stress or volatility, pursuant to proposed Rule 5.51 (current Rule 8.7), Market-Makers remain obligated to maintain two sided markets and engage in a course of dealings that must be reasonable calculated to contribute to the maintenance of a fair and orderly market, which includes refraining from making bids or offers that are inconsistent with such course of dealings and updating quotations in response to changed market conditions. The Exchange may take disciplinary action against any substantial or continued failure of these obligations. Therefore, the Exchange does not believe that the continuing to provide for a quote width requirement is necessary nor will it impact the maintenance of fair and orderly markets because Market-Makers already quote at a bid/ask spread much narrower than the requirements and are required to continuously fulfill their obligations to engage in a course of dealings reasonably calculated to contribute to the maintenance of a fair and orderly market. The Exchange also notes that under proposed Rule 5.51 (current Rule 8.7), in connection with a Market-Maker's obligations to maintain fair and orderly markets, it may not make bids or offers inconsistent with this requirement, and, if the Exchange finds any substantial or continued failure by a Market-Maker regarding this requirement, the Market-Maker will be subject to disciplinary action or suspension or revocation of its registration or appointment(s). As such, Market-Makers must continue to submit quotes in accordance with this standard.

The Exchange also notes a proposed non-substantive change (not presented in the table above) to delete the language under current 8.7(d) which provides that Market-Makers remain subject to all obligations imposed by current Rule 8.7, and, to the extent another obligation contained elsewhere in current Rule 8.7 is inconsistent with an obligation contained in current paragraph (d) of Rule 8.7 (*i.e.,* continuous quoting obligations) with respect to a class, current paragraph (d) shall govern. The Affiliated Options Exchanges' corresponding rules do not provide for the same, as a Market-Maker is expected to uphold all obligations under the rules and in no circumstance circumvent its other, equally important obligations (*e.g.,* constituting a course of dealings reasonably calculated to contribute to the maintenance of a fair and orderly market) in order to continuously quote. Therefore, this proposed change will not impact a Market-Maker's obligations under any of the rules, but instead is designed to ensure that a Market-Maker upholds each of its obligations. The proposed change conforms the Exchange's rules to the Affiliated Options Exchanges' rules. Similarly, the proposed rule change removes Interpretation and Policy .02, which states that the obligations of a Market-Maker with respect to those classes of option contracts to which the Market-Maker holds an Appointment shall take precedence over his other Market-Maker obligations. The Exchange notes that a Market-Maker's obligations only pertain to its appointed classes, which renders this provision unnecessary. This is also consistent with the quoting obligation provisions of the Affiliated Options Exchanges.

Proposed Rule 5.53 (Good Standing for Market-Makers)

Proposed Rule 5.53, which covers good standing for Market-Makers, is identical to the corresponding rules of the Affiliated Options Exchange.[28] The Exchange currently does not have a similar, consolidated rule that covers good standing for Market-Makers. This change is designed to harmonize Market-Maker requirements across the Exchange and the Affiliated Options Exchanges which provide clear requirements for Market-Makers to maintain good standing as a Market-Maker. The proposed rule states that for a Market-Maker to remain in good standing, a Market-Maker must: (1) Continue to meet the requirements established in Exchange Act Rule 15c3–1(a)(6)(i), the general requirements for Trading Permit Holders set forth in Chapter 3 of the Rules (as proposed), and the Market-Maker requirements set forth in Chapter 5 of the Rules (as proposed); (2) comply with the Rules as well as the Rules of the Clearing Corporation and the Federal Reserve Board; and (3) pay on a timely basis such participation, transaction, and other fees as the Exchange prescribes. The rule also provides that the Exchange may suspend or terminate a Trading Permit Holder's registration as a Market-Maker or a Market-Maker's appointment to a class, or otherwise withdraw the good standing of a Market-Maker as provided in the Rules, if the Market-Maker ceases to maintain any of these conditions for approval or violates any of its agreements with the Exchange or any of the provisions of the Rules. The proposed rule does not impose any new obligations or requirements for Market-Makers but are merely provides for the standards, currently in place under other rules or regulations, for which the Exchange may measure a Market-Maker's good standing.

Proposed Rule 5.54 (DPMs)

The proposed rule deletes current Rule 8.85(a)(vi), which states that a DPM must segregate in a manner prescribed by the Exchange all transactions consummated by the DPM in securities allocated to the DPM and any other transactions consummated by or on behalf of the DPM that are related to the DPM's DPM business, and current Rule 8.85(c)(v), which states the DPM shall segregate in a manner prescribed by the Exchange the DPM's business and activities as a DPM from the DPM's other businesses and activities (*i.e.* segregated accounts for DPM-related

obligation''. The Exchange also notes that these exclusions were adopted on EDGX Options when that exchange was established.

[27] *See supra* note 27.

[28] *See* C2 Rule 8.4; EDGX Options Rule 22.4; and BZX Options Rule 22.4.

transactions from the firm's general Market-Maker accounts or accounts in relation to other trading activities or capacities). This is consistent with EDGX Options Rules (which, of the Affiliated Options Exchanges, also has DPMs), which do not require DPMs to maintain segregated accounts for that of their general Market Maker or other trading activities. These provisions were implemented in the past to ensure the financial stability of, then, newly formed small DPM firms. Today, DPMs now need larger financial infrastructure to trade as a DPM and the Exchange determines if firms are appropriately situated act as a DPM pursuant to proposed Rule 3.53 (current Rule 8.83) by considering, among other things, the firms' adequacy of capital and operational capacity. This reduces the risk that a DPM's financial integrity would be adversely impacted by financial losses that may be incurred by the DPM in connection with its other businesses and activities.[29] Finally, the proposed rule change removes current paragraph (e) regarding Trading Permits per appointment costs, in line with the changes made to the overall Market-Maker appointment costs and assignments under proposed Rule 5.50 (described in detail above).

Miscellaneous Market-Maker Rules

Current rule	Proposed rule	Corresponding other exchange rule	Substantive change	Description of change
Rule 8.8 (Restriction on Acting as Market-Maker and Floor Broker).	Rule 8.25 (Restriction on Acting as Market-Maker and Floor Broker).	N/A	N	None (aside from updating cross-references).
Rule 8.9 (Securities Accounts and Orders of Market-Makers).	Rule 7.6 (Securities Accounts and Orders of Market-Makers).	C2 Rule 8.7, EDGX Options Rule 22.7, BZX Options Rule 22.7.	N	Conforms to corresponding rules of the Affiliated Options Exchanges (including Interpretation and Policy .01 to BZX/EDGX Rule 22.7). Maintains provisions specific to Cboe Options rules. Deletes redundancies, including those provisions already covered under other Rules (e.g. Rule 6.55.03), updates language to read in plain English
Rule 8.10 (Financial Arrangements of Market-Makers).	Rule 11.6(b) (Market-Maker Financial Requirements).	N/A	N	None.
Rule 8.17 (Stopping of Option Order).	Rule 5.58 (Stopping of Option Orders) of Section D (Market-Maker Appointments and Obligations).	N/A	N	None.
Rule 8.60 (Evaluation of Trading Crowd Performance).	N/A	N/A	N: however, see below for further details.	Removes current rule which is no longer in practice by the Exchange and unnecessary given the authority of the Exchange to evaluate and determine satisfactory Market-Maker performance and fulfillment of obligations, as well as authority to take disciplinary action for failure to satisfy Market-Maker requirements through various other Exchange rules.
Rule 8.80 (DPM Defined)	Rule 1.1	N/A	N	Replaces reference to Rule 8.1 in current Rule 1.1 with current Rule 8.1 language which defines a DPM.
Rule 8.86 (DPM Financial Requirements).	Rule 11.6 (Financial Arrangements of Market-Makers).	C2 Rule 8.8	Y: see below for further details.	Moves to proposed Rule 11.6(a) and removes the $100,000 net liquidating equity requirement as it is no longer applicable to the current DPM and marketplace structures. Conforms Rule 11.6(a) to corresponding C2 rule. The Market-Maker language covers all Maker-Maker types, thus DPMs.

Proposed Deletion of Current Rule 8.60

The proposed rule change deletes current Rule 8.60 which provides for the Exchange evaluation of trading crowd performance. The current rule provides that the Exchange periodically evaluate the performance of DPMs, Market-Makers, and other Trading Permit Holders both individually and collectively as trading crowds in order to determine whether they are satisfactorily meeting their market responsibilities. The Exchange may do so by means of a survey, and, if the Exchange finds that such participant has failed to satisfy its Market-Making requirements then the Exchange may, among other things, suspend, terminate or restrict registration or appointment to a class or classes, reallocate (*i.e.* reappoint, as proposed) class(es) or restrict allocation of classes, and so on, and give notice and an opportunity for a market participant to have a formal hearing or informal hearing, depending on the action under consideration. The proposed rule change deletes current Rule 8.60 as it is no longer implemented by the Exchange. The Exchange does not take such surveys or make determinations pursuant to Rule 8.60 because the Exchange exercises its authority under other rules to ensure that Market-Makers (and Market-Maker types) fulfil their Market-Making requirements, and to take appropriate disciplinary actions for a participant's failure to do so. The Exchange may make the same determinations and take action against a participant for failing to meet their respective Market-Maker obligations under the current rules (moved to proposed Rules 3.53, 5.50, 5.51, 5.52, 5.53, 5.54, 5.55, and 5.56). Moreover, the Exchange must follow the notice provision to terminate or condition a participant's approval to act as a DPM under proposed Rule 3.53, as well as the notice and proceeding requirements for disciplinary actions under Chapter 17. Because the Exchange does not take surveys or make determinations under Rule 8.60, and instead, currently ensures that participants fulfill their respective Market-Making requirements pursuant to multiple other rules, the proposed rule change does not alter the manner in which the Exchange determines whether Market-Making requirements are met nor the actions and procedures necessary to discipline a participant for failure of such obligations. The proposed rule change merely removes a rule that is not essential to the function and continuity of the Exchange and its Market-Maker program.

Proposed Rule 11.6

The proposed rule change moves current Rule 8.86 to proposed Rule 11.6(a) and removes the $100,000 net liquidating equity requirement as it is no longer applicable to current DPM structures. This is consistent with corresponding C2 Rule 8.8. Current Rule 8.86 was enacted (almost 20 years ago) to ensure the financial stability of newly formed, small DPM firms who were not previously net capital computing firms, as a number of small firms were not net capital computing based on an exemption (*i.e.,* the ''(b)(1) exemption'') in Exchange Act Rule 15c3–1. However, due to changes in the market and, as stated above, the large infrastructure

[29] The Exchange also already surveils for a firm's DPM requirements by DPM-specific acronyms and firm IDs.

now needed to trade as a DPM, in which the Exchange determines if appropriately situated to act as a DPM pursuant to proposed Rule 3.53 (current Rule 8.83), the number of firms who can be a DPM has decreased significantly and the size of DPM firms, including their adequacy of capital and operational capacity, has increased significantly. As a result, current DPMs have capital well beyond the $100,000 net liquidating requirement, which eliminates the need for the Exchange to surveil for compliance with this requirement and will enable the Exchange to better allocate its surveillance resources, focusing on enhanced surveillance in connection with Exchange rules permitting, requiring, or prohibiting liquidation and rules requiring liquidation in a reasonable and orderly fashion.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[30] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [31] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [32] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the proposed rule changes are generally intended to add or align certain system functionality currently offered by the Exchange and the Cboe Affiliated Exchanges (specifically, the Affiliated Options Exchanges) in order to provide a consistent technology offering for the Cboe Affiliated Exchanges. A consistent technology offering, in turn, will simplify the technology implementation, changes and maintenance by Exchange participants that are also participants on the Affiliated Options Exchanges. The proposed rule change does not propose to implement new or unique functionality that has not been previously filed with the Commission or is not available on the Affiliated Options Exchanges. The Exchange notes that many of the proposed changes are generally based on rules of the Affiliated Options Exchanges and differ only to the extent necessary to conform to the Exchange's current rules, retain intended differences unique to Cboe Options market-model, functionality and/or rule text and not applicable to the Affiliated Options Exchanges. Where applicable,[33] the Exchange has substantively mirrored the Affiliated Options Exchange rules or certain Market-Maker requirement language within the Affiliated Options Exchange rules, because consistent rules will simplify the regulatory requirements and increase the understanding of the Exchange's operations for TPHs that are also participants on the Cboe Affiliated Options Exchanges. The Exchange notes that the proposed changes to make its rules consistent with the Affiliated Options Exchange's rule do not impose new or novel obligations for Market-Makers or does not differ from the Exchange's current authority over Market-Makers; the proposed rules based on the Affiliated Options Exchanges' rules are substantially similar to the current rules. The proposed rule change would provide greater harmonization between the rules of the Cboe Affiliated Exchanges, resulting in greater uniformity, bolstered collective understanding of the Exchange's rules and the Affiliated Options Exchanges for participants, and less burdensome and more efficient regulatory compliance. As such, the proposed rule change would foster cooperation and coordination with persons engaged in facilitating transactions in securities and would remove impediments to and perfect the mechanism of a free and open market and a national market system.

The proposed change to harmonize the Exchange's rules and processes with the Affiliate Options Exchanges by allowing a Market-Maker to select class appointments that apply to classes during all trading sessions, thus applying Market-Maker obligations across all trading sessions, will remove impediments to and perfect the mechanism of a free and open market and a national market system by harmonizing the application of appointments with that of the Affiliated Options Exchange rules. The application class appointments to all trading sessions will not have an impact of the protection of investors or cause any additional burden to Market-Maker's because a Market-Maker's continuous obligations will continue to apply only when quoting in their appointed classes, therefore, the proposed change will have negligible, if any, impact on a Market-Maker's continuous quoting obligations as they may continue to choose when to actively quote and have their obligations to their appointed classes apply.

The proposed changes to the appointment cost provisions (both in connection with Market-Makers, generally, and DPMs) will remove impediments to and perfect the mechanism of a free and open market and national market system because it will provide rules for investor that accurately reflect the structure of the Exchange's fees schedule upon migration.[34] Furthermore, the Exchange believes that the proposed change will serve to incentivize more market-making across classes as Market-Makers will no longer be limited to a 1.0 appointment cost or having to acquire additional Trading Permits to select appointments in more classes, thereby benefitting all market participants.

The proposed change to remove the condition that a requisite number of Market-Makers where the Exchange determines to designate a class without a DPM or LMM removes impediments to and perfects the mechanism of a free and open market and national market system and, in general, protects investors, because it is consistent with the rules of EDGX Options (previously filed with the Commission) which also has a DPM program and lists many of the same classes. The Exchange believes that the current condition to this determination is no longer necessary given that all classes now trade on the System (*i.e.* Hybrid) and its Market-Maker program has grown to adequately cover the classes that necessitate market-maker liquidity. In addition to this, the rules allow for the Exchange to appropriately address the case where further market-making in a class might be needed. Therefore, the Exchange believes that the proposed change will not have any significant impact on the trading of classes and functions of the Exchange.

The Exchange also believes that by making Market-Maker obligations consistent, to the extent possible while

[30] 15 U.S.C. 78f(b).

[31] 15 U.S.C. 78f(b)(5).

[32] *Id.*

[33] Proposed Rules 3.52, 5.50, 5.51, 5.52, 5.53, 5.56, 7.6, and 11.6.

[34] *See supra* note 23.

maintaining Exchange specific rule text and obligations, with those of the Affiliated Options Exchanges the proposed rule change fosters cooperation and coordination with persons engaged in facilitating transactions in securities, as well as removes impediments to and perfects the mechanism of a free and open market and national market system. The Exchange notes that the proposed changes to the Market-Maker obligation provisions are substantially similar to the current obligations, therefore will have de minimus impact on market participants. The proposed changes do not alter the authority and/or discretion of the Exchange in connection with Market-Makers, significantly alter the obligations of Market-Makers, nor impose any significant additional burden. Instead, the Exchange believes the changes will result in greater uniformity for Market-Maker obligations across the Exchange and its affiliates, thereby bolstering participants' collective understanding of Market-Maker obligations across the affiliated exchanges and resulting in less burdensome regulatory compliance.

In particular, the Exchange believes the proposed rule change to amend certain provisions in connection with a Market Makers' quoting obligations will remove impediments to and perfect the mechanism of a free and open market and a national market system. By conforming the quoting obligations, to the extent possible to maintain differences unique to the Exchange, to that of the Affiliated Options Exchange rules, the proposed change will remove impediments to and perfect the mechanism of a free and open market and national market system. As stated, the proposed rules in connection with Market-Marker obligations largely make non-substantive changes to update and simplify the rules by reorganizing and consolidating provisions, simplifying language, updating language to plain English and removing redundancies. For example, proposed Rule 5.51 makes only non-substantive changes to the rule governing a Market-Maker's general obligations, most of which remove redundant provisions that are already covered under the umbrella of a Market-Maker's obligation to engage in dealing to maintain fair and orderly markets. The proposed substantive changes that harmonize Market-Maker obligations with those of the Affiliated Options Exchange include adding exclusions to a Market-Maker's the firm quote requirement, removing the quote width requirement, adding certain series excluded from continuous quoting obligations, conforming the series expiration of 9 months to the 270-day period, adding provision governing good standing for Market-Makers, and removing the requirement that DPMs maintain segregated accounts for DPM-related transactions (addressed in the paragraph below). These proposed changes are reasonable and do not affect investor protection because the proposed changes do not present any novel or unique issues, as they have been previously filed with the Commission. Market-Makers continue to comply with the firm quote requirement under current Rule 8.51 and Rule 602 of Regulation NMS and the proposed exceptions to a Market-Maker's firm quote are consistent with the rules of the Affiliated Options Exchanges and remove impediments to and perfect the mechanism of a free and open market and national market system by providing exceptions to firm quotes with malfunctions and unusual market conditions arise. The proposed change from the 9 month expiration time to the 270 expiration time is an industry practice currently in place, as Market-Makers generally already monitor expirations by a defined count of 270 days, as opposed to a nine month count in which the number of days continuously varies. In addition, Market-Makers on the Affiliated Options Exchanges quote in many of the same classes available on the Exchange but do not have a bid/ask requirement when quoting on those exchanges. The Exchange notes that removing this requirement will not impact market participants because Market-Maker's already submit two-sided quotes consistently at a much tighter spread than the Exchange-determined quote widths and Market-Makers are obliged to continue to engage in dealings that maintain a fair and orderly market. The proposed rule providing for good standing requirements for Market-Makers will serve to protect investors because it provides under a single rule the requirements, which are already in place pursuant to the rules and regulations, that the Exchange will refer to in order to determine if a Market-Maker is fit to continue making markets on the Exchange. This rule mirrors that of the Affiliated Options Exchanges' corresponding rules.

The Exchange believes that the proposed updates to certain provisions of the DPM requirements, overall, serve to remove impediments to and perfect the mechanism of a free and open national market system. The proposed change to remove the requirement that each DPM has at least two Designees who are nominees of the DPM removes an unnecessary compliance burden for DPMs for which the cost of maintaining two designees far outweighs the benefit, if any, of the rule. Further, like all member organizations a DPM will continue to be required to maintain at least one nominee and may choose to maintain multiple nominees. The proposed removal of the net DPM liquidation requirement and the requirement that a firm segregate accounts between DPM-related transactions and that of its general Market-Maker account or accounts related to other trading activities or capacities requirement will also lift a compliance burden for DPMs as these provisions are no longer necessary to ensure financial integrity or to mitigate losses given the current financial status and infrastructure of DPMs. As stated, the Exchange determines if a DPM has the adequacy of capital and operational capacity necessary to perform and take on the potential risks as a DPM.

The Exchange believes that removing the designation of two Market-Makers in FLEX classes and instead automatically appointing FLEX class appointments when a Market-Maker (approved for FLEX) selects an appointment in the same Non-FLEX class will not alter the obligations of a FLEX Market-Maker, as they will continue to be required to maintain an appointment in a Non-FLEX class, which will then automatically appoint them the FLEX class. The proposed rule change removes impediments to and perfects the mechanism of a free and open market and national market system by simplifying the FLEX appointment process through the automatic FLEX class appointments in connection with a Market-Maker's selection of class appointments for its general Market-Making requirements, and continuing to ensure that each FLEX class will have appointed Market-Makers to provide liquidity in that class, in addition to all other market participants.

The proposed change to allow the Exchange the discretion to terminate an On-Floor LMM (as opposed to automatic termination) when it decides to terminate the Off-Floor DPM and/or Off-Floor LMM in that class will serve to remove impediments to and perfect the mechanism of a free and open market and national market system by allowing an On-Floor LMM that may be high performing to continue its appointment in that class instead of disrupting the On-Floor LMM's appointment and obligations by automatic termination.

The proposed removal of the rule relating to the Exchange's evaluation of a trading crowd performance removes a

rule that is no longer in practice by the Exchange as the Exchange's evaluation, determinations, and ability to sanction Market-Makers and Market-Maker types are currently implemented under various other Market-Maker related rules.

The Exchange believes the proposed reorganization of Rules to move all Rules that relate to Market-Makers and Market-Maker types, including: (1) Related to registration (as well as approvals, eligibility, termination, etc.) and general Market-Maker functions; (2) Market-Maker appointments; (3) Market-Maker obligations and entitlements; and 4) other rules in connection with Market-Makers under the same chapters, will also benefit investors and remove impediments to and perfect the mechanism of a free and open market and a national market system. The majority of the changes in the proposed rule change move rules from the current Rulebook to the shell Rulebook with no substantive changes. Indeed, many of the proposed non-substantive changes removes impediments to and perfects the mechanism of a free and open market and national market system by providing up-to-date rules that accurately reflect the manner in which the Exchange, its Market-Maker program, and its market participants currently function by removing provisions that are not invoked by the Exchange or currently in practice by its participants and are not necessary to, nor impact, the Exchange's Market-Maker program, which protects investors by providing accurate and up-to-date rules. The proposed non-substantive changes to the Rules also provide additional detail in the rule regarding current functionality, make the Rules more plain English, update cross-references and paragraph lettering and numbering, delete duplicative or unnecessary language and language that is no longer applicable to the current functions of the Exchange, simplify and streamline rule language, and update terms to provide consistency throughout the proposed Market-Maker rules, all of which benefits investors. The Exchange believes these changes and transparency the proposed changes provide will protect investors, as they provide more clarity and reduce complexity within the Rules, making the rule easier to understand and comply with.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe the proposed rule change will impose any burden on intramarket competition, as they will apply to all potential Market-Makers and Market-Maker types (*i.e.* applicants), and all Market-Makers and Market-Maker types in the same manner. The Exchange reiterates that a majority of the proposed rule change is intended to harmonize the Exchange rules with that of the Affiliated Options Exchanges' rules. Thus, the Exchange believes this proposed rule change will reduce the burden on Exchange participants by providing consistent rules among the affiliated exchanges upon migration. Such proposed rule changes in this filing conform to the approved rules of the Affiliated Options Exchanges, which have already been filed with the Commission. In addition to this, the Exchange does not believes that the other proposed changes will impose any burden on intramarket competition because such changes serve to update and remove provisions or requirements that are no longer necessary in the function and maintenance of the Exchange and its Market-Maker program, or are already ensured and/or implemented via other rules of the Exchange. As such, these proposed changes will not impose any burden on intramarket competition, but rather, will serve to relieve certain compliance burdens for Market-Makers or surveillance burdens for the Exchange, which will make available more market-making resources to allocate toward classes that may need and consume more liquidity, or more enhanced surveillance resources to monitor for Market-Maker compliance, including general obligations, quoting obligations, and account maintenance.

The Exchange does not believe the proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act, because majority of the proposed change to the Market-Maker rules (*i.e.,* registration, appointments, good standing, general obligations, and quoting obligations) is based on the rules of the Affiliated Options Exchange, previously filed with the Commission. The Exchange also notes that to the degree that other exchanges have varying obligations for Market-Makers, market participants on other exchanges are welcome to become Market-Makers on the Exchange if they determine that this proposed rule change has made market making on Cboe Options more attractive or favorable. The proposed changes to the rules that reflect functionality that will be in place come October 7, 2019, will not impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act but rather provide clear, accurate rules for market participants surrounding the completion of migration.

The proposed non-substantive changes are not intended to have any impact on competition, as they do not impact trading on Cboe Options.

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

Because the foregoing rule 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 if consistent with the protection of investors and the public interest, provided that the self-regulatory organization has given 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,[35] the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[36] and Rule 19b–4(f)(6) thereunder.[37]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

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.

[35] The Exchange has fulfilled this requirement.

[36] 15 U.S.C. 78s(b)(3)(A).

[37] 17 CFR 240.19b–4(f)(6).

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–CBOE–2019–059 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–CBOE–2019–059. 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–CBOE–2019–059 and should be submitted on or before October 16, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[38]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–20698 Filed 9–24–19; 8:45 am]

BILLING CODE 8011–01–P

[38] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

Privacy Act of 1974; System of Records

AGENCY: U.S. Small Business Administration.

ACTION: Notice of a Modified System of Records.

SUMMARY: The U.S. Small Business Administration (SBA) proposes to update a system of records titled, Veteran Programs Training and Counseling Records (SBA 39), to its inventory of records systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended. Publication of this notice complies with the Privacy Act and the Office of Management and Budget (OMB) Circular A–130 requirement for agencies to publish a notice in the **Federal Register** whenever the agency establishes a new system of records. The SBA's Office of Veterans Business Development (OVBD) manages grant programs related to the counseling and training services for veterans. The OVBD maintains a System of Records including include registration forms, participant/client surveys, interviews, resource partner surveys, which includes personal information such as name, gender, race, ethnicity, service, and pay grade, which are used to analyze the population of veterans who are seeking training.

DATES: Submit comments on or before October 25, 2019. This revised system will be effective upon publication.

FOR FURTHER INFORMATION CONTACT: Martin Williams, Veterans Affairs Specialist, 409 3rd Street SW, Suite 5700 Washington, DC 20416.

ADDRESSES: Submit written comments to Martin Williams, Veterans Affairs Specialist, 409 3rd Street SW, Suite 5700 Washington, DC 20416.

SUPPLEMENTARY INFORMATION: A system of records is a group of any records under the control of a Federal agency from which information is retrieved by the name of an individual or by a number, symbol or other identifier assigned to the individual. The Privacy Act, 5 U.S.C. 552a, requires each Federal agency to publish in the **Federal Register** a system of records notice (SORN) identifying and describing each system of records the agency maintains, the purposes for which the agency uses the personally identifiable information (PII) in the system, the routine uses for which the agency discloses such information outside the agency, and how individuals can exercise their rights related to their PII information. The SBA's Office of Veterans Business Development (OVBD) manages grant programs related to the counseling and training services for veterans, National Guard & Reserve members, transitioning service members, military spouses and their dependents. These services include the Boots to Business & Boots to Business Reboot Programs, Veterans Business Outreach Center Program, Women Veteran Entrepreneurship Program, Service-Disabled Veteran Entrepreneurship Training Program and the Veteran Federal Procurement Entrepreneurship Training Program. VBOCs, and other OVBD grantees, implement SBA's Veterans programs and initiatives as authorized by section 32 of the Small Business Act (15 U.S.C. 657b). In order to measure program performance, implement standardized outreach efforts and register participants for training/counseling, information is collected through various methods. These methods include registration forms, participant/client surveys, interviews, resource partner surveys, and data obtained through data sharing agreements with other Federal agencies. Collected information is used to analyze the population of veterans who are seeking entrepreneurial training, identify trends among participants, facilitate communication between the Office of Veterans Business Development and training/counseling participants, and to evaluate the performance of the OVBD programs.

SYSTEM NAME AND NUMBER:

Veteran Programs Training and Counseling Records (SBA 39).

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

SBA Headquarters, 409 3rd Street SW, Washington, DC 20416.

SYSTEM MANAGER(S):

Martin Williams, Veterans Affairs Specialist, 409 3rd Street SW, Suite 5700, Washington, DC 20416, 202–205–6157.

. . .

CATEGORIES OF RECORDS IN THE SYSTEM:

The records in this system include:

1. Course data.
2. Personal Data (Last Name, First Name, Middle Name, Date of Birth, Post-separation email, Post-separation phone number).
3. Military Service data (DoD ID Number, Grade, Service, Component, Guard/Reserve Status, Military Installation, Anticipated Separation Date).
4. Demographics (Gender, Race, Ethnicity).

5. Previous business ownership experience data.

6. Transition Assistance Program data (eForm Sequence ID, opt-in Federal Agencies, Additional Entrepreneurship Track Training—Selection, Additional Entrepreneurship Track Training—Completion Date, Pre-Separation Service Member Signature date, eForm last change date).

7. Course/counseling/training survey Data.

8. Economic Impact Data (Jobs Created, Capital Infusion, Revenue Growth, Government Contract Awards, etc.).

RECORD SOURCE CATEGORIES:

Information contained within this system is obtained from:

1. Individuals covered by this system of records (*e.g.,* transitioning service member, veterans, dependents)

2. SBA Resource Partners

3. The Defense Enrollment Eligibility Reporting System (DEERS)

4. The Defense Manpower Data Center (DMDC)

. . .

HISTORY:

Veteran Programs Training and Counseling Records, published October 27, 2015 at 80 FR 65,843 (*https://www.govinfo.gov/content/pkg/FR-2015-10-27/pdf/2015-27257.pdf*).

Dated: September 19, 2019.

Martin Williams,

Veterans Affairs Specialist, Office of Veterans Business Development.

[FR Doc. 2019–20687 Filed 9–24–19; 8:45 am]

BILLING CODE 8026–03–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #16131 and #16132; ILLINOIS Disaster Number IL–00057]

Presidential Declaration of a Major Disaster for Public Assistance Only for the State of Illinois

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of Illinois (FEMA–4461–DR), dated 09/19/2019.

Incident: Severe Storms and Flooding.

Incident Period: 02/24/2019 through 07/03/2019.

DATES: Issued on 09/19/2019.

Physical Loan Application Deadline Date: 11/18/2019.

Economic Injury (EIDL) Loan Application Deadline Date: 06/19/2020.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 09/19/2019, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Adams, Alexander, Bureau, Calhoun, Carroll, Cass, Fulton, Greene, Hancock, Henderson, Henry, Jackson, Jersey, Knox, Madison, Mercer, Monroe, Morgan, Pike, Randolph, Rock Island, Saint Clair, Schuyler, Scott, Stephenson, Union, and Whiteside

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations with Credit Available Elsewhere ...	2.750
Non-Profit Organizations without Credit Available Elsewhere	2.750
For Economic Injury:	
Non-Profit Organizations without Credit Available Elsewhere	2.750

The number assigned to this disaster for physical damage is 161316 and for economic injury is 161320.

(Catalog of Federal Domestic Assistance Number 59008)

James Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2019–20860 Filed 9–24–19; 8:45 am]

BILLING CODE 8026–03–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #16133 and #16134; LOUISIANA Disaster Number LA–00097]

Presidential Declaration of a Major Disaster for Public Assistance Only for the State of Louisiana

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of Louisiana (FEMA–4462–DR), dated 09/19/2019.

Incident: Flooding.

Incident Period: 05/10/2019 through 07/24/2019.

DATES: Issued on 09/19/2019.

Physical Loan Application Deadline Date: 11/18/2019.

Economic Injury (EIDL) Loan Application Deadline Date: 06/19/2020.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 09/19/2019, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Parishes: Assumption, Caldwell, Catahoula, Concordia, East Carroll, Franklin, Iberville, Ouachita, Pointe Coupee, Rapides, Saint Martin, Terrebonne, West Feliciana

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations with Credit Available Elsewhere ...	2.750
Non-Profit Organizations without Credit Available Elsewhere	2.750
For Economic Injury:	
Non-Profit Organizations without Credit Available Elsewhere	2.750

The number assigned to this disaster for physical damage is 161336 and for economic injury is 161340.

(Catalog of Federal Domestic Assistance Number 59008)

James Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2019–20859 Filed 9–24–19; 8:45 am]

BILLING CODE 8026–03–P

DEPARTMENT OF STATE

[Public Notice: 10902]

Notice of Determinations; Culturally Significant Objects Imported for Exhibition—Determinations: ''Marino Marini: Arcadian Nudes'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects to be included in the exhibition ''Marino Marini: Arcadian Nudes,'' imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at the Center for Italian Modern Art, New York, New York, from on or about October 17, 2019, until on or about June 13, 2020, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Chi D. Tran, Paralegal Specialist, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, and Delegation of Authority No. 236–3 of August 28, 2000.

Marie Therese Porter Royce,

Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2019–20771 Filed 9–24–19; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 10908]

Notice of Open Meeting of Advisory Committee on International Law

A meeting of the Department of State's Advisory Committee on International Law will take place on Friday, October 18, 2019, from 9:30 a.m. to 5:00 p.m. at the George Washington University Law School, Michael K. Young Faculty Conference Center, 716 20th St. NW, 5th Floor, Washington, DC. Acting Legal Adviser Marik String will chair the meeting, which will be open to the public up to the capacity of the meeting room. It is anticipated that the meeting will include discussions on privileges and immunities for international organizations, International Criminal Court reform, and the role of states in the development and interpretation of international law.

Members of the public who wish to attend should contact the Office of the Legal Adviser by October 11 at *welcherar@state.gov* or 202–647–1646 and provide their name, professional affiliation, address, and phone number. A valid photo ID is required for admission to the meeting. Attendees who require reasonable accommodation should make their requests by October 9. Requests received after that date will be considered but might not be possible to accommodate.

Alison Welcher,

Executive Director, Advisory Committee on International Law, Department of State.

[FR Doc. 2019–20807 Filed 9–24–19; 8:45 am]

BILLING CODE 4710–08–P

DEPARTMENT OF STATE

[Public Notice:10903]

Notice of Determinations; Culturally Significant Objects Imported for Exhibition—Determinations: ''The Pencil is a Key: Drawings by Incarcerated Artists'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects to be included in the exhibition ''The Pencil is a Key: Drawings by Incarcerated Artists,'' imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to a loan agreement with the foreign owner or custodian. I also determine that the exhibition or display of the exhibit objects at The Drawing Center, New York, New York, from on or about October 11, 2019, until on or about January 5, 2020, at the Museum of Contemporary Art, Cleveland, in Cleveland, Ohio, from on or about June 5, 2020, until on or about September 6, 2020, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Chi D. Tran, Paralegal Specialist, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, and Delegation of Authority No. 236–3 of August 28, 2000.

Marie Therese Porter Royce,

Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2019–20772 Filed 9–24–19; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: #10904]

Notice of Determinations; Culturally Significant Objects Imported for Exhibition—Determinations: ''Berthe Morisot: Impressionist Original'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects to be included in the exhibition ''Berthe Morisot: Impressionist Original,'' imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at The Museum of Fine Arts, Houston, in Houston, Texas, from on or about October 20, 2019, until on or about January 12, 2020, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Chi D. Tran, Paralegal Specialist, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order

12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, and Delegation of Authority No. 236–3 of August 28, 2000.

Marie Therese Porter Royce,

Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2019–20773 Filed 9–24–19; 8:45 am]

BILLING CODE 4710–05–P

SURFACE TRANSPORTATION BOARD

[Docket No. EP 670 (Sub-No. 3)]

Renewal of Rail Energy Transportation Advisory Committee

AGENCY: Surface Transportation Board.

ACTION: Notice of intent to renew charter.

SUMMARY: In accordance with the Federal Advisory Committee Act, notice is hereby given that the Surface Transportation Board (Board) intends to renew the charter of the Rail Energy Transportation Advisory Committee (RETAC).

ADDRESSES: A copy of the charter is available on the Board's website at *https://www.stb.gov/stb/rail/retac.html.*

FOR FURTHER INFORMATION CONTACT: Kristen Nunnally, Designated Federal Officer, at (202) 245–0312. Assistance for the hearing impaired is available through the Federal Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: RETAC was established by the Board on September 24, 2007, to provide advice and guidance to the Board, on a continuing basis, and to provide a forum for the discussion of emerging issues and concerns regarding the transportation by rail of energy resources, including, but not necessarily limited to, coal and biofuels (such as ethanol), and petroleum. RETAC functions solely as an advisory body and complies with the provisions of the Federal Advisory Committee Act (FACA), 5 U.S.C. app., and its implementing regulations.

RETAC consists of approximately 25 voting members, excluding the governmental representatives. The membership comprises a balanced representation of individuals experienced in issues affecting the transportation of energy resources, including no fewer than: 5 representatives from the Class I railroads; 3 representatives from Class II and III railroads; 3 representatives from coal producers; 5 representatives from electric utilities (including at least one rural electric cooperative and one state- or municipally-owned utility); 4 representatives from biofuel feedstock growers or providers, and biofuel refiners, processors, and distributors; 2 representatives from private car owners, car lessors, or car manufacturers; and, 1 representative from the petroleum shipping industry. The Committee may also include up to 2 members with relevant experience but not necessarily affiliated with one of the aforementioned industries or sectors. All voting members of the Committee serve in a representative capacity on behalf of their respective industry or stakeholder group. The Board Members are *ex officio* (non-voting) members of RETAC. Representatives from the U.S. Departments of Agriculture, Energy, and Transportation; and the Federal Energy Regulatory Commission may be invited to serve on the Committee in an advisory capacity as *ex officio* (non-voting) members.

RETAC meets at least twice a year, and meetings are open to the public, consistent with the Government in the Sunshine Act, Public Law 94–409 (1976).

Further information about RETAC is available on the Board's website (*https://www.stb.gov/stb/rail/retac.html*) and at the General Services Administration's FACA database (*https://facadatabase.gov/*).

Decided: September 20, 2019.

By the Board, Allison C. Davis, Director, Office of Proceedings.

Regena Smith-Bernard,

Clearance Clerk.

[FR Doc. 2019–20805 Filed 9–24–19; 8:45 am]

BILLING CODE 4915–01–P

SURFACE TRANSPORTATION BOARD

[Docket No. EP 290 (Sub-No. 5) (2019–4)]

Quarterly Rail Cost Adjustment Factor

AGENCY: Surface Transportation Board.

ACTION: Approval of rail cost adjustment factor.

SUMMARY: The Board approves the fourth quarter 2019 Rail Cost Adjustment Factor (RCAF) and cost index filed by the Association of American Railroads. The fourth quarter 2019 RCAF (Unadjusted) is 1.075. The fourth quarter 2019 RCAF (Adjusted) is 0.454. The fourth quarter 2019 RCAF–5 is 0.427.

DATES: *Applicable:* October 1, 2019.

FOR FURTHER INFORMATION CONTACT: Pedro Ramirez at (202) 245–0333. Assistance for the hearing impaired is available through Federal Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: The Board's decision is posted at *http://www.stb.gov.* Copies of the decision may be purchased by contacting the Office of Public Assistance, Governmental Affairs, and Compliance at (202) 245–0238.

Decided: September 19, 2019.

By the Board, Board Members Begeman, Fuchs, and Oberman.

Raina Contee,

Clearance Clerk.

[FR Doc. 2019–20794 Filed 9–24–19; 8:45 am]

BILLING CODE 4915–01–P

SURFACE TRANSPORTATION BOARD

[Docket No. EP 519 (Sub-No. 5)]

Renewal of National Grain Car Council

AGENCY: Surface Transportation Board.

ACTION: Notice of intent to renew charter.

SUMMARY: In accordance with the Federal Advisory Committee Act, notice is hereby given that the Surface Transportation Board (Board) intends to renew the charter of the National Grain Car Council (NGCC).

ADDRESSES: A copy of the charter is available on the Board's website at *https://www.stb.gov/stb/rail/graincar_council.html.*

FOR FURTHER INFORMATION CONTACT: Michael Small, Designated Federal Officer, at (202) 245–0381. Assistance for the hearing impaired is available through the Federal Relay Service at (800) 8778339.

SUPPLEMENTARY INFORMATION: The NGCC functions as a continuing working group to facilitate private-sector solutions and recommendations to the Board on matters affecting grain transportation. The NGCC functions solely as an advisory body and complies with the provisions of the Federal Advisory Committee Act (FACA), 5 U.S.C. app., and its implementing regulations.

The NGCC consists of approximately 42 members, excluding the governmental representatives. The membership comprises a balanced representation of individuals knowledgeable in the transportation of grain, including no fewer than 14 members from the Class I railroads (one marketing and one car management representative from each Class I), 7 representatives from Class II and III carriers, 14 representatives from grain shippers and receivers, and 7

representatives from private car owners and car manufacturers. The members of the Board are *ex officio* (non-voting) members of the NGCC, and the Vice Chairman of the Board is designated as Co-Chairman of the NGCC.

The NGCC meets at least annually, and meetings are open to the public, consistent with the Government in the Sunshine Act, Public Law 94–409 (1976).

Further information about the NGCC is available on the Board's website (*https://www.stb.gov/stb/rail/graincar_council.html*) and at the General Services Administration's FACA database (*https://facadatabase.gov/*).

Decided: September 20, 2019.

By the Board, Allison C. Davis, Director, Office of Proceedings.

Kenyatta Clay,

Clearance Clerk.

[FR Doc. 2019–20786 Filed 9–24–19; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0586]

Agency Information Collection Activity Under OMB Review: Department of Veterans Affairs Acquisition Regulation (VAAR) Clause 852.211–72, Technical Industry Standards

AGENCY: Office of Acquisition and Logistics, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Office of Acquisition and Logistics, Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

DATES: Comments must be submitted on or before October 25, 2019.

ADDRESSES: Submit written comments on the collection of information through *www.Regulations.gov*, or to Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: VA Desk Officer; 725 17th St. NW, Washington, DC 20503 or send through electronic mail to *oira_submission@omb.eop.gov.* Please refer to ''OMB Control No. 2900–0586'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Danny S. Green, Office of Quality, Performance and Risk (OQPR), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, (202) 421–1354 or email *danny.green2@va.gov.* Please refer to ''OMB Control No. 2900–0586'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Authority: 44 U.S.C. 3501–21.

Title: Department of Veterans Affairs Acquisition Regulation (VAAR) Clause 852.211–72, Technical Industry Standards.

OMB Control Number: 2900–0586.

Type of Review: Extension of a currently approved information collection.

Abstract: This Paperwork Reduction Act (PRA) submission seeks renewal with changes of Office of Management and Budget (OMB) approval No. 2900–0586 as follows: Due to the decreased number of respondents, the total annual burden hours decreased by 666, from 1,225 to 559. However, the average burden time per response has not changed.

VAAR clause 852.211–72, Technical Industry Standards, requires that items offered for sale to VA under the solicitation conform to certain technical industry standards, such as United States Department of Agriculture (USDA) or the USDA Institutional Meat Purchase Specifications (IMPS) and that the contractor furnish evidence to VA that the items meet that requirement. The evidence is normally in the form of a tag or seal affixed to the item, such as a label on beef product. In most cases, this requires no additional effort on the part of the contractor, as the items come from the factory with the tags already in place, as part of the manufacturer's standard manufacturing operation. Occasionally, for items not already meeting standards or for items not previously tested, a contractor will have to furnish a certificate from an acceptable laboratory certifying that the items furnished have been tested in accordance with, and conform to, the specified standards. Only firms whose products have not previously been tested to ensure the products meet the industry standards required under the solicitation and contract will be required to submit a separate certificate. The information will be used to ensure that the items being purchased meet minimum safety standards and to protect VA employees, VA beneficiaries, and the public.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 84 FR 29285 on June 21, 2019.

Affected Public: Business or other for-profit and not-for-profit institutions.

Estimated Annual Burden: 559 Burden Hours.

Estimated Average Burden Per Respondent: 30 Minutes.

Frequency of Response: One per bid or offer received.

Estimated Number of Respondents: 1,118.

By direction of the Secretary:

Danny S. Green,

Interim VA Clearance Officer, Office of Quality, Performance and Risk, Department of Veterans Affairs.

[FR Doc. 2019–20722 Filed 9–24–19; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Loan Guaranty: Assistance to Eligible Individuals in Acquiring Specially Adapted Housing; Cost-of-Construction Index

AGENCY: Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: VA announces that the aggregate amounts of assistance available under the Specially Adapted Housing (SAH) grant program will increase by 5.51 percent for Fiscal Year (FY) 2020.

DATES: The increases in aggregate amounts are effective October 1, 2019.

FOR FURTHER INFORMATION CONTACT: Jason Latona, Chief, Specially Adapted Housing, Loan Guaranty Service (262C), Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, (202) 461–9201. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: In accordance with 38 United States Code (U.S.C) 2102(e), 38 U.S.C. 2102A(b)(2), 38 U.S.C. 2102B(b)(2), and 38 Code of Federal Regulations (CFR) 36.4411, the Secretary of Veterans Affairs announces for FY 2020 the aggregate amounts of assistance available to veterans and Servicemembers eligible for SAH program grants.

Section 2102(e)(2) authorizes the Secretary to increase the aggregate amounts of SAH assistance annually based on a residential home cost-of-construction index. Per 38 CFR 36.4411(a), the Secretary uses the

Turner Building Cost Index for this purpose.

In the most recent quarter for which the Turner Building Cost Index is available, 2nd Quarter 2019, the index showed an increase of 5.51 percent over the index value listed by 2nd Quarter 2018. Turner Construction Company, Cost Index, *http://www.turnerconstruction.com/cost-index* (last visited Aug. 7, 2019). Pursuant to 38 CFR 36.4411(a), therefore, the aggregate amounts of assistance for SAH grants made pursuant to 38 U.S.C. 2101(a) and 2101(b) will increase by 5.51 percent for FY 2020.

Sections 2102A(b)(2) and 2102B(b)(2) require the Secretary to apply the same percentage calculated pursuant to section 2102(e) to grants authorized pursuant to sections 2102A and 2102B. As such, the maximum amount of assistance available under these grants will also increase by 5.51 percent for FY 2020.

The increases are effective as of October 1, 2019. 38 U.S.C. 2102(e), 2102A(b)(2), and 38 U.S.C. 2102B(b)(2).

Specially Adapted Housing: Aggregate Amounts of Assistance Available During Fiscal Year 2020

Section 2101(a) Grants and Temporary Residence Adaptation (TRA) Grants

Effective October 1, 2019, the aggregate amount of assistance available for SAH grants made pursuant to 38 U.S.C. 2101(a) will be $90,364 during FY 2020. The maximum TRA grant made to an individual who satisfies the eligibility criteria under 38 U.S.C. 2101(a) and 2102A will be $39,669 during FY 2020.

Section 2101(b) Grants and TRA Grants

Effective as of October 1, 2019, the aggregate amount of assistance available for SAH grants made pursuant to 38 U.S.C. 2101(b) will be $18,074 during FY 2020. The maximum TRA grant made to an individual who satisfies the eligibility criteria under 38 U.S.C. 2101(b) and 2102A will be $7,083 during FY 2020.

Section 2102B Grants

Effective as of October 1, 2019, the amount of assistance available for SAH grants made pursuant to 38 U.S.C. 2102B will be $90,364 during FY 2020; however, the Secretary may waive this limitation for a veteran if the Secretary determines a waiver is necessary for the rehabilitation program of the veteran.

Signing Authority

The Secretary of Veterans Affairs approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Pamela Powers, Chief of Staff, Department of Veterans Affairs, approved this document on September 17, 2019, for publication.

Dated: September 19, 2019.

Jeffrey M. Martin,

Assistant Director, Office of Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.

[FR Doc. 2019–20728 Filed 9–24–19; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

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Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 1100, 1107 and 1114

Premarket Tobacco Product Applications and Recordkeeping Requirements; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1100, 1107, and 1114

[Docket No. FDA–2019–N–2854]

RIN 0910–AH44

Premarket Tobacco Product Applications and Recordkeeping Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a proposed rule that would set forth requirements for premarket tobacco product applications (PMTAs) and would require manufacturers to maintain records establishing that their tobacco products are legally marketed. The proposed rule would help to ensure that PMTAs contain sufficient information for FDA to determine whether a marketing order should be issued for a new tobacco product, including detailed information regarding the physical aspects of a tobacco product, as well as full reports of information to demonstrate the scope of, and details regarding, investigations that may show the potential health risks of the product. The proposed rule would codify the general procedures FDA would follow when evaluating PMTAs, including application acceptance, application filing, and inspections, and would also create postmarket reporting requirements for applicants that receive marketing orders. The proposed rule would allow for the submission of PMTAs in alternative formats in certain instances to reduce the burden of submitting a PMTA for modifications to a product that previously received a PMTA marketing order or resubmitting a PMTA to address deficiencies specified in a no marketing order. The proposed rule would also require tobacco product manufacturers to keep records regarding the legal marketing of certain tobacco products without a PMTA, such as documents showing that a tobacco product is not required to undergo premarket review or has received premarket authorization.

DATES: Submit either electronic or written comments on the proposed rule by November 25, 2019.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

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

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

Written/Paper Submissions

Submit written/paper submissions as follows:

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

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–N–2854 for ''Premarket Tobacco Product Applications and Recordkeeping Requirements.'' 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.

• 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.fda.gov/regulatory-information/dockets-management.*

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.

Submit comments on information collection issues to the Office of Management and Budget in the following ways: Fax to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or email to *oira_submission@omb.eop.gov.* All comments should be identified with the title, ''Premarket Tobacco Product Applications and Recordkeeping Requirements.''

FOR FURTHER INFORMATION CONTACT: Paul Hart or Samantha Loh Collado at the Office of Regulations, Center for Tobacco Products (CTP), Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993, 877–287–1373, *AskCTP@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

Executive Summary
A. Purpose of the Regulatory Action
B. Legal Authority
C. Summary of Major Provisions
D. Costs and Benefits
Table of Abbreviations/Commonly Used Acronyms

I. Background
II. Legal Authority
III. Proposed Regulations for the Maintenance of Records Demonstrating That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007 (Part 1100, Proposed Subpart C)
A. Purpose and Scope (Proposed § 1100.200)
B. Definitions (Proposed § 1100.202)
C. Recordkeeping Requirements (Proposed § 1100.204)
IV. Proposed Regulations for the Maintenance of Records Relating to Exemptions From the Requirements of Demonstrating Substantial Equivalence (Proposed § 1107.3)
A. Definition
B. Record Maintenance
C. Record Quality
D. Record Retention
V. Proposed Regulations for Premarket Tobacco Product Applications (Proposed Part 1114)
VI. General (Proposed Part 1114, Subpart A)
A. Scope (Proposed § 1114.1)
B. Definitions (Proposed § 1114.3)
VII. Premarket Tobacco Product Applications (Proposed Part 1114, Subpart B)
A. Application Submission (Proposed § 1114.5)
B. Required Content and Format (Proposed § 1114.7)
C. Amendments (Proposed § 1114.9)
D. Withdrawal by Applicant (Proposed § 1114.11)
E. Change in Ownership of an Application (Proposed § 1114.13)
F. Supplemental Application Submission (Proposed § 1114.15)
G. Resubmissions (Proposed § 1114.17)
VIII. FDA Review (Proposed Part 1114, Subpart C)
A. Communications Between FDA and Applicants (Proposed § 1114.25)
B. Review Procedure (Proposed § 1114.27)
C. FDA Action on an Application (Proposed § 1114.29)
D. Issuance of a Marketing Order (Proposed § 1114.31)
E. Issuance of a No Marketing Order (Proposed § 1114.33)
F. Withdrawal of a Marketing Order (Proposed § 1114.35)
G. Temporary Suspension of a Marketing Order (Proposed § 1114.37)
IX. Postmarket Requirements (Proposed Part 1114, Subpart D)
A. Postmarket Changes (Proposed § 1114.39)
B. Reporting Requirements (Proposed § 1114.41)
X. Miscellaneous (Proposed Part 1114, Subpart E)
A. Record Retention (Proposed § 1114.45)
B. Confidentiality (Proposed § 1114.47)
C. Electronic Submission (Proposed § 1114.49)
XI. Paperwork Reduction Act of 1995
XII. Executive Order 13132: Federalism
XIII. Consultation and Coordination With Indian Tribal Governments
XIV. Analysis of Environmental Impact
XV. Preliminary Economic Analysis of Impacts
XVI. Proposed Effective Date
XVII. References

Executive Summary

A. Purpose of the Regulatory Action

This proposed rule would interpret and set forth requirements related to the content and format of PMTAs, the procedure by which FDA would review PMTAs, and the maintenance of records regarding the legal marketing of certain tobacco products without PMTAs. The proposed content and format requirements for PMTAs would assist FDA in completing initial, procedural reviews of applications, which include a determination of whether an application has sufficient information for FDA to initiate a substantive review of the PMTA. These content requirements would require an applicant to submit detailed information regarding the physical aspects of its new tobacco product and full reports of information regarding investigations that may show the health risks of the new tobacco product and whether it presents the same or different risks compared to other tobacco products. FDA is proposing to require the submission of these health risk investigations to ensure it understands the full scope of what is known about the potential health risks of a new tobacco product.

FDA is basing this proposed rule on the experience the Agency has gained reviewing several types of premarket applications submitted by industry, including substantial equivalence (SE) reports, requests for exemptions from the SE requirements, modified risk tobacco product applications (MRTPAs), and PMTAs. FDA has received thousands of premarket applications that range widely in the level of detail they contain. For example, some have very little of the information that is necessary for FDA to complete its statutorily required review, while other applications are more detailed and provide the necessary sufficient supporting information. This experience has been helpful in developing the proposed rule, which describes the information FDA is proposing that an applicant must include in a PMTA for FDA to be able to complete a substantive review of an application.

Although FDA has conducted acceptance and filing reviews of hundreds of PMTAs, it is still gaining experience in applying the statutory authorization standard to PMTAs because few have contained sufficient information to reach substantive review. The main focus of the proposed rule's content requirements is the threshold amount of information necessary for application filing, rather than every piece of information necessary to receive a marketing order both because FDA is still gaining experience in applying the authorization standard to PMTAs and because at this time, FDA believes applicants have some flexibility in the types of scientific information they can submit in order to provide sufficient health risk information to meet the standard.

The proposed rule also addresses issues such as the procedures by which FDA will review a PMTA, the retention of records related to the PMTA, confidentiality of application information, electronic submission of the PMTA and amendments, and postmarket reporting requirements. The proposed rule would also create requirements for the maintenance of records demonstrating the legal marketing status of grandfathered tobacco products and products that are exempt from the requirements of demonstrating substantial equivalence.

B. Legal Authority

This proposed rule is being issued under FDA's authority to require premarket review of new tobacco products under section 910 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 387j), FDA's authority to require records and reports under section 909(a) of the FD&C Act (21 U.S.C. 387i(a)), FDA's authorities related to adulterated and misbranded tobacco products under sections 902 and 903 (21 U.S.C. 387b and 387c), as well as FDA's rulemaking and inspection authorities under sections 701(a) and 704 of the FD&C Act (21 U.S.C. 371(a) and 374).

C. Summary of Major Provisions

The proposed rule would create requirements for tobacco product manufacturers to maintain records regarding the legal marketing of grandfathered tobacco products and products that are exempt from the requirements of demonstrating substantial equivalence. This proposed rule would also set forth content and format requirements for PMTAs. Under the proposed rule, a PMTA must contain information necessary for FDA to determine whether it should issue a marketing order for a new tobacco product under section 910(c)(1)(A) of the FD&C Act. Specifically, the PMTA must enable FDA to find whether: There is a showing that marketing of the new tobacco product would be appropriate for the protection of the public health; the methods used in, or the facilities and controls used for, the manufacture,

processing, or packing of the product conform to the requirements of section 906(e) of the FD&C Act (21 U.S.C. 387f(e)); the product labeling is not false or misleading in any particular; and the product complies with any applicable product standard in effect under section 907 of the FD&C Act (21 U.S.C. 387g) or there is adequate information to justify a deviation from such standard. The proposed rule would also allow applicants to submit a supplemental PMTA or a resubmission, which would reduce the burden of submitting and reviewing an application. A supplemental PMTA could be submitted in situations where an applicant is seeking authorization for a new tobacco product that is a modified version of a tobacco product for which they have already received a PMTA marketing order. A resubmission could be submitted to address application deficiencies following the issuance of a no marketing order. The proposed rule would also require the submission of postmarket reports by applicants that receive a PMTA marketing order.

In addition, the proposed rule would explain how an applicant could amend or withdraw a PMTA and how an applicant may transfer ownership of a PMTA to a new owner. The proposed rule also addresses FDA communications with applicants and identifies the actions that FDA may take after receipt of a PMTA. The proposed rule addresses when FDA may withdraw a PMTA marketing order and explains how long an applicant would be required to maintain the records related to the PMTA and postmarket reports. The proposed rule would also set forth FDA's disclosure procedures regarding PMTAs and require the electronic submission of PMTAs, unless the applicant requests and obtains a waiver.

D. Costs and Benefits

If finalized, the proposed rule would create cost savings for firms and for FDA by reducing the number of follow-on submissions for PMTAs (*i.e.,* additional PMTAs submitted for the same product(s) after FDA refuses to accept or file, or issues a no marketing order in response to, an initial PMTA). The proposed rule would also create cost savings for FDA by reducing the cost of review, reducing the number of deficiency letters we would issue during substantive scientific review, and eliminating the need to process unnecessary data. We estimate that average annualized benefits over 20 years would equal $5.54 million at a 7 percent discount rate and $5.44 million at a 3 percent discount rate.

If finalized, the proposed rule would create costs for firms and for FDA by increasing the number of complete PMTA submissions for deemed and originally regulated tobacco products. Moreover, because this is the first regulation to account for the costs of the PMTA requirements for originally regulated products, we also include the costs to submit and review PMTAs for these tobacco products; we already included the costs to submit and review PMTAs for deemed tobacco products in the final regulatory impact analysis for the final rule entitled ''Deeming Tobacco Products To Be Subject to the Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations Restricting the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Product Packages and Advertisements'' (Deeming Rule), which was published in the **Federal Register** of May 10, 2016 (81 FR 28973). Firms would incur costs to maintain and submit postmarket reports, and we would incur costs to review postmarket reports. Finally, firms would incur costs to read and understand the rule and costs to maintain records for some grandfathered products. We estimate that average annualized costs over 20 years would equal $7.05 million at a 7 percent discount rate and $6.76 million at a 3 percent discount rate.

Table of Abbreviations/Commonly Used Acronyms

Abbreviation/ acronym	What it means
FDA	Food and Drug Administration.
CTP	Center for Tobacco Products.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
EA	Environmental assessment.
ENDS	Electronic nicotine delivery systems.
FEI	Facility Establishment Identifier.
APPH	Appropriate for the protection of public health.
CAS	Chemical Abstracts Service.
FOIA	Freedom of Information Act.
GLP	Good laboratory practice.
HPHC	Harmful and potentially harmful constituent.
IUPAC	International Union of Pure and Applied Chemistry.
ICH	International Council for Harmonization.
IRB	Institutional Review Board.
ISO	International Organization for Standardization.
MRTPA	Modified risk tobacco product application.
NEPA	National Environmental Policy Act of 1969.
NNK	4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone.
NNN	N-nitrosonornicotine.
NTRM	Nontobacco related material.
NYTS	National youth tobacco survey.
OMB	Office of management and budget.
PDU	Power delivery unit.
PG/VG	Propylene glycol/vegetable glycerin.
PMTA	Premarket tobacco product application.
PRIA	Preliminary regulatory impact analysis.
RYO	Roll-your-own.
SE	Substantial equivalence.
The Secretary	The Secretary of Health and Human Services.
STN	Submission tracking number.
TPMF	Tobacco product master file.
TSNA	Tobacco specific nitrosamine.
TPSAC	Tobacco products scientific advisory committee.
UNII	Unique Ingredients Identifier.

I. Background

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) provides FDA with the authority to regulate tobacco products under the FD&C Act. The FD&C Act, as amended by the Tobacco Control Act, generally requires that before a new tobacco product may be introduced or delivered for introduction into interstate commerce, it must undergo premarket review by FDA. Section 910(a)(1) of the FD&C Act defines a ''new tobacco product'' as: (1) Any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or (2) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007 (21 U.S.C. 387j(a)(1)).

The FD&C Act establishes three premarket review pathways [1] for a new tobacco product:

- Submission of a PMTA under section 910(b);

[1] As described in the Preliminary Economic Analysis of Impacts (Ref. 118), we expect that manufacturers will submit PMTAs primarily for ENDS and will generally submit SE Reports or exemption requests for cigars and other deemed products. We also expect that a number of cigars and pipe tobacco products are grandfathered tobacco products (see section III of this document) not subject to premarket review. This is consistent with FDA's experience so far in issuing SE marketing orders for cigars and determining cigars to be grandfathered tobacco products, and is also consistent with the regulatory impact analysis for the Deeming Rule (''Deeming Tobacco Products To Be Subject to the Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations Restricting the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Product Packages and Advertisements,'' (81 FR 28973) (May 10, 2016)).

• Submission of an application intended to demonstrate that the new tobacco product is substantially equivalent to a predicate tobacco product under section 905(j)(1)(A) (21 U.S.C. 387e(j)(1)(A)) (SE Report);[2] and

• Submission of a request for an exemption under section 905(j)(3) (implemented at 21 CFR 1107.1) (exemption request).

Generally, if a new tobacco product is marketed without either a PMTA or SE marketing order or a finding of exemption from substantial equivalence, it is adulterated under section 902 of the FD&C Act and misbranded under section 903 of the FD&C Act and subject to enforcement action.

Since 2010, FDA has received thousands of premarket applications for tobacco products, hundreds of which have been PMTAs. Of these PMTAs, FDA has completed its full substantive review on two sets of bundled PMTAs, which are single submissions containing PMTAs for a number of similar or related tobacco products (totaling 12 applications), all of which received marketing orders. To assist manufacturers in preparing PMTAs, FDA has issued guidance, conducted webinars, met with manufacturers, hosted a public meeting regarding premarket submissions, and posted the technical project lead reviews (which describe the reviews completed on specific PMTAs) and marketing orders issued to date. If finalized, the proposed rule would interpret and set forth requirements related to the PMTA premarket pathway and outline the information needed for FDA to determine whether it will issue a marketing order under the pathway.

FDA has also processed hundreds of exemption requests and thousands of voluntarily-submitted grandfathered status reviews. The proposed rule would state the records that a company would be required to keep regarding the legal marketing of its tobacco product.

II. Legal Authority

As described in the following paragraphs, FDA is proposing requirements for the content, format, submission, and review of PMTAs, as well as other requirements related to PMTAs, including recordkeeping requirements, and postmarket reporting. FDA is also proposing recordkeeping requirements regarding the legal marketing of grandfathered tobacco products and products that are exempt from the requirements of demonstrating substantial equivalence. In accordance with section 5 of the Tobacco Control Act, FDA intends that the requirements that would be established by this proposed rule be severable and that the invalidation of any provision of this proposed rule would not affect the validity of any other part of this rule.

Section 910(a)(2) of the FD&C Act requires that a new tobacco product be the subject of a PMTA marketing order unless FDA has issued an order finding it to be substantially equivalent to a predicate product, or exempt from the requirements of demonstrating substantial equivalence.[3] A manufacturer may choose to submit a PMTA under section 910(b) of the FD&C Act to satisfy the requirements of premarket review. Section 910(b)(1) describes the required contents of a PMTA, and in addition to the items specified in section 910(b)(1)(A)–(F), allows FDA to require applicants to submit other information relevant to the subject matter of the application under section 910(b)(1)(G). Section 910(c)(2) of the FD&C Act requires FDA to issue an order denying a PMTA if it finds that: The applicant has not made a showing that marketing the product would be appropriate for the protection of the public health; the methods used in, or the facilities or controls used for, the manufacture, processing, or packing of the product do not conform to the requirements of section 906(e) of the FD&C Act; the proposed labeling is false or misleading in any particular; or the product has not been shown to meet the requirements of a product standard in effect and there is a lack of adequate information to justify a deviation from the standard, if applicable.

Section 909(a) of the FD&C Act authorizes FDA to issue regulations requiring tobacco product manufacturers or importers to maintain records, make reports, and provide information as may be reasonably required to assure that their tobacco products are not adulterated or misbranded and to otherwise protect public health. Section 910(f) of the FD&C Act allows FDA to require that applicants establish and maintain records, and submit reports to enable FDA to determine, or facilitate a determination of, whether there are or may be grounds for withdrawing or temporarily suspending an order.

Section 910(d)(1) of the FD&C Act grants FDA authority to issue an order withdrawing a marketing order if FDA finds:

• That the continued marketing of such tobacco product no longer is appropriate for the protection of the public health;

• that the application contained or was accompanied by an untrue statement of a material fact;

• that the applicant:

○ Has failed to establish a system for maintaining records, or has repeatedly or deliberately failed to maintain records or to make reports, required by an applicable regulation under section 909 of the FD&C Act;

○ has refused to permit access to, or copying or verification of, such records as required by section 704 of the FD&C Act; or

○ has not complied with the requirements of section 905 of the FD&C Act;

• on the basis of new information before the Secretary of Health and Human Services (the Secretary) with respect to such tobacco product, evaluated together with the evidence before the Secretary when the application was reviewed, that the methods used in, or the facilities and controls used for, the manufacture, processing, packing, or installation of such tobacco product do not conform with the requirements of section 906(e) of the FD&C Act and were not brought into conformity with such requirements within a reasonable time after receipt of written notice from the Secretary of nonconformity;

• on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when the application was reviewed, that the labeling of such tobacco product, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary of such fact; or

• on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when such order was issued, that such tobacco product is not shown to conform in all respects to a tobacco product standard which is in effect under section 907 of the FD&C Act, compliance with which was a condition to the issuance of an order relating to the application, and that there is a lack of adequate information to justify the deviation from such standard, if applicable.

[2] Additionally, section 910(a)(2)(B) of the FD&C Act also allows for the continued marketing of new tobacco products first introduced or delivered for introduction into interstate commerce for commercial distribution after February 15, 2007, and prior to March 22, 2011, for which an applicant submitted an SE Report prior to March 23, 2011 (''provisional tobacco products''), unless FDA issues an order that the tobacco product is not substantially equivalent.

[3] See section I for a discussion of provisional tobacco products and their relation to the premarket review requirements.

Under section 902(6) of the FD&C Act, a tobacco product is adulterated if it is required to have premarket review and does not have an order in effect under section 910(c)(1)(A)(i), or if it is in violation of an order under section 910(c)(1)(A) of the FD&C Act. In addition, section 701(a) of the FD&C Act gives FDA general rulemaking authority to issue regulations for the efficient enforcement of the FD&C Act and section 704 of the FD&C Act provides FDA with general inspection authority.

III. Proposed Regulations for the Maintenance of Records Demonstrating That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007 (Part 1100, Proposed Subpart C)

The proposed rule would add subpart C regarding records to Part 1100 of subchapter K of title 21.

A. Purpose and Scope (Proposed § 1100.200)

Proposed § 1100.200 states that subpart C of part 1100 would establish requirements for the maintenance of records by tobacco product manufacturers who introduce a grandfathered tobacco product, or deliver it for introduction, into interstate commerce. FDA is proposing requirements for tobacco product manufacturers to maintain records regarding the legal marketing of their tobacco products under the authority of section 909 of the FD&C Act. Under section 902(6)(A), a tobacco product is adulterated if it is required by section 910(a) of the FD&C Act to have premarket review and does not have an order in effect under section 910(c)(1)(A)(i). The records that would be required under this subpart would demonstrate that a tobacco product is grandfathered and therefore not required by section 910(a) to have premarket review and are not adulterated if marketed without an FDA order. FDA is basing these requirements on its experience gained by performing thousands of grandfathered status reviews conducted during its review of substantial equivalence reports and at manufacturers' voluntary requests. In the absence of these required records, manufacturers do not always maintain sufficient documentation to demonstrate whether their tobacco product is grandfathered. The records that would be required under this rule would allow FDA to more quickly and efficiently determine whether a tobacco product is grandfathered.

B. Definitions (Proposed § 1100.202)

Proposed § 1100.202 sets forth the meaning of terms as they apply to proposed part 1100 and includes the following definitions from the FD&C Act:

1. Tobacco Product

As defined in section 201(rr)(1) of the FD&C Act (21 U.S.C. 321(rr)(1)), the term ''tobacco product'' means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than the tobacco used in manufacturing a component, part, or accessory of a tobacco product). The term ''tobacco product'' does not mean an article that under the FD&C Act is a drug (section 201(g)(1)), a device (section 201(h)), or a combination product (section 503(g) (21 U.S.C. 353(g))).

2. Tobacco Product Manufacturer

As defined in section 900(20) of the FD&C Act (21 U.S.C. 387(20)), the term ''tobacco product manufacturer'' means any person, including a repacker or relabeler, who: (1) Manufacturers, fabricates, assembles, processes, or labels a tobacco product or (2) imports a finished tobacco product for sale or distribution in the United States. FDA interprets ''manufactures, fabricates, assembles, processes, or labels'' as including, but not being limited to: (1) Repackaging or otherwise changing the container, wrapper, or labeling of any tobacco product package; (2) reconstituting tobacco leaves; or (3) applying any chemical, additive, or substance to the tobacco leaf other than potable water in the form of steam or mist. Manufacturing activities typically do not include the activities of de-stemming, drying, or packaging tobacco leaves; mechanically removing foreign material from tobacco leaves; and humidifying tobacco leaves with nothing other than potable water in the form of steam or mist. For the purposes of this definition ''finished tobacco product'' would mean a tobacco product, including all components and parts, sealed in final packaging (*e.g.,* filters or filter tubes sold separately to consumers or as part of kits).

In addition, FDA proposes the following definitions:

3. Commercially Marketed

FDA proposes to define ''commercially marketed'' to mean the offering of a tobacco product for sale to consumers in all or parts of the United States. Factors FDA may consider include advertising or other means used to communicate that the tobacco product is available for purchase. Tobacco products that are exclusively in a test market are not commercially marketed.

4. Grandfathered Tobacco Product

FDA proposes to define a ''grandfathered tobacco product'' to mean a tobacco product that was commercially marketed in the United States on February 15, 2007. This term does not include tobacco products exclusively marketed in a test market as of that date. FDA interprets the statutory phrase ''as of February 15, 2007,'' as meaning that the tobacco product was commercially marketed in the United States ''on February 15, 2007,'' and this interpretation is based on a plain language reading of the term ''as of.'' The proposed definition reflects this interpretation, which has been included as part of previously issued regulations and guidance.[4] This definition is also in the proposed rule, ''Content and Format of Substantial Equivalence Reports; Food and Drug Administration Actions on Substantial Equivalence Reports'' (SE Proposed Rule), which was published in the **Federal Register** of April 2, 2019 (84 FR 12740).[5] A grandfathered tobacco product is not subject to the premarket requirements of section 910 of the FD&C Act.

A tobacco product that the applicant test marketed after February 15, 2007, is not a grandfathered tobacco product because it was not commercially marketed in the United States as of February 15, 2007 and, therefore, it is a new tobacco product subject to premarket review under section 910(a) of the FD&C Act.

As described in the SE Proposed Rule and in the definition of ''new tobacco product'' proposed in 21 CFR part 1114 below, FDA is considering whether to add the following definition of test marketing: ''test marketing'' means distributing or offering for sale (which

[4] See the final rule ''Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products'' (81 FR 28973 at 28978, May 10, 2016) and the guidance ''Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007'' (Grandfathered Tobacco Product Guidance) (79 FR 58358, September 29, 2014), available at *https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/guidance.*

[5] FDA intends the PMTA provisions in this proposed rule to be consistent with the SE Proposed Rule wherever it is appropriate. FDA intends to harmonize any differences between definitions in these proposed rules when issuing final rules.

may be shown by advertisements, etc.) a tobacco product in the United States for the purpose of determining consumer response or other consumer reaction to the tobacco product, with or without the user knowing it is a test product, in which any of the following criteria apply:

- Offered in a limited number of regions;
- Offered for a limited time; or
- Offered to a chosen set of the population or specific demographic group.

C. Recordkeeping Requirements (Proposed § 1100.204)

1. Required Records

Consistent with the authority to require recordkeeping under section 909 of the FD&C Act, proposed § 1100.204(a) would require any tobacco product manufacturer that introduces a grandfathered tobacco product, or delivers it for introduction, into interstate commerce to maintain records and information necessary to adequately demonstrate that the tobacco product was commercially marketed in the United States as of February 15, 2007. This proposed requirement would ensure that records are available to FDA during an inspection. The proposed rule would not require tobacco product manufacturers to maintain records for all of the types of information listed in § 1100.204(a); rather, the list provides examples of the types of records that may be used to demonstrate that a tobacco product was commercially marketed in the United States as of February 15, 2007. These records may include items such as:

(1) Dated copies of advertisements;
(2) Dated catalog pages;
(3) Dated promotional material;
(4) Dated trade publications;
(5) Dated bills of lading;
(6) Dated freight bills;
(7) Dated waybills;
(8) Dated invoices;
(9) Dated purchase orders;
(10) Dated customer receipts;
(11) Dated manufacturing documents;
(12) Dated distributor or retailer inventory lists; or
(13) Any other dated document that demonstrates that the tobacco product was commercially marketed (not exclusively in test markets) in the United States as of February 15, 2007.

For additional information on records related to grandfathered tobacco products, see the Grandfathered Tobacco Product Guidance.

2. Record Maintenance

Proposed § 1100.204(b) would require that all records required to be maintained under this part be legible, in the English language, and available for inspection and copying by officers or employees duly designated by the Secretary. FDA is also proposing that documents that have been translated from another language into English must be accompanied by: The original language version of the document, a signed statement by an authorized representative of the manufacturer certifying that the English language translation is complete and accurate, and a brief statement of the qualifications of the person who made the translation (*e.g.,* education and experience). This information would help FDA ensure that the English language translations of documents are complete and accurately reflect the content of the original documents.

3. Record Retention

Proposed § 1100.204(c) would require that the records and documents demonstrating that the tobacco product was commercially marketed be retained for a period of 4 years from the date that either FDA makes a grandfather determination or the tobacco product manufacturer permanently ceases the introduction or delivery for introduction into interstate commerce of the tobacco product, whichever occurs sooner. FDA has selected 4 years as a means to help ensure that the records would be available for at least one biennial FDA inspection under section 704 and 905(g) of the FD&C Act. FDA's biennial inspections under section 905(g) are required to occur at least once in every 2-year period after a manufacturer registers an establishment with FDA, which could result in inspections occurring nearly 4 years apart. Retaining records for 4 years after a manufacturer permanently ceases introduction or delivery for introduction into interstate commerce of the tobacco product would allow FDA to verify the grandfathered status of the product during the time period in which it is offered for sale to consumers. Manufacturers that only temporarily cease the introduction or delivery for introduction into interstate commerce of the tobacco product would still need to retain the records to allow FDA to verify the grandfathered status of the product when they resume marketing the product. Additionally, manufacturers might also want to retain records for longer than 4 years to help establish their product is grandfathered for use as a predicate product in an SE Report.

IV. Proposed Regulations for the Maintenance of Records Relating to Exemptions From the Requirements of Demonstrating Substantial Equivalence (Proposed § 1107.3)

The proposed rule would add § 1107.3 to part 1107 of subchapter K of title 21. Proposed § 1107.3 would establish recordkeeping requirements related to tobacco products that are exempt from the requirements of demonstrating substantial equivalence under section 910(a)(2)(A)(ii) of the FD&C Act. Consistent with the authority to require recordkeeping under section 909 of the FD&C Act, proposed § 1107.3 would require applicants that submitted an abbreviated report under section 905(j)(1)(A)(ii) of the FD&C Act, and received a letter from FDA acknowledging the receipt of an abbreviated report, to maintain all records necessary to support the exemption for at least 4 years from the date FDA issues an acknowledgement letter in response to an abbreviated report. The proposed rule would require the applicant to maintain records that are legible, written in English, and available for inspection and copying by officers or employees designated by the Secretary. Applicants may want to retain the records for a longer period if, for example they intend to submit a subsequent exemption request for a modification to the tobacco product.

A. Definition

Proposed § 1107.3(a) would define ''grandfathered tobacco product'' as a tobacco product that was commercially marketed in the United States on February 15, 2007. The term would not include a tobacco product exclusively in test markets as of that date. FDA interprets the phrase ''as of February 15, 2007,'' as meaning that the tobacco product was commercially marketed in the United States ''on February 15, 2007,'' this interpretation is based on a plain language reading of the term ''as of.'' [6]

B. Record Maintenance

The proposed rule would require applicants to maintain all documents that support their abbreviated report, which includes the documents listed in proposed § 1107.3(b)(1). The proposed rule would not require an applicant to create new or additional records; rather, it would require an applicant to maintain the records it has, obtains, or creates (including those created on its behalf, such as by a contract research organization) that support its abbreviated report. This includes

[6] *Id.*

documents an applicant would be required to create by other regulatory or statutory sections such as the submission of exemption requests under § 1107.1, PMTAs under section 910(b) of the FD&C Act (or proposed part 1114 when finalized), SE Reports under section 905(j) FD&C Act, and tobacco product manufacturing requirements issued under section 906(e) of the FD&C Act. The records an applicant would be required to maintain include, but are not limited to:

- A copy of the abbreviated report and, if applicable, the exemption request and all amendments thereto;
- A copy of the acknowledgement letter issued in response to an abbreviated report and, if applicable, a copy of the exemption order issued by FDA;
- Documents related to formulation of product, product specifications, packaging, and related items. Product formulation would include, for example, items such as the types of information described in proposed § 1114.7(i) as described in section VII.B.;
- Documents showing that design specifications are consistently met. This could include, for example, information about testing procedures that are carried out before the product is released to market, such as the information described in proposed § 1114.7(j) as described in section VII.B.;
- Product labeling. As defined in section 201(m) of the FD&C Act, ''labeling'' means all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article. This would include, for example, specimens of all labeling for the new tobacco product, including labels, inserts, onserts, instructions, and other accompanying information. The specimens of labeling would include all panels, reflect the actual size and color proposed to be used for the tobacco product, and include any warning label statements and other information required by regulation or statute, as applicable;
- Documents related to product packing and storage conditions;
- Analytical test method records, including:
  - Performance criteria;
  - Validation or verification documentation; and
  - Reports/results from these test methods; and
- Source data and related summaries.

In addition to the documents specified in proposed § 1107.3(b)(1), proposed § 1107.3(b)(2) through (b)(4) would require tobacco product manufacturers to maintain records that support a determination that their exemption request meets the requirements of section 905(j)(3)(A)(i) of the FD&C Act that the modification to a product additive described in the exemption request was a minor modification made to a tobacco product that can be sold under the FD&C Act. This means that applicants would need to maintain records demonstrating that the modification is being made to either a grandfathered tobacco product or a new tobacco product that has satisfied the premarket review requirements of section 910(a)(2) of the FD&C Act. For abbreviated reports based on a modification to a grandfathered tobacco product, proposed § 1107.3(b)(2) would require applicants to maintain the documentation in § 1100.204 to demonstrate that the product that is being modified is legally marketed. For abbreviated reports based on a modification to a tobacco product that has previously received an exemption order in response to a request under § 1107.1 (and for which the applicant has submitted an abbreviated report under 905(j)(1)(A)(ii)), or a marketing order from FDA (*i.e.,* an order from FDA authorizing the marketing of the new tobacco product after review of an SE Report or PMTA), proposed § 1107.3(b)(3) would require applicants to maintain a copy of the exemption or marketing order to demonstrate the product being modified is legally marketed. For abbreviated reports based on a modification to a tobacco product that is being marketed consistent with section 910(a)(2)(B) of the FD&C Act for which FDA has not issued an SE marketing order, an applicant would be required to maintain all communications to and from FDA relating to the pending SE Report, such as a letter acknowledging receipt of the report.

C. Record Quality

Proposed § 1107.3(c) would require the records to be legible, in the English language, and available for inspection and copying by officers or employees duly designated by the Secretary. FDA is also proposing that documents that have been translated from another language into English must be accompanied by: (1) The original language version of the document, (2) a signed statement by an authorized representative of the manufacturer certifying that the English language translation is complete and accurate, and (3) a brief statement of the qualifications of the person who made the translation (*e.g.,* education and experience). This information would help FDA ensure that the English language translations of documents are complete and accurately reflect the content of the original documents.

D. Record Retention

Proposed § 1107.3(d) would require the records described in § 1107.3 to be maintained for a period of not less than 4 years from the date on which FDA issues an acknowledgement letter in response to an abbreviated report. FDA has selected 4 years as a means to help ensure that the records would be available for at least one biennial FDA inspection under section 704 and 905(g) of the FD&C Act. FDA's biennial inspections under section 905(g) of the FD&C Act are required to occur at least once in every 2-year period after a manufacturer registers an establishment with FDA, which could result in inspections occurring nearly 4 years apart.

V. Proposed Regulations for Premarket Tobacco Product Applications (Proposed Part 1114)

The proposed rule would add part 1114 to subchapter K of Title 21. The requirements set forth in this proposed part would apply to PMTAs for new tobacco products. Proposed subpart A sets out the scope and definitions that apply to this proposed part. Proposed subpart B sets out the proposed criteria for PMTA submission, content and format of PMTAs, application amendments, withdrawal of an application by an applicant, supplemental PMTAs, resubmissions, and change in ownership or contact information for a PMTA. Proposed subpart C describes how FDA proposes to review and act on applications, including provisions for withdrawal and temporary suspension of orders. Proposed subpart D describes proposed postmarket restrictions, reporting requirements, and inactivation and reactivation of a marketing order. Proposed subpart E sets out proposed miscellaneous requirements such as record retention, confidentiality, and electronic submissions.

VI. General (Proposed Part 1114, Subpart A)

A. Scope (Proposed § 1114.1)

Proposed § 1114.1 describes the scope of proposed part 1114 and its application to the submission, review, and postmarket requirements related to PMTAs. Proposed § 1114.1 provides that proposed part 1114 would not apply to MRTPAs, except instances where a single application is submitted under section 911(l)(4) of the FD&C Act instead of a separate PMTA and MRTPA

for the product. Under the proposed rule, an applicant that submits a single application seeking both a PMTA marketing order and a modified risk order under section 911(g) would need to meet the requirements of both part 1114 and section 911 of the FD&C Act. This section also notes that references in the proposed rule to regulatory sections of the Code of Federal Regulations (CFR) are to chapter I of title 21, unless otherwise noted. This means that any CFR reference that begins with ''part'' or the section symbol (§) should be read as if it were preceded by ''21 CFR'' (*e.g.,* § 1114.1 refers to 21 CFR 1114.1, part 58 refers to 21 CFR part 58).

B. Definitions (Proposed § 1114.3)

Proposed § 1114.3 sets forth the meaning of terms as they apply to proposed part 1114. Proposed § 1114.3 includes the following definitions from the FD&C Act:

1. Additive

As defined in section 900(1) of the FD&C Act, ''additive'' means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), except that such term does not include tobacco, or a pesticide chemical residue in or on raw tobacco or a pesticide chemical.

An additive can be a type of ingredient in a tobacco product; an example is methyl salicylate in smokeless tobacco, which can serve as an absorption enhancer and affect the characteristics of the tobacco product by changing the rate of absorption into the body. Tobacco is not an additive.

2. Brand

As defined in section 900(2) of the FD&C Act, ''brand'' means a variety of tobacco product distinguished by the tobacco used, tar content, nicotine content, flavoring used, size, filtration, packaging, logo, registered trademark, brand name, identifiable pattern of colors, or any combination of such attributes.

3. Characteristics

As defined in section 910(a)(3)(B) of the FD&C Act, ''characteristics'' means the materials, ingredients, design, composition, heating source, or other features of a tobacco product. The terms used in the definition of characteristic (materials, ingredients, design, etc.) are defined in proposed § 1114.3.

4. Label

As defined in section 201(k) of the FD&C Act (21 U.S.C. 321(k)), ''label'' means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of the FD&C Act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

5. Labeling

As defined in section 201(m) of the FD&C Act, ''labeling'' means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers or (2) accompanying such article.

6. New Tobacco Product

As defined in section 910(a)(1) of the FD&C Act, ''new tobacco product'' means: (1) Any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or (2) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.

Under the FD&C Act, and as reflected in the proposed definition, new tobacco products include those that are new because they have been rendered new through any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007 (21 U.S.C. 387j(a)(1)(B)). For example, modifications to cigarette paper, container closure systems (*e.g.,* change from glass to plastic e-liquid vials or from plastic to tin container closures), product quantity, specifications that change characteristics (*e.g.,* a modification to a different tobacco cut size) would render a tobacco product new.

Manufacturers sometimes co-package tobacco products. Co-packaging two or more legally marketed tobacco products, where there are no changes, including no change to the container closure system(s), does not result in a new tobacco product. Examples include a carton of cigarette packs and a variety pack of three smokeless tins shrink-wrapped together where the cigarette packs and smokeless tins, respectively, could be legally marketed separately. However, if a manufacturer wishes to co-package two or more tobacco products (including their respective container closure systems), premarket review is required for any new tobacco product that the manufacturer intends to include in the co-package. An example includes shrink-wrapping grandfathered tobacco filler (in its unmodified container closure system) with new rolling papers; here premarket authorization would be required for the rolling papers. In addition, co-packaging two or more tobacco products within the same container closure system results in a new tobacco product, unless such co-packaged product is grandfathered. Examples include an RYO kit where rolling papers are placed inside the tin of tobacco filler, and shrink-wrapping together two soft-packs of cigarettes, neither of which had been individually shrink-wrapped prior to being co-packaged. FDA invites comment on approaches to its review of these types of PMTAs, including, where relevant, how co-packaging products impacts consumer use and behavior.

In addition, for purposes of determining whether a tobacco product is new under section 910 of the FD&C Act, and therefore requires premarket authorization prior to marketing, a ''tobacco product'' can be considered to encompass the whole product (*e.g.,* a pack of cigarettes or a tin of loose tobacco), and is not limited to a single unit or portion of the whole product (*e.g.,* a single cigarette or a single snus pouch). *See Philip Morris USA Inc.* v. *U.S. Food & Drug Admin.,* 202 F. Supp. 3d 31, 55–57 (D.D.C. 2016) (finding that a change in product quantity results in a new tobacco product under the Tobacco Control Act). Consequently, a change in product quantity (*e.g.,* decreasing the weight of a smokeless package from 24 grams to 15 grams) results in a new tobacco product subject to premarket review since such a modification ''necessarily entails a change in the amount of the constituent ingredients and additives within the tobacco product, including nicotine'' (id. at 56).

FDA also interprets section 910(a)(1)(A) of the FD&C Act to mean

that a tobacco product marketed exclusively in test markets on February 15, 2007, is a new tobacco product that is subject to premarket review by FDA. A tobacco product that the applicant test marketed after February 15, 2007, is also a new tobacco product subject to premarket review under section 910(a) of the FD&C Act because it was not commercially marketed in the United States as of February 15, 2007.

Because the terms ''test marketing'' and ''commercially marketed'' are not interchangeable, FDA is considering whether it would be useful to applicants for the rule to expand on or further define the terms ''test marketing'' and ''commercially marketed.'' Specifically, as set forth in the description of proposed part 1100 and described in the SE Proposed Rule, FDA is considering whether to add the following definition of test marketing: ''test marketing'' means distributing or offering for sale (which may be shown by advertisements, etc.) a tobacco product in the United States for the purpose of determining consumer response or other consumer reaction to the tobacco product, with or without the user knowing it is a test product, in which any of the following criteria apply:

- Offered in a limited number of regions;
- Offered for a limited time; or
- Offered to a chosen set of the population or specific demographic group.

As set forth in the description of proposed part 1100, FDA is considering whether to define ''commercially marketed'' to mean offering a tobacco product for sale to consumers in all or in parts of the United States. Factors FDA may consider include advertising or other means used to communicate that the tobacco product was available for purchase, including dated advertisements, dated catalog pages, dated promotional material, dated trade publications, dated bills of lading, dated freight bills, dated waybills, dated invoices, dated purchase orders, dated manufacturing documents, inventory lists, or any other document that demonstrates that the product was commercially marketed (other than exclusively in test markets) in the United States as of February 15, 2007. FDA invites comment on what evidence would be sufficient to demonstrate that a product was commercially marketed (other than in test markets) as of February 15, 2007.

FDA is inviting comments on: (1) Whether the rule should further expand on the interpretation or include definitions of these terms, (2) the substance of the definitions, if included, and (3) whether or not the approach described is adequate to protect the public health.

7. Package or Packaging

As defined in section 900(13) of the FD&C Act, the term ''package,'' also referred to in the proposed rule as ''packaging,'' means a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane), in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers. A subset of package is the container closure system (also defined in this proposed rule). For example, the carton holding multiple soft packs of cigarettes is considered the package, and each soft pack with surrounding cellophane is considered the container closure system. Packaging that constitutes the container closure system is intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of the tobacco product (*e.g.,* leaching substances that are then incorporated into a consumable tobacco product), but packaging that is not the container closure system is not intended or reasonably expected to affect or alter the characteristics of the tobacco product.

8. Tobacco Product

As defined in section 201(rr) of the FD&C Act, the term ''tobacco product'' means any product that is made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). The term ''tobacco product'' does not mean an article that is a drug under section 201(g)(1), a device under section 201(h), or a combination product described in section 503(g) of the FD&C Act.

9. Tobacco Product Manufacturer

As defined in section 900(20) of the FD&C Act, the term ''tobacco product manufacturer'' means any person, including any repacker or relabeler, who: (1) Manufactures, fabricates, assembles, processes, or labels a tobacco product or (2) imports a finished tobacco product for sale or distribution in the United States. FDA interprets ''manufactures, fabricates, assembles, processes, or labels'' as including, but not being limited to: (1) Repackaging or otherwise changing the container, wrapper, or labeling of any tobacco product package; (2) reconstituting tobacco leaves; or (3) applying any chemical, additive, or substance to the tobacco leaf other than potable water in the form of steam or mist. Manufacturing activities typically do not include the activities of de-stemming, drying, or packaging tobacco leaves; mechanically removing foreign material from tobacco leaves; and humidifying tobacco leaves with nothing other than potable water in the form of steam or mist. A proposed definition for the term ''finished tobacco product'' is also included in the proposed rule.

In addition, FDA proposes the following definitions:

10. Accessory

FDA proposes to define ''accessory'' as any product that is intended or reasonably expected to be used with or for the human consumption of a tobacco product; does not contain tobacco and is not made or derived from tobacco; and meets either of the following:

(1) Is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product or

(2) is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a tobacco product, but:

(i) Solely controls moisture and/or temperature of a stored product or

(ii) solely provides an external heat source to initiate but not maintain combustion of a tobacco product.

This matches the definition of accessory set forth in § 1100.3 and contained in the SE Proposed Rule. Examples of accessories are ashtrays and spittoons because they do not contain tobacco, are not derived from tobacco, and do not affect or alter the performance, composition, constituents, or characteristics of a tobacco product. Examples of accessories also include humidors or refrigerators that solely control the moisture and/or temperature of a stored product and conventional matches and lighters that solely provide an external heat source to initiate but not maintain combustion of a tobacco product.

11. Adverse Experience

FDA proposes to define ''adverse experience'' as any unfavorable physical or psychological effect in a person that is temporally associated with the use of or exposure to a tobacco product, whether or not the person uses the tobacco product, and whether or not the effect is considered to be related to the use of or exposure to the tobacco product.

12. Applicant

FDA proposes to define ''applicant'' as any person that submits a premarket tobacco product application to receive a marketing order for a new tobacco product.

13. Component or Part

FDA proposes to define ''component or part'' as any software or assembly of materials intended or reasonably expected: (1) To alter or affect the tobacco product's performance, composition, constituents, or characteristics; or (2) to be used with or for the human consumption of a tobacco product. Component or part excludes anything that is an accessory of a tobacco product. A container closure system (which is also defined in this proposed section) is considered a component or part. With respect to these definitions, FDA notes that ''component'' and ''part'' are separate and distinct terms within chapter IX of the FD&C Act. However, for purposes of this proposed rule, FDA is using the terms ''component'' and ''part'' interchangeably and without emphasizing a distinction between the terms. FDA may clarify the distinctions between ''component'' and ''part'' in the future. This proposed definition matches the definition in § 1100.3 and that was published in the SE Proposed Rule and FDA invites comments on this approach in the PMTA context.

14. Composition

FDA proposes to define ''composition'' as the materials in a tobacco product, including ingredients, additives, and biological organisms. The term includes the manner in which the materials, for example, ingredients, additives, and biological organisms, are arranged and integrated to produce a tobacco product. Composition refers primarily to the chemical and biological properties of a tobacco product, whereas design refers to the physical properties of a tobacco product. A biological organism refers to any living biological entity, such as an animal, plant, fungus, or bacterium. This proposed definition matches the definition published in the SE Proposed Rule.

15. Constituent

FDA proposes to define ''constituent'' as any chemical or chemical compound in a tobacco product or in tobacco smoke or emission that is or potentially is inhaled, ingested, or absorbed into the body. Examples of constituents include harmful or potentially harmful constituents, total particulate matter, nicotine-free dry particulate matter, and water. A constituent also could include any other chemical or chemical compound contained in or produced by a tobacco product under conditions of use. This proposed definition matches the definition that was published in the SE Proposed Rule.

16. Container Closure System

FDA proposes to define ''container closure system'' as any packaging materials that are a component or part of the tobacco product. This proposed definition matches the definition published in the SE Proposed Rule.

Examples of what is typically a container closure system include the blister pack around a dissolvable tablet (in this example, if there is a box around a blister pack, the box is not considered a container closure system if it is not intended or reasonably expected to alter or affect the dissolvable tablet), the can that contains and protects a moist snuff product, and the plastic-wrapped hard pack or soft pack used to contain and protect cigarettes. A container closure system is a component or part of a tobacco product because of its potential to alter or affect the performance, composition, constituents, or other physical characteristics of the product.

In addition, considering a distinct subset of packaging (*i.e.,* container closure system) to be a component or part is consistent with the FD&C Act. For example, section 903(a)(2) of the FD&C Act describes when, under certain conditions, a tobacco product ''in package form'' is misbranded, thereby recognizing that at least some portion of the package is subsumed within the ''tobacco product'' (and the components and parts thereof). Similarly, the definition of ''additive'' in section 900(1) of the FD&C Act as any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substance intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), except that such term does not include tobacco or a pesticide chemical residue in or on raw tobacco or a pesticide chemical, further evinces Congress's understanding that packaging is not entirely separable from the tobacco product. Finally, the definition of ''package'' in section 900(13) of the FD&C Act does not dictate a contrary result and can be reasonably interpreted to mean that a distinct subset of packaging is also a component or part of a tobacco product.

According to the proposed definition above, packaging constitutes the container closure system if it is intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product, even if it is also used to protect or contain the tobacco product. For example, packaging materials constitute the container closure system if substances within that packaging are intended or reasonably expected to affect product moisture, *e.g.,* when the manufacturer changes the package of a moist snuff from plastic to fiberboard, which can affect microbial stability and tobacco-specific nitrosamine (TSNA) formation during storage (Ref. 1). Another example of this is when menthol or other ingredients are applied to the inner foil to become incorporated into the consumed product (Ref. 2). Packaging materials may also be intended or reasonably expected to affect the characteristics of a tobacco product by impacting the rate of leaching into, and ultimately, the amount of substances found in, the consumable tobacco product. In fact, it has been demonstrated that compounds in packaging materials may also diffuse into snuff and affect its characteristics (Ref. 3). Thus, for example, packaging material that affects the characteristics of a tobacco product by impacting the moisture level or shelf life of a tobacco product is a container closure system (*e.g.,* a plastic versus a metal container of smokeless tobacco). A difference in tobacco moisture is reasonably expected to affect microbial growth in the product, extraction efficiency, and total exposure to nicotine or the carcinogens N-nitrosonornicotine (NNN) or 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK) (Refs. 4 and 5).

Treating a distinct subset of packaging as a component or part thus furthers the fundamental purpose of the Tobacco Control Act to protect the public health. This interpretation is also consistent with the broad definition of ''tobacco product,'' as well the definition of ''additive,'' which includes substances that may be reasonably expected to result, directly or indirectly, in it becoming a component or otherwise affecting the characteristics of any tobacco product—and not just substances that do *in fact* have such effects. This shows that Congress did not intend for FDA to be required to show that the container closure system did in fact alter or affect the tobacco product's performance, composition, constituents, or other characteristics. Indeed, if FDA were to adopt a narrow

construction of ''tobacco product'' to exclude these materials, it would impede the Agency's ability to evaluate whether authorizing the marketing of the tobacco product would be appropriate for the protection of the public health, thereby leaving the Agency unable to fully execute its mission to protect the public health.

17. Design

FDA proposes to define ''design'' to mean the form and structure concerning, and the manner in which components or parts, ingredients, software, and materials are integrated to produce a tobacco product. This term refers to the physical properties of a tobacco product and matches the definition published in the SE Proposed Rule. Examples of design parameters include ventilation, paper porosity, filter efficiency, battery voltage and current operating range, and electrical heater coil resistance.

18. Finished Tobacco Product

FDA proposes to define ''finished tobacco product'' to mean a tobacco product, including all components and parts, sealed in final packaging (*e.g.,* filters or filter tubes sold separately to consumers or as part of kits, e-liquids sold separately or packaged with an e-cigarette). This proposed definition matches the definition published in the SE Proposed Rule.

19. Harmful or Potentially Harmful Constituent (HPHC)

FDA proposes to define ''harmful or potentially harmful constituent'' as any chemical or chemical compound in a tobacco product or tobacco smoke or emission that: (1) Is or potentially is inhaled, ingested, or absorbed into the body, including as an aerosol or any other emission and (2) causes or has the potential to cause direct or indirect harm to users or nonusers of tobacco products. This proposed definition matches the definition published in the SE Proposed Rule.

The established list of HPHCs can be found on FDA's website at *https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/harmful-and-potentially-harmful-constituents-tobacco-products-and-tobacco-smoke-established-list* (77 FR 20034, April 3, 2012). FDA issued a notice in the **Federal Register** of August 5, 2019 (84 FR 38032), seeking public comment on the proposed addition of 19 constituents to the established list of HPHCs. FDA is proposing these additions to reflect the range of tobacco products now subject to FDA's tobacco product authorities, including deemed products such as ENDS. FDA will finalize the addition of these HPHCs to the established list, as appropriate, after reviewing public comment and general intends to make any future updates to the established list of HPHCs through a similar notice and comment process.

20. Heating Source

FDA proposes to define ''heating source'' as the source of energy used to burn or heat the tobacco product. This proposed definition matches the definition published in the SE Proposed Rule. Examples of a heating source include a flame or a rechargeable battery.

21. Ingredient

FDA proposes to define ''ingredient'' as tobacco, substances, compounds, or additives added to the tobacco, paper, filter, or any other component or part of a tobacco product, including substances and compounds reasonably expected to be formed through a chemical reaction during tobacco product manufacturing. This proposed definition matches the definition published in the SE Proposed Rule. For example, an ingredient may be a single chemical substance, leaf tobacco, or the product of a reaction, such as a chemical reaction, in manufacturing. Examples of substances and compounds (ingredients) reasonably expected to be formed through a chemical reaction during tobacco product manufacturing include the following:

- The reaction of sugars with amines to form families of compounds with new carbon-nitrogen bonds, including Maillard reaction products and Amadori compounds.
- The reaction of sodium hydroxide with citric acid to form sodium citrate.
- The production of ethyl alcohol, a residual solvent, from ethyl acetate during production of tipping paper adhesive.
- Products of thermolytic reactions, such as the production of carboxylic acids from sugar esters.
- Products of enzymatically or nonenzymatically catalyzed reactions, such as the hydrolytic production of flavor or aroma precursors from nonvolatile glucosides.
- Products of acid-base reactions, such as removal of a proton from protonated nicotine to generate the basic form of nicotine (''free'' nicotine).

22. Line Data

FDA proposes to define ''line data'' to mean an analyzable dataset of observations for each individual study participant, laboratory animal, or test replicate. Line data typically provides information that is more useful to FDA's review of an application than data in its more 'raw' forms because it allows information about time, people, and places involved in investigations to be organized and reviewed quickly, and it facilitates tracking of different categories of cases. FDA is proposing to require that an applicant submit line data rather than source data to allow for a more efficient review process. As described in proposed § 1114.45, applicants would be required to retain all source data in the event that FDA needs to inspect the data as part of its application review.

23. Material

FDA proposes to define ''material'' to mean an assembly of ingredients. Materials are assembled to form the tobacco product, or components or parts of tobacco product. This proposed definition matches the definition published in the SE Proposed Rule. For example, material would include the glue or paper pulp for a cigarette where the paper pulp includes multiple ingredients (*e.g.,* multiple types of tobacco, water, and flavors) assembled into the paper (or pulp depending on the water content). Another example of a material is a plastic composed of chemical substances that houses electrical components.

24. Marketing Order

FDA proposes to define ''marketing order'' to mean the order described in section 910(c)(1)(A)(i) of the FD&C Act that authorizes the new tobacco product to be introduced or delivered for introduction into interstate commerce.

25. No Marketing Order

FDA proposes to define ''no marketing order'' to mean the order described in section 910(c)(1)(A)(ii) of the FD&C Act that the product may not be introduced or delivered for introduction into interstate commerce.

26. Other Features

FDA proposes to define ''other features'' to mean any distinguishing qualities of a tobacco product similar to those specifically enumerated in section 910(a)(3)(B) of the FD&C Act. This proposed definition matches the definition published in the SE Proposed Rule. The definition would include: (a) HPHCs (the definition of new tobacco product includes any modification to any constituents, including smoke constituents, section 910(a)(1)(B) of the FD&C Act), and (b) any other product characteristics that relate to the chemical, biological, or physical properties of the tobacco product. Other features also would encompass other

product characteristics that relate to the chemical, biological, and physical properties of the product that would not be included as a material, ingredient, design, composition, or heating source.

27. Premarket Tobacco Product Application or PMTA

FDA proposes to define ''premarket tobacco product application'' or ''PMTA'' to mean the application described in section 910(b) of the FD&C Act. This term includes the initial premarket tobacco product application and all subsequent amendments.

28. Serious Adverse Experience

FDA proposes to define ''serious adverse experience'' to mean an adverse experience that results in any of the following outcomes:

(a) Death;

(b) a life-threatening condition or illness;

(c) inpatient hospitalization or prolongation of existing hospitalization;

(d) a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions (*e.g.,* seizures not that do not result in hospitalization, burns that result in damage to a limb or nerve damage);

(e) a congenital anomaly/birth defect; or

(f) any other adverse experience that, based upon appropriate medical judgment, may jeopardize the health of a person and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition. This could include, for example, carbon monoxide poisoning, which if left untreated, could result in long term and possibly delayed brain damage or heart damage.

29. Unexpected Adverse Experience

FDA proposes to define ''unexpected adverse experience'' to mean an adverse experience occurring in one or more persons in which the nature, severity, or frequency of the experience is not consistent with:

(a) The known or foreseeable risks associated with the use or exposure to the tobacco product as described in the PMTA (including the results of human subject investigations) and other relevant sources of information, such as the product labeling and postmarket reports;

(b) the expected natural progression of any underlying disease, disorder, or condition of the persons(s) experiencing the adverse experience and the person's predisposing risk factor profile for the adverse experience; or

(c) the results of nonclinical investigations.

VII. Premarket Tobacco Product Applications (Proposed Part 1114, Subpart B)

A. Application Submission (Proposed § 1114.5)

Proposed § 1114.5 explains that if an applicant seeks a marketing order under the PMTA pathway for its new tobacco product, it would be required to submit a PMTA to FDA and receive a marketing order before the tobacco product may be introduced or delivered for introduction into interstate commerce. An applicant submitting a PMTA to FDA should include all information required to be in a PMTA as part of its initial submission, including all sections specified in proposed § 1114.7(a), except for product samples which, if required, must be submitted after a PMTA is accepted for review as described in the discussion of proposed § 1114.7(e) in section VII.B.5. Submitting a complete application as part of an initial submission is important because, as explained in the discussion of proposed § 1114.27 in section VIII.B, FDA may refuse to accept or file an incomplete application for review.

B. Required Content and Format (Proposed § 1114.7)

1. General

Proposed § 1114.7(a) would require each PMTA to contain sufficient information necessary for FDA to determine whether the grounds for denial of an application listed in section 910(c)(2) of the FD&C Act apply to the PMTA, which includes the following sections:

- General information (as described in § 1114.7(c));
- Descriptive information (as described in § 1114.7(d));
- Product samples (as described in § 1114.7(e));
- Labeling (as described in § 1114.7(f));
- Statement of compliance with part 25 (21 CFR part 25) (as described in § 1114.7(g));
- Summary (as described in § 1114.7(h));
- Product formulation (as described in § 1114.7(i));
- Manufacturing (as described in § 1114.7(j));
- Health risk investigations (as described in § 1114.7(k)); and
- Certification statement (as described in § 1114.7(l)).

As described in the discussion of proposed § 1114.27(a)(1) in section VIII.B, if the application does not appear to contain these sections and the information required therein (except for product samples), the Agency may refuse to accept the application for review. As described in section VIII.B on proposed § 1114.27(b)(1), if a PMTA does not contain sufficient information required by these sections to permit a substantive review, including substantive information regarding broad areas of scientific information noted where appropriate in this document, FDA may refuse to file the application.

2. Format

Proposed § 1114.7(b) provides the general requirements for the format of the application and would require the applicant to submit the application with the appropriate FDA form (Ref. 6). Proposed § 1114.7(b)(1), would require the application and any amendments to contain a comprehensive index and table of contents and be well organized, legible, and written in the English language. The comprehensive index would include the listing of files and data associated with those files (*e.g.,* for an application that is electronically submitted, the comprehensive index would include the listing of files and associated metadata). FDA is also proposing that documents that have been translated from another language into English must be accompanied by the original language version of the document, a signed statement by an authorized representative of the manufacturer certifying that the English language translation is complete and accurate, and a brief statement of the qualifications of the person who made the translation (*e.g.,* education and experience). This information would help FDA ensure that the English language translations of documents are complete and accurately reflect the content of the original documents.

As described in proposed § 1114.49, FDA is proposing that the PMTA and all supporting documents must be submitted to FDA in an electronic format that the Agency can process, review, and archive, unless the Agency has previously granted a waiver from these requirements. An application would not be considered received until CTP's Document Control Center has received an application that the Agency can process, review, and archive. Applicants that are unable to submit their applications in electronic format would be permitted to obtain a waiver from the electronic filing requirement, in accordance with § 1114.49. FDA has provided information on our website about technical specifications, including electronic formats that would allow FDA to process, review, and archive the

application.[7] FDA intends to update this information as needed to accommodate changes in technology.

FDA is proposing these format requirements using its authority under sections 701 and 910 of the FD&C Act to efficiently enforce premarket review requirements. The requirements in proposed § 1114.7(b) are intended to address some of the problems we have seen with applications to date. For example, some applications have been submitted to FDA in a proprietary or password protected format without providing FDA access or password information. Following up with an applicant to obtain access or password information takes time and contributes to delays. In addition, some electronic submissions have not been in a static format, and thus, the pages reformat, renumber, rebullet, or re-date each time the document is accessed. Receiving applications with these issues affects our ability to cross-reference, share (internally), and efficiently evaluate information. Lastly, because FDA is required under regulations governing Federal records to maintain many files long term, and in a ''sustainable'' format (for more information on sustainable formats, please refer to National Archives and Records Administration Bulletin 2014–04, *https://www.archives.gov/records-mgmt/bulletins/2014/2014-04.html*), proposed § 1114.7(b) would ensure that these files can be managed, opened, and read by the Agency for the duration of the retention period.

Finally, proposed § 1114.7(b)(2) would allow an applicant to include content in a PMTA by cross-reference to a tobacco product master file (TPMF) or a pending MRTPA for the same tobacco product submitted under section 911 of the FD&C Act (21 U.S.C. 387k). TPMFs allow individuals to rely on the information contained in a TPMF in a submission to FDA without the TPMF owner having to disclose the information to those individuals. TPMFs are typically used to prevent the disclosure of information that contains trade secrets or confidential commercial information. One situation in which TPMFs might be useful in submitting a PMTA is where an applicant is seeking marketing authorization for a new tobacco product that is made using a component or part, or ingredient that is purchased from another tobacco product manufacturer (*e.g.,* blended tobacco or an e-liquid). Applicants must demonstrate they have the right to reference the TPMF to be able to include content by cross-reference, such as by having the master file holder provide a letter of authorization. Applicants must specify the master file number and clearly identify the specific content that it is incorporating into its PMTA. For FDA's current thinking on the use of master files, please consult the guidance for industry ''Tobacco Product Master Files.'' [8]

Applicants may also include content in a PMTA by cross-reference to a pending MRTPA for the same tobacco product.[9] FDA recommends that applicants seeking to market a new tobacco product that has not previously received marketing authorization as a modified risk tobacco product submit a single application under section 911(l)(4) of the FD&C Act (*i.e.,* a combined PMTA and MRTPA); however, where an applicant chooses to submit a separate PMTA and MRTPA, FDA recommends that an applicant submit the full text of any common content (*e.g.,* the manufacturing or product formulation sections) in only one application and include it in the other by cross-reference. This approach would prevent any transcription errors and would also allow for a more effective review by FDA because the content would only need to be reviewed once to be considered as part of both applications.

Under the proposed rule, except as described in subpart B, FDA would not consider content included by cross-reference to any other sources of information outside of a submission. An applicant may use internal cross-references for any content that would need to be referenced in multiple sections of a PMTA (*i.e.,* include the full text of the content in one section and use cross-references to the content in other sections), rather than including the full text of the same information multiple times. If an applicant wishes to include information it has previously submitted to FDA other than a master file or a pending MRTPA (*e.g.,* portions of an SE Report or previously submitted PMTA for a different product), the applicant would be required to include the full text of such information in its PMTA. FDA is proposing this restriction because cross-referencing information from other types of applications (*e.g.,* SE Reports, previously submitted PMTAs for different products) can make review difficult and contribute to delays in the review process. An applicant may also submit a single premarket submission for multiple products (*i.e.,* a bundled PMTA) and a single, combined cover letter and table of contents across all products; however, when FDA receives a premarket submission that covers multiple new tobacco products, we intend to consider information on each product as a separate, individual PMTA and it is important to identify the content that pertains to each product.

3. General Information

Proposed § 1114.7(c) lists the information that would be required to be included in the General Information section of the PMTA. This information consists of general administrative information that includes the type of submission, the new tobacco product with unique identifiers, and contact information. The table, as set forth in proposed § 1114.7(c), would include requirements to submit general information related to electronic nicotine delivery systems (ENDS) product category and several subcategories of ENDS. FDA generally considers ENDS to be electronic nicotine delivery systems that deliver aerosolized e-liquid when inhaled. The term ''e-cigarette'' refers to an electronic device that delivers e-liquid in aerosol form into the mouth and lungs when inhaled; it is also sometimes referred to as an aerosolizing apparatus. An open e-cigarette, also referred to as a refillable e-cigarette, is an e-cigarette that includes a reservoir that a user can refill with an e-liquid of their choosing. A closed e-cigarette is an e-cigarette that includes an e-liquid reservoir that is not refillable, such as a disposable cigalike, or that uses e-liquid contained in replaceable cartridges or pods that are not intended to be refillable. For additional information on ENDS, consult the guidance ''Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems.''

The PMTA would be required to include the following information using the FDA-provided form (Ref. 6), as appropriate:

- Applicant name, address, and contact information;
- The name, address, and contact information for the authorized

[7] For more information on electronic submission, including electronic submission file formats and specification, please visit FDA's web page at: *https://www.fda.gov/industry/fda-esubmitter/using-esubmitter-prepare-tobacco-product-submissions.*

[8] Available at: *https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/guidance.*

[9] FDA has not included MRTPAs that resulted in a modified risk order in the list of documents that an applicant may cross-reference as part of a PMTA. Because a new tobacco product must receive an order under section 910 of the FD&C to be introduced or delivered for introduction into interstate commerce, FDA does not intend to act on a MRTPA unless the product has a pending application seeking, or has already received, marketing authorization under section 910. Such an approach would allow FDA to efficiently enforce section 911 of the FD&C Act by focusing its efforts on only those applications that could potentially result in a tobacco product being introduced to the market.

representative or U.S. agent (for a foreign applicant). As required by § 1105.10(a)(5) for application acceptance, a foreign applicant must identify a U.S. agent (*i.e.,* an individual located in the United States who is authorized to act on behalf of the applicant for the submission) to help FDA ensure adequate notice is provided to applicants for official Agency communications, assist FDA in communicating with the foreign applicant, and help the Agency to efficiently process applications and avoid delays.

- Information to uniquely identify the product. Providing unique identifying information is important to aid in FDA's review because it ensures FDA has information readily available to distinguish the tobacco product from other tobacco products, including additional new tobacco products in a bundled submission (*i.e.,* more than one application contained in a single submission), and assists FDA in performing its acceptance and filing reviews. The required unique identifying information would include:
  - The manufacturer;
  - Product name(s), including the brand and subbrand (or other commercial name(s) used in commercial distribution);
  - Product category; product subcategory; and product properties, as provided by the tables in proposed § 1114.7(c). The applicant would select and provide the appropriate category, subcategory, and product properties for the new tobacco product. This product-specific information is required under sections 910(b)(1)(B) and (G) of the FD&C Act and the proposed rule would require its inclusion in the general information section to help FDA quickly check whether the product is within CTP's purview and identify the specific product that is the subject of the submission. For more information regarding product properties and why specific properties would be a required part of an application, see the discussion of proposed § 1114.7(i)(1) in section VII.B.9. It is important to note that for the characterizing flavor product property, the applicant would be required to state ''none'' if it does not consider the product to have a characterizing flavor. Applicants that have questions regarding how to describe their product's characterizing flavor are encouraged to contact FDA prior to submission.

For each type of tobacco product, the applicant should also include any additional properties to fully identify the tobacco product, if applicable. For example, use of product descriptors such as ''extra-long'' should be identified. While failure to include such additional properties to help uniquely identify the tobacco product would not serve as the basis for FDA refusing to accept an application under proposed § 1114.27(a)(1), it would likely slow down the substantive review process.

- The type of PMTA. The applicant would be required to state the type of PMTA the applicant is submitting (*i.e.,* PMTA, supplemental PMTA, or resubmission);
- Whether the applicant requests that FDA refer the PMTA to the Tobacco Products Scientific Advisory Committee (TPSAC). An applicant should briefly describe its justification for a request to refer the PMTA to TPSAC. FDA retains the discretion to refer an application to TPSAC, but will consider an applicant's request as part of its determination.
- Identifying information regarding any prior submissions relating to the new tobacco product, including submission tracking numbers (STNs), where applicable. The types of prior submissions may include premarket applications, such as PMTAs, SE Reports, and exemption requests, as well as other submissions to FDA including MRTPAs and submissions related to investigational tobacco products. The regulatory history of a tobacco product can provide useful context for FDA's review of a submission;
- Dates and purpose of any prior meetings with FDA regarding the new tobacco product;
- Address and the Facility Establishment Identifier (FEI) number(s) of the establishment(s) involved in the manufacturer of the new tobacco product. This information would assist the Agency with environmental impact considerations and determinations under part 25 by helping FDA understand the location of manufacturing and scale of products that would be manufactured. Additionally, it helps FDA schedule and conduct facility inspections;
- A brief statement regarding how the PMTA satisfies the content requirements of section 910(b)(1) of the FD&C Act. This could consist of a table reproducing the section 910(b)(1) requirements and listing the sections or page numbers of the PMTA that satisfy the requirements. FDA is requiring this brief statement under authority of sections 701(a) and 910(b)(1)(G) of the FD&C Act, which would allow FDA to more quickly locate application content necessary to determine whether a PMTA should be accepted and filed for further review under proposed § 1114.27;
- A brief description of how permitting the marketing of the new tobacco product is expected to be appropriate for the protection of the public health (APPH). This description should be no more than a sentence or two that highlights the key product characteristics and study results the applicant believes would make the marketing of the product APPH (*e.g.,* the product delivers significantly lower levels of a specific HPHCs to users than the tobacco products they are currently consuming, which studies indicate may result in decreased morbidity and mortality); and
- A list identifying all enclosures, labels, and labeling being submitted with the application. This list will help FDA identify application content and ensure a PMTA contains all the information the applicant intended to submit.

4. Descriptive Information

Proposed § 1114.7(d) would require applicants to provide descriptive information in this section that outlines the major aspects of the new tobacco product, which is required to be submitted under sections 910(b)(1)(A), (D), and (G) of the FD&C Act. This information would include:

- A concise description of the new tobacco product (*e.g.,* the product is a portioned smokeless tobacco product made using a blend of burley and bright tobacco);
- A statement identifying all tobacco product standards issued under section 907 of the FD&C Act that are applicable to the new tobacco product and a brief description of how the new tobacco product fully meets the identified tobacco product standard(s). If the new tobacco product deviates from such standard(s), if applicable, the proposed rule would require the application to include adequate information to identify and justify those deviations;
- The product name(s) as designated on the product's label;
- A description of problems identified in prototypes that are the subject of studies contained in the application, or previous or similar versions of the new tobacco product that were marketed, if any. If there are previous or similar versions that are the subject of studies in the application or were marketed, the proposed rule would require the applicant to include a bibliography of all reports regarding the previous or similar version of the product, whether adverse or supportive. FDA would require this information under section 910(b)(1)(A) and (G) of the FD&C Act to assess whether any known issues with a predecessor product that

could affect the health risks of the new tobacco product have been addressed;

• Any restrictions on the sale, distribution, advertising, or promotion of the new tobacco product (as described in section 910(c)(1)(B) of the FD&C Act) that the applicant proposes to be included as part of a marketing order, if issued. The applicant may choose to propose restrictions on the sales and distribution of the tobacco product to help support a showing that the marketing of the product is appropriate for the protection of the public health (*e.g.,* a restriction that decreases the likelihood that those who do not currently use tobacco products will initiate tobacco product use with the new tobacco product). If an applicant does not wish to propose any additional restrictions, it would be required to explicitly state that it proposes no restrictions. As described in proposed § 1114.31, FDA will consider these proposed restrictions during its review of the PMTA and, where appropriate, include the restrictions in the marketing order for the product together with any additional restrictions FDA may require.

5. Samples of New Tobacco Products and Components or Parts

Section 910(b)(1)(E) of the FD&C Act requires an applicant to submit samples of a tobacco product and its components as FDA may reasonably require. After FDA accepts a submission, FDA will determine whether it will require product samples and, if so, issue instructions on how and where to submit the samples, and the number of samples that are required. Proposed § 1114.7(e) would require an applicant to submit samples of the finished tobacco product and its components in accordance with instructions issued to the applicant after a PMTA is accepted for review, as well as to submit additional samples if required by FDA during application review. FDA generally expects that product samples will be a required part of a PMTA and that an applicant should be prepared to submit them in accordance with FDA instructions within 30 days after submitting a PMTA. There may be situations in which sample submission may not be necessary, including, in some circumstances, PMTAs that are resubmitted for the same product after a no marketing order (such as resubmissions as described in § 1114.17) or PMTAs submitted for modifications to an authorized product where the modifications do not require review of new samples as part of the PMTA evaluation process. Presubmission meetings with FDA may help provide additional information about whether product samples will need to be included in a PMTA; however, in most situations, FDA will only be able to determine the need for product samples after a PMTA is accepted for review.

FDA is proposing to have applicants submit samples as required by FDA after acceptance of an application rather than as part of an initial submission. This would allow FDA to determine the need for samples, allow the samples to be tracked and identified as part of the correct application, and submitted to testing facilities that are adequately prepared to accept the samples (*e.g.,* one that has a refrigerated unit if the product needs to be stored at a certain temperature). Additionally, by having applicants submit samples after FDA accepts an application, applicants will be able to avoid the effort and expense of submitting samples if the application is not accepted for review or if samples are not required. As described in proposed § 1114.27, if required by FDA, product samples would be necessary for application filing and FDA intends to refuse to file a PMTA for a lack of product samples if the applicant has not submitted samples in accordance with FDA's instructions by the time FDA is prepared to make its filing determination. FDA intends to notify an applicant if it determines after PMTA acceptance that product samples are not required for PMTA filing; however, even in such a situation, FDA may request product samples during substantive review after an application is filed, as needed.

6. Labeling and Marketing Plans

Proposed § 1114.7(f) of the FD&C Act would require that a PMTA contain specimens of labeling and the applicant's marketing plans for the new tobacco product.

a. *Labeling.* Section 910(b)(1)(F) of the FD&C Act requires that a PMTA contain specimens of the proposed labeling to be used for the tobacco product. Proposed § 1114.7(f)(1) would elaborate on this requirement and require the application to contain specimens of all proposed labeling for the new tobacco product, including labels, inserts, onserts, instructions, and other accompanying information. The specimens of labeling would be required to include all panels and reflect the actual size and color proposed to be used for such tobacco product. The labels must include any warning statements required by statute or regulation such as the Federal Cigarette Labeling and Advertising Act, the Comprehensive Smokeless Tobacco Health and Education Act, or the minimum required warning statements contained in 21 CFR part 1143.

As described in proposed § 1114.33, product labeling is an important part of FDA's review of an application because FDA must deny a PMTA under section 910(c)(2)(C) of the FD&C Act where it finds, based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular. Additionally, product labeling can be an important part of FDA's determination under section 910(c)(2)(A) of the FD&C Act of whether there is a showing that permitting the marketing of the product would be APPH because it can be used to help show perception of the risks of the product and the ability of individuals to understand the labeling, including any instructions for use, as described in proposed § 1114.7(k)(1)(iv).

b. *Marketing Plan.* Proposed § 1114.7(f)(2) would require a PMTA to contain a description of the applicant's marketing plans for the tobacco product that an applicant has developed by the time of submission and concerning at least the first year of marketing after an applicant receives a marketing order, including information relating to labeling, advertising, marketing, promotion, and sales and distribution of its new tobacco product. FDA is proposing to require the submission of marketing plans as part of a PMTA under its authority in section 910(b)(1)(G) of the FD&C Act to require other information relevant to the subject matter of the application because marketing plans can provide important information regarding whether permitting the marketing of the new tobacco product would be APPH. Specifically, marketing plans can inform FDA's consideration under section 910(c)(4) of the FD&C Act of the potential risks and benefits of the tobacco product to the population as a whole, including whether the marketing of the product would increase or decrease the likelihood that those who do not use tobacco products, including youth and young adults, will start using them.

FDA is proposing to require the submission of marketing plans to help it understand and prevent or minimize the potential harm that could be caused by the marketing of a new tobacco product. Consistent with its mission to protect the public health, FDA seeks to limit youth exposure to the labeling, advertising, marketing, or promotion of a new tobacco product in order to limit uptake of the new tobacco product by nonusers of tobacco products, especially youth. FDA must also assess potential uptake of the new tobacco product by current tobacco product users who

would have otherwise stopped using tobacco products and how use of the new tobacco product may affect poly use behaviors and subsequent tobacco use. Applicants may have information that allows them to carefully target the marketing for a particular product to reach only its intended consumers of legal age. In reviewing the marketing plans contained in a PMTA, FDA intends to consider how an applicant will target the marketing of its new tobacco product to reach its intended consumers of legal age and to assess potential effect on nonusers. FDA will also consider how the applicant intends to minimize the extent to which youth can access the product and are exposed to its marketing. Where FDA determines that restrictions on the sales and distribution of the new tobacco product (including access to, and the advertising and promotion of, the tobacco product) would be APPH, FDA can impose such restrictions under the terms of a marketing order as described in section VIII.D.

The applicant's marketing plans will help FDA determine whether permitting the marketing of the new tobacco product would be APPH because they will provide input that is critical to FDA's determination of the likelihood of changes in tobacco product use behavior, especially when considered in conjunction with other information contained in the application. FDA will review the marketing plan to evaluate potential youth access to, and youth exposure to the labeling, advertising, marketing, or promotion of, a new tobacco product. For example, heavy use of online social media to promote a tobacco product without access restrictions, as opposed to actions such as paper mailings directed only to current smokers of legal age, indicates the potential for youth to be exposed to the promotion of the product. This information would help FDA make its APPH determination by showing whether a PMTA fully or accurately accounts for the likelihood of changes in tobacco product use behavior that may occur as a result of marketing the new tobacco product. For example, if the PMTA does not address youth access to the product, youth exposure to the product's labeling, advertising, marketing, and promotion, and youth initiation, such as describing how it proposes to restrict the sale or distribution of its product to limit potential youth access to the product (*e.g.,* selling the tobacco product in adult-only establishments) or exposure to advertising (*e.g.,* using age verification controls for digital advertising), FDA may be unable to determine that the applicant has made a showing that permitting the marketing of the new tobacco product would be APPH. FDA expects that companies seeking authorization will have prepared plans for potential marketing that they expect to undertake during at least an initial period of marketing, such that providing these plans as part of the application would not require significant resources.

Additionally, as set forth in proposed § 1114.41, FDA would require each applicant that receives a marketing order to continue to report its marketing plans, along with items such as copies of the product's labeling, advertising, marketing, and promotion, and the results of the implementation of such plans. Continuing to monitor the marketing plans for the new tobacco product once on the market is important to help FDA evaluate both the potential for changes to tobacco product use behavior and the implementation of any restrictions in the marketing order. As described in section VIII.F., where FDA finds that the continued marketing of a new tobacco product is no longer APPH, such as where changes in the marketing of a new tobacco product result or are likely to result in a significant increase in youth initiation not foreseen in FDA's review of a PMTA, FDA would withdraw the marketing order for a product.

There is a well-established body of scientific evidence regarding the effect of advertising and marketing on tobacco product initiation (*see e.g.,* Refs. 7–10), which FDA must consider as part of its basis for determining whether permitting the marketing of a product would be appropriate for the protection of the public health under section 910(c)(4) of the FD&C Act. The impact of tobacco advertising and marketing on youth and young adult tobacco use behavior has been well documented. The 2012 Surgeon General's report, *Preventing Tobacco Use Among Youth and Young Adults,* synthesizes more than 30 years of research on the topic and states that the strong empirical evidence, along with the tobacco industry's own internal documents and trial testimony, as well as widely accepted principles of advertising and marketing, support the conclusion that tobacco manufacturers' advertising, marketing, and promotions recruit new users as youth and continue to reinforce use among young adults. (Ref. 12). The National Cancer Institute made a similar conclusion it its monograph, *The Role of the Media in Promoting and Reducing Tobacco Use,* that the total weight of evidence—from multiple types of studies, conducted by investigators from different disciplines, and using data from many countries—demonstrates a causal relationship between tobacco advertising and promotion and increased tobacco use. (Ref. 8). A variety of research has found that exposure to advertising is associated with susceptibility to use tobacco products and the actual use of tobacco products (*see e.g.,* Refs. 13–21). For example, research has found that the use of certain kinds of imagery, such as logos and cartoons, have an impact on youth tobacco initiation (*see, e.g.,* Refs. 22–24) and that a key tactic of tobacco companies seeking to attract and recruit youth users is to use advertising and marketing with aspirational imagery and themes known to resonate with younger audiences, such as independence, popularity, rebelliousness, attractiveness, and being cool (Ref. 12).

Marketing plans would provide information about the ways and frequency with which consumers would be exposed to tobacco product advertising, marketing, promotion, and other communication activities. This information can provide valuable insight into the likelihood that nonusers, particularly youth, would initiate tobacco product use. An analysis of the 2011 National Youth Tobacco Survey (NYTS) found that adolescents who reported frequent exposure to tobacco advertising at the point of sale and on the internet had significantly higher odds of ever using e-cigarettes and that there was a dose-response association between the number of marketing channels to which they were exposed and whether they used tobacco products. (Refs. 21 and 25). An analysis of 2014 NYTS data assessing exposure to e-cigarette advertising in different channels (*i.e.,* internet, print, television and movies, retail stores) found that as the number of channels of e-cigarette marketing exposure increased, the likelihood of use and susceptibility also increased. (Refs. 25–27).

Proposed § 1114.7(f)(2) would require, as part of the description of the marketing plans, that the PMTA specify information such as the intended target audience(s), media and distribution channels, specific tactics, total dollar amount(s) of media buys and marketing and promotional activities, and timing for the activities, including, but not limited to, information describing the items listed below. As used in proposed § 1114.7(f)(2), other consumer-directed activities include any other types of action regarding the new tobacco product that may reach consumers, such as communications that are intended to

inform retailers' communications with consumers. If an applicant does not intend to use any advertising, marketing, promotion, or other communication activities directed at consumers regarding its new tobacco product, or the applicants has not developed marketing plans by the time of filing, the PMTA must contain a statement to that effect in this section of the application. The types of information that the marketing plan section would be required to contain include, but are not limited to:

- Any plans to use competent and reliable data sources, tools, technologies, and methodologies to establish, maintain, and monitor highly targeted marketing plans and media buys. This could include, for example, use of and sources of first and second-party age-verified data, public records, industry-standard syndicated research services, and embedded tracking pixels in digital advertising;
- A description of the target adult audiences by age-range(s) (including young adult audiences ages 18–24) and other demographic and psychographic characteristics. Examples of demographic characteristics include, but are not limited to race, ethnicity, and geographic location (*e.g.,* urban, rural). Examples of types of psychographic characteristics include, but are not limited to hobbies, interests, risk-taking behaviors, tobacco use behaviors, purchase behaviors, and online search behaviors;
- A description of the target audience insights (*e.g.,* demographics, psychographics, findings from consumer research) the applicant is using to inform its marketing plans, including its strategic approach, key messages and themes, creative direction, and potential tactics or marketing channels. FDA generally expects that applicants will have conducted market or consumer research to determine, and gain information regarding, its target audience. This could include product-specific insights (*e.g.,* target audience impressions of one product being just as harmful as another, preference of a certain brand), as well as other beliefs, interests, motivations, or behaviors that can be used to tailor a manufacturers approach to marketing the product. This could also include information regarding where the target audience tends to consume marketing and advertising (*e.g.,* television programs the target audience watches, social media influencers the target audience follows, websites and retail locations the target audience frequents) that can be used to tailor its approach, select relevant marketing tactics, and use relevant marketing channels. The applicant should describe such insights in this section of the application;
- Any means by which youth-access to the tobacco product or youth-exposure to the tobacco product labeling, advertising, marketing, and promotion would be limited. FDA expects that applications will contain information regarding how the applicant intends to prevent sales or distribution to individuals below the legal purchasing age. Such information could include, for example, whether and how the company intends to: utilize independent, third-party age and identity-verification software on its website(s); distribute its product only to age-restricted locations; and limit the quantity of its product that an adult customer may purchase within a given period of time;
- Plans to use owned, earned, shared, or paid social media to advertise or promote the tobacco product. While media categories often overlap, owned media typically consists of a company's own media properties they control, such as the company's product-branded website. Earned media typically consists of unpaid media publicity, consumer interest or pick up of advertising or promotion, such as a news article about the product or a social media influencer talking about a company's product or sharing's a company's social media post without payment. Shared media typically consists of a company's social media properties, such as a company's social media accounts and content. Paid media consists of advertising and promotion that a company pays for, such as advertising appearing on television and radio, in and around retail stores, and in digital media, including content shared by a social media influencer who a company pays to promote to the tobacco product;
- Plans to use partners, sponsors, influencers (*e.g.,* celebrities, cultural icons, individuals with substantial followers on social media), bloggers, or brand ambassadors to create labeling for, market, advertise or promote the tobacco product;
- Plans to conduct in-person consumer engagements, including events at which the tobacco product will be demonstrated or sampled. Applicants planning to conduct in-person engagements should include a description of how access would be restricted to individuals at or above the Federal minimum age of purchase; and
- Plans to use earned media, public relations, or other communications outreach to promote the tobacco product. Earned media could consist of actions such as plans to pitch stories about the new tobacco product to newspapers without compensation. Public relations could consist of actions such as using a public-relations firm to promote the tobacco product. Other communications to promote the product could consist of actions such as direct mail to consumers.

FDA invites comment on the specific information in the proposed marketing plans section, and whether FDA should require additional information related to marketing plans and the basis for any such additional provisions.

At this time, FDA is not proposing to require the submission of advertising for application filing, except where used as stimuli in studies (*e.g.,* stimuli in perception studies). Specifically, in addition to the marketing plan requirements in this section, proposed § 1114.7(k)(1)(iv) would require a PMTA to contain full reports of information concerning investigations that are published, known to, or should be known to, the applicant regarding the impact of the tobacco product's label, labeling, and advertising on perceptions of the product and tobacco product use intentions.

7. Statement of Compliance With Part 25

A PMTA must contain an environmental assessment (EA) prepared in accordance with § 25.40 or a valid claim of a categorical exclusion, if applicable. Pursuant to § 25.15(a), all submissions requesting FDA action require the submission of either a claim of categorical exclusion or an EA. In accordance with § 25.40(a), an environmental assessment must include, at a minimum, brief discussions of: The need for the proposed action; alternatives to the proposed action as required by section 102(2)(E) of the National Environmental Policy Act of 1969 (NEPA); the environmental impacts of the proposed action and alternatives; the agencies and persons consulted during the preparation of the EA, and the relevant environmental issues relating to the use and disposal of the tobacco product. Although applicants may wish to review the categorical exclusions specific to tobacco product applications at § 25.35, the only categorical exclusion currently available for a marketing order is for the substantial equivalence premarket pathway, not for PMTAs. If the applicant believes the action would qualify for an available categorical exclusion, the applicant would be required to state under § 25.15(a) and (d) that the action qualifies for a categorical exclusion, cite to the claimed exclusion, and state that to the applicant's

knowledge no extraordinary circumstances exist under § 25.21.

If the new tobacco product resulted from modification(s) to a legally marketed predecessor product (*i.e.,* a grandfathered tobacco product or a product that has received marketing authorization from FDA), the environmental assessment also would be required to include a statement indicating whether the new tobacco product is intended to: (1) Replace the predecessor tobacco product once the new tobacco product receives market authorization and is commercially marketed; (2) be a line extension of the predecessor tobacco product; (3) be marketed along with the predecessor product by the same manufacturer; and/or (4) be marketed along with the predecessor tobacco product by a different manufacturer (*e.g.,* by a manufacturer other than the manufacturer of the predecessor tobacco product). The change in what is available in the marketplace is a factor FDA considers in determining whether the issuance of a marketing order may significantly affect the quality of the human environment as part of its NEPA review, *e.g.,* the new product may present different disposal issues if more product remains after consumer use or if the materials that the new product is composed of degrade differently.

Failure to include an EA in a PMTA is grounds for FDA to refuse to accept an application and failure to include an adequate EA is sufficient grounds under § 25.15 for FDA to refuse to file the PMTA or refuse to issue a marketing order. (See the discussion of proposed §§ 1114.27 and 1114.29 in section VIII.)

8. Summary

Proposed § 1114.7(h) would require the application to contain a summary of the application contents in sufficient detail to provide FDA with an adequate understanding of the data and information in the application. FDA is proposing to require the summary under authority of sections 701(a) and 910(b)(1)(G) of the FD&C Act because it will provide FDA with an understanding of the information contained in the PMTA and allow FDA to plan and conduct a more efficient review of the detailed technical information the summary describes. The summary would also help reviewers understand the product and the accompanying scientific data more quickly and would allow applicants to highlight information they believe demonstrates their product should receive a marketing order. The summary should discuss all aspects of the PMTA and synthesize the application into a well-structured, unified document. The summary should serve as a briefing document that highlights the most important aspects of the application, with each section consisting of a page or two focused on information that the applicant believes contributes to a finding that permitting the marketing of the product would be APPH. The applicant would be required to summarize the content included in the PMTA in a manner that describes the operation of the product, the health risks of the new tobacco product, the product's effect on tobacco use behavior of current users, the product's effect on tobacco use initiation by nonusers, and the product's effect on the population as a whole. The summary section would be required to contain a discussion of the following items, where applicable, and explicitly identify areas in which there is a lack of information, if any:

- A summary of the product formulation section of the application. This section should provide a high-level description of the product formulation section of the application, highlighting information such as key ingredients, constituent levels, and design aspects of the product. See the discussion of proposed § 1114.7(i) in section VII.B.9;
- A summary of the manufacturing section of the application. This section should provide an overview of the manufacturing section of the application, including activities at each facility, and highlighting information such as major aspects of the manufacturing and controls, especially those that the applicant believes contribute to a finding that permitting the marketing of the product would be APPH (*e.g.,* an aspect of the manufacturing process that results in lower levels of HPHCs than other tobacco products in the same category). See the discussion of proposed § 1114.7(j) in section VII.B.12.;
- A summary of the health risk investigations section of the application. This section should briefly describe and synthesize the findings of each investigation describing:
  - The health risks of the tobacco product to both users and nonusers of the product and whether the tobacco product presents less health risk than other tobacco products, such as the risk of cancers (*e.g.,* lung, mouth, pancreatic), heart disease, stroke, or lung disease, compared to other categories of tobacco products and other tobacco products within the category, if known. See the discussion of proposed § 1114.7(k)(1)(i) in section VII.B.13.a.i.;
  - The impact the product and its marketing will have on the likelihood of changes in tobacco use behavior of tobacco product users, including cessation, switching (*i.e.,* to a different tobacco product), and poly use (*i.e.,* using the new tobacco product in conjunction with one or more other tobacco products). See the discussion of proposed § 1114.7(k)(1)(ii) in section VII.B.13.a.ii.;
  - The impact the product and its marketing will have on the likelihood of tobacco use initiation by tobacco products nonusers, especially youth and young adults, including among never users and former users, and the likelihood of poly use and switching behaviors. See the discussion of proposed § 1114.7(k)(1)(iii) in section VII.B.13.a.iii.;
  - How users and nonusers perceive the tobacco product and its label, labeling, and advertising, how the label, labeling, and advertising affect use intentions, and whether users are able to understand the labeling and instructions for use and use the product in accordance with those instructions. See the discussion of proposed § 1114.7(k)(1)(iv) in section VII.B.13.a.iv.; and
  - The impact of human factors on the health risks to product users and nonusers including, for example, how various use and misuse scenarios may impact the health risks posed by the product. See the discussion of proposed § 1114.7(k)(1)(v)) in section VII.B.13.a.v.

The proposed rule also would require the summary to contain a concluding discussion demonstrating how the data and information contained in the PMTA both constitute valid scientific evidence and establish that permitting the marketing of the new tobacco product would be APPH, as determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product. FDA recommends that this discussion include estimates of the effect that the new tobacco product may have on the health of the population as a whole, such as effects on tobacco use initiation switching and cessation, and reductions in premature mortality, or increases in life-years lived. The estimates should integrate all of the information in the PMTA regarding the product and its potential effects on health, including, but not limited to adverse experiences, tobacco use behavior, and tobacco use initiation to provide an overall assessment of the potential effect that the product's marketing has or may have on overall tobacco-related morbidity and mortality. It is important to also include information regarding adverse experiences associated with use of or exposure to a product where the individual suffering the adverse

experience did not use the product because it can help FDA determine health risks for nonusers such as the effects of second-hand exposure or accidental exposure (*e.g.,* skin burns from accidental exposure to liquid nicotine, harmful effects resulting from a child drinking an e-liquid, respiratory difficulties from second-hand exposure to an e-cigarette).

Additionally, reporting information regarding all adverse experiences that are temporally associated with the use of or exposure to the product will help the applicant avoid self-selection bias of what is reported to FDA and help identify harmful effects that are not obviously attributable to the product. As an illustration, an applicant may make an overall assessment of whether the product will have a net benefit on population health by accounting for potential reductions in disease risk (compared to other tobacco products) and the potential for current tobacco users to switch to the new tobacco product, and weighing that against the potential for nontobacco users to use the tobacco product and the accompanying potential increases in disease risks among those new tobacco product users. An applicant should provide quantitative assessments in the concluding discussion wherever possible; however, an applicant may provide qualitative assessments where appropriate for the type of investigation(s) on which the assessment is based (*e.g.,* focus group or interview-type studies).

The summary's concluding discussion must also briefly describe why the data and scientific information on which the applicant relies in concluding that permitting the marketing of the product would be APPH constitute valid scientific evidence. Section 910(c)(5)(A) of the FD&C Act requires FDA to make its determination of whether the marketing of a new tobacco product is APPH, where appropriate, on the basis of well-controlled investigations; however, under section 910(c)(5)(B) of the FD&C Act, where FDA determines that there exists valid scientific evidence other than well-controlled investigations that is sufficient to evaluate the product, FDA may use such evidence. As discussed in more detail in section VIII.D. regarding proposed § 1114.31, FDA considers valid scientific evidence to be evidence gathered using well-established or standardized methodologies from which it can be concluded by qualified experts that there is reasonable assurance of the reliability of its findings. Thus, if an application contains information regarding another tobacco product (*e.g.,* published literature, marketing information) with appropriate bridging studies and describes the relationship to the product that is the subject of the application, FDA will review that information to determine whether it is valid scientific evidence sufficient to demonstrate that permitting the marketing of a product would be APPH.

9. Product Formulation

Section 910(b)(1)(B) of the FD&C Act requires that a PMTA contain a full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of such tobacco product. Proposed § 1114.7(i) would implement FDA's interpretation of this statutory requirement, together with its authority under section 910(b)(1)(G) of the FD&C Act, by requiring a PMTA to contain the following information:

a. Components or parts, materials, ingredients, constituents, and additives. Under the proposed rule, the application would be required to contain a full statement (*i.e.,* a listing) of the product components or parts, materials, ingredients other than tobacco, tobacco ingredients, HPHCs, and the container closure system.

i. Components or parts. Proposed § 1114.7(i)(1)(i) would require the application to state the quantity, function, and purpose of, and where applicable, target specifications of each component or part in the product. This information should also include an explanation of how each component or part is, or can be, integrated into the product design, and the purpose and function of each component or part. Where the tobacco product contains software components, the rule would require:

- A description of the software or technology (*e.g.,* Bluetooth);
- A description of the purpose of the software or technology, such as monitoring where the tobacco product is located, activated, or used;
- A description of the data collected by the software and how this information will be used by the applicant.

This information is especially important as it may not be readily apparent from the component or part's identity what function and purpose it may serve. For example, software used in or with a product may have functions and purposed that are not immediately clear, such as use monitoring and location tracking functions, and may be able to function in conjunction with other electronic devices, such as a smart phone.

ii. Materials. Proposed § 1114.7(i)(1)(ii) would require that the application include the following information for each material in the product because materials can affect the performance of the product. For example, in portioned smokeless tobacco products, the materials used in the pouch can affect the rate at which nicotine is released and specifications such as pouch fabric air permeability can provide information about how quickly nicotine can be delivered to the consumer. For ENDS, the material used in the construction of an electrical heater coil influences its resistance and the temperature reached by the coil, which in turn may affect the type and amount of HPHCs produced in aerosol. The rule would require:

- The material name and common name (if applicable);
- The component or part where it is located;
- The subcomponent or subpart where it is located (if applicable);
- The function of the material;
- Quantities (including ranges or means and acceptance limits);
- Specifications (including quality, grades, and suppliers) used for the new tobacco product (including any specification variations, if applicable); and
- Any other material properties that fully characterize the new tobacco product, such as pouch material porosity or air permeability for portioned smokeless products. While failure to include additional material properties to fully characterize the tobacco product would not serve as the basis for FDA refusing to accept or file an application under proposed § 1114.27(a)(1), it may slow down the substantive review process.

iii. Ingredients other than tobacco. Proposed § 1114.7(i)(1)(iii) would require that the application contain information on ingredients other than tobacco (information on tobacco ingredients is addressed in proposed § 1114.7 (i)(1)(iv)). The required information would include:

- International Union of Pure and Applied Chemistry (IUPAC) chemical name and common name (if applicable);
- Chemical Abstracts Service (CAS) number or FDA Unique Ingredients Identifier (UNII). Both the IUPAC and CAS or UNII would be required to ensure FDA has the relevant information associated with each identifier and to allow FDA to efficiently differentiate between similar ingredients;
- The function of the ingredient;

• The quantity of the ingredient, with the unit of measure (including ranges or means, and acceptance limits);
• The specifications (including purity or grade and supplier); and
• For complex purchased ingredients, each single chemical substance would be required to be reported separately.

Additionally, FDA recommends that an application contain any other ingredient information to fully characterize the new tobacco product, as applicable. While failure to include other ingredient information to fully characterize the tobacco product would not serve as the basis for FDA refusing to accept or file an application under proposed § 1114.27(a)(1), it may slow down the substantive review process.

iv. Tobacco ingredients. Proposed § 1114.7(i)(1)(iv) would require information regarding tobacco ingredients, including:

• The type(s) of tobacco, including grade(s) and variety or varieties. This information is important to determining the public health impact of the products because different grades and varieties have different constituent profiles. The application would also need to contain information on the applicant's grading system so that FDA understands the meaning of the grade;
• The quantity, with the unit of measure (including ranges or means, and acceptance limits), of each tobacco ingredient in the new tobacco product;
• The specification(s) of tobacco used for the new tobacco product (with any specification variation, if applicable); and
• A description of any genetic engineering that impacts characteristics, such as the constituent profile.

Additionally, FDA recommends a PMTA also contain any other information about tobacco ingredients to fully characterize the new tobacco product, as applicable, such as country of origin, which can affect constituent levels (Ref. 28). While failure to include other information about tobacco ingredients to fully characterize the tobacco product would not serve as the basis for FDA refusing to accept or file an application under proposed § 1114.27(a)(1), it may slow down the substantive review process.

If the new tobacco product does not contain tobacco (*e.g.,* rolling paper or tipping paper), this section of the application would be required to specifically state that the product does not contain tobacco.

FDA is proposing in § 1114.7(i)(1) that ingredient quantities be reported as mass per gram of tobacco for nonportioned tobacco products and as mass per portion for portioned tobacco products. These specific measurements provide consistent, complete information that would allow FDA to understand the ingredient quantities. In contrast, if ingredient quantities were reported as percentages, FDA would have to make assumptions about the denominator used to calculate the percentage. For example, if xylitol were reported as 10 percent of a portioned moist snuff, FDA would not able to determine if xylitol was 10 percent of the mass of the tobacco filler or of the entire product (containing filler, paper, etc.). For more information on uniquely identifying components, ingredients, and additives and reporting their quantities, please refer to FDA's guidance for industry ''Listing of Ingredients in Tobacco Products.''

v. Constituents. Proposed § 1114.7(i)(1)(v) would require a full statement of the constituents, including HPHCs and other constituents, contained within, or emitted from (including its smoke or aerosol), the product, including any reaction products from leaching or aging. FDA considers constituents to be properties of the new tobacco product, a full statement of which is required to be in a PMTA by section 910(b)(1)(B) of the FD&C Act. The constituents contained within, and delivered from, the product can be detected through constituent testing on the product. The constituent testing should reflect the various conditions under which consumers may use the product (*e.g.,* light use, typical use, and heavy use) and the types of products that consumers are likely to use in conjunction with the product. For example, an open (refillable) e-cigarette should be tested with a variety of e-liquids that consumers are likely to consume using the e-cigarette. The reports of constituent testing must be conducted in the manner required by, and include all information that is specified in, proposed § 1114.7(i)(1)(v), including the full test data.

FDA published an initial list of the constituents that it has identified as HPHCs in the **Federal Register** of April 3, 2012, which it intends to update periodically by providing the public with notice and the opportunity to submit comments. FDA is currently seeking public comment on its proposal to add 19 constituents to the established list of HPHCs.[10] An application would not be required to contain testing for all HPHCs on the initial list; rather, it would be required to contain testing for HPHCs that are contained within and can be delivered by the type of product and contain a description of why the HPHCs that were tested are appropriate for the type of product. The HPHC list can be helpful to applicants in preparing a description of why the HPHCs for which it tested are appropriate for the product type, including, where appropriate, why an applicant did not test for certain HPHCs. For example, a PMTA for a smokeless tobacco product would not be required to contain testing results for HPHCs that are a byproduct of combustion (*e.g.,* carbon monoxide) where the product does not contain or deliver such constituents. However, a PMTA for a tobacco product that an applicant claims aerosolizes a substance but does not combust it, such as an e-cigarette or heated tobacco product, should provide evidence, such as testing for HPHCs that result from complete or incomplete combustion, to demonstrate that the product is not combusted. For recommendations on constituent testing for ENDS products, please see the ''Guidance for Industry, Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems.'' Constituent testing data FDA is proposing that a PMTA contain for all products includes:

• The constituent names in alphabetical order;
• The common name(s);
• The CAS number;
• The mean quantity and variance with unit of measure;
• The number of samples and measurement replicates for each sample. As stated in proposed § 1114.7(i)(4)(iv), the testing would be required to be conducted using a sufficient sample size and number of replicates to substantiate the results of the type of testing conducted;
• A description of method procedure, method validation information and rationale for selecting each test method (as would be required by § 1114.7(i)(4)(v));
• The name and location of the testing laboratory or laboratories and documentation showing that the laboratory or laboratories is (or are) accredited by a nationally or internationally recognized external accreditation organization (as would be required by § 1114.7(i)(4)(i));
• The length of time between dates of manufacture and date(s) of testing (as would be required by § 1114.7(i)(4)(ii));
• Storage conditions of the tobacco product before it was tested. It is important for FDA to understand the storage conditions before testing because they could affect the quantity of volatile organic compounds or promote microbial growth in the tobacco product

[10] 84 FR 38032 (August 5, 2019).

(as would be required by § 1114.7(i)(4)(iii));

- Reports of constituent testing that include test protocols, any deviation(s) from the test protocols, quantitative acceptance criteria, line data, and a summary of the results, for each applicable parameter (as would be required by § 1114.7(i)(4)(vi); and
- Complete descriptions of any smoking or aerosol-generating regimens used for analytical testing that are not standardized or widely accepted by the scientific community, if applicable (as would be required by § 1114.7(i)(4)(vii).

For combusted or inhaled tobacco products, constituent smoke or aerosol yields from the new product would be required to be determined using intense and nonintense smoking or aerosol-generating regimens, where established. Two smoking or aerosol-generating regimens are required, where established, in order to understand the way that constituent yields delivered by a tobacco product can change over a range of different smoking conditions. If constituent yields were only reported from a single smoking or aerosol-generating regimen, FDA would have limited and potentially misleading information about constituent yields produced by a given tobacco product. Many studies demonstrate that different smoking regimens result in different constituent yields from the same product (Ref. 29–30). By requiring both an intense and a nonintense smoking or aerosol generating regimen, where established, FDA would have a better understanding of quantities of each constituent that may be produced by the tobacco product when used under different conditions. If an alternative to the established smoking regimens (*e.g.,* International Organization for Standardization (ISO) and Health Canada Intense (HCI) regimens for cigarettes) is used, such as where intense and nonintense smoking or aerosol generating regimens have not been established, the applicant would be required to provide an explanation of why the alternative provides comparable results to the intense and nonintense smoking regimens.

vi. Container closure system. Proposed § 1114.7(i)(1)(vi) would require that the application contain a description of the container closure system for the new tobacco product, if applicable, including information describing how the container closure system protects and preserves the product from damage during transport, environmental contaminants, and leaching and migration of constituents into the new tobacco product. The description would also need to describe design features developed to prevent the risk of accidental exposure, if any (*e.g.,* child resistant packaging for e-liquids). These descriptions are important to FDA's review of the product because they will help demonstrate that the product used by consumers is in the same condition as that described in the application and manufactured by the applicant, and also provide information regarding whether the container closure system has any features that could prevent accidental exposure (*e.g.,* a feature that prevents e-liquid from being accidentally ingested by children). Additionally, evidence demonstrates that the container closure system used can change the characteristics of the product. Packaging materials constitute the container closure system if substances within that packaging are intended or reasonably expected to affect product moisture, *e.g.,* when the manufacturer changes the container closure system of a moist snuff from plastic to fiberboard, which can affect microbial stability and TSNA formation during storage. Another example of this is when menthol or other ingredients are applied to the inner foil to become incorporated into the consumed product (Ref. 2). The container closure system may also be intended or reasonably expected to affect the characteristics of a tobacco product by impacting the rate of leaching into, and ultimately, the amount of substances found in, the consumable tobacco product. In fact, it has been demonstrated that compounds in the container closure system may also diffuse into snuff and affect its characteristics (Ref. 3). Thus, for example, packaging material that affects the characteristics of a tobacco product by impacting the moisture level or shelf life of a tobacco product is a container closure system (*e.g.,* a plastic versus a metal container of smokeless tobacco) because a difference in tobacco moisture is reasonably expected to affect microbial growth in the product, extraction efficiency, and total exposure to nicotine or the carcinogens NNN or NNK. For additional examples of container closure systems that may support a finding that permitting an ENDS to be marketed would be APPH, see the ''Guidance for Industry, Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems.''

vii. Statement of tobacco blending, reconstitution, manipulation. Finally, the proposed rule would require a full statement of the tobacco blending, reconstitution, or manipulation, where applicable. This may include manufacturer specifications, and tobacco types, quantities, and tobacco grading systems. This information is important because it helps FDA understand the characteristics of the tobacco product. Information on tobacco grades and grading systems used by an applicant (where applicable) will help FDA understand the quality of tobacco used, which can provide important information since the specified tobacco grades may impact the tobacco chemistry (*e.g.,* the nicotine content) and, thereby, the chemical composition of the tobacco product (Ref. 31).

b. Other properties. Proposed section § 1114.7(i)(2) describes additional parts of FDA's interpretation of the requirement in section 910(b)(1)(B) of the FD&C Act to provide a full statement of the product properties and, together with FDA's authority under section 910(b)(1)(G), would require the applicant to provide a full description of the properties of the tobacco product that includes:

i. Product dimensions and construction. The product dimensions and the overall construction of the product using a diagram or schematic drawing that clearly depicts the finished product and its components with dimensions, operating parameters, and materials. Under the proposed definition for finished tobacco product (which includes all components and parts, sealed in final packaging), the dimensions and schematic drawings would be required to include the final packaging. The diagram or schematic is an annotated graphical representation that will help FDA understand the applicant's nomenclature, how the components and parts function together, and the overall principles of operation of the finished tobacco product.

ii. Design parameters and test data. All design parameters of the product and test data, specifying nominal values or the explicit range of values as well as the design tolerance (*i.e.,* upper and lower range limits), where appropriate. Design parameters can change the health impact of the tobacco product by affecting the level of constituents that reach the user or nonuser and are also necessary to fully characterize a tobacco product. Tables 1 through 20 in proposed § 1114.7(i)(2)(ii)(B) provide the parameters that would be required for different categories of tobacco products. As part of the full description of the properties of the tobacco product, the proposed rule would also require, as included in the tables, a quantitative description of the performance criteria, including test protocols, line data, and a summary of the results, for each applicable design parameter and manufacturing step. The test data is a

required part of the PMTA to demonstrate the product consistently meets the nominal values or range of values as well as the design tolerance. The proposed parameters and their importance to understanding their impact on public health are described below.

Note that in addition to the parameters listed in tables 8 to 20 of the draft codified, FDA is also providing additional design parameters that it recommends including in a PMTA for certain types of deemed tobacco products in just the preamble. FDA is considering whether it should require the submission of these additional design parameters as part of the final rule and is requesting public comment regarding whether FDA should include these parameters as requirements in the final rule, whether FDA should recommend or require additional design parameters, and, if so, the basis for including additional design parameters.

Table 1 in proposed § 1114.7(i)(2)(ii)(B) describes the design parameters and information on performance criteria to be provided for cigarettes. These parameters are a necessary part of the application because they are needed to fully characterize the product and changes in these parameters may affect the cigarette's impact on the public health, as described below:

- Cigarette mass may affect smoke constituent yields (Ref. 32).
- Cigarette length may alter tobacco biomarker levels (Ref. 33).
- Cigarette diameter may affect filter efficiency and, in turn, smoke constituent yields (Ref. 34).
- Puff count can directly affect smoke constituent yields (Ref. 35).
- Cigarette draw resistance may result in differences in the difficulty of pulling air through the tobacco rod and, in turn, affect smoke constituent yields (Ref. 36).
- Tobacco rod length may alter tobacco biomarker levels (Ref. 33).
- Tobacco filler mass may affect smoke constituent yields (Ref. 32).
- Tobacco rod density may modify burn properties and smoke constituent yields (Refs. 37 and 38).
- Tobacco cut size alters the size of the tobacco pieces, which may result in more particulate matter (Ref. 39).
- Tobacco moisture may affect puff count (Ref. 40).
- Cigarette paper length and cigarette paper width may affect smoke constituent yields (Ref. 32).
- Cigarette paper base paper basis weight may affect puff count and smoke constituent yields (Ref. 41).
- Cigarette paper base paper porosity may affect smoke constituent yields (Ref. 41).
- Cigarette paper band porosity may affect smoke constituent yields because band porosity allows for the overall assessment of the weighted change in air flow through the cigarette paper during active puffing (Ref. 42).
- Cigarette paper band diffusivity may affect smoke constituent yields because it mimics air flow during smoldering (Ref. 43).
- Cigarette paper band width may affect ventilation and, in turn, smoke constituent yields (Ref. 44).
- Cigarette paper band space may affect ignition propensity and, in turn, puff count (Ref. 45).
- Filter efficiency may affect smoke constituent yields (Ref. 44).
- Filter diameter, filter mass, filter tow crimping index, denier per filament, total denier, filter density, and filter length may affect filter efficiency and, in turn, smoke constituent yields (Ref. 46).
- Filter pressure drop may affect smoke constituent yields (Ref. 47).
- Plug wrap, including length, width, basis weight, porosity, and caliper, contributes to the overall ventilation (Ref. 44).
- Tipping paper, including length, width, and basis weight, may affect smoke constituent yields (Ref. 48).
- Filter ventilation, including location and number of holes and rows, may affect smoke constituent yields (Ref. 34).

Table 2 in proposed § 1114.7(i)(2)(ii)(B) describes the design parameters and information on performance criteria to be provided for new portioned and non-portioned smokeless tobacco products. These parameters are a necessary part of the applications because they are needed to fully characterize the product and changes in these parameters may affect the smokeless tobacco product's impact on public health, as described below:

- Tobacco cut size may alter the particle surface area and accessibility of saliva to get to the surfaces of the tobacco, thereby affecting the amount and rate of constituents released from the product (Ref. 49).
- Tobacco moisture may affect microbial growth in the product, extraction efficiency, and total exposure to nicotine, NNN, and NNK (Refs. 4 and 5).
- Portion mass may affect user exposure to a tobacco product and, in turn, HPHCs contained in each portion (Ref. 50).
- Portion length may affect the constituents in each portion (Ref. 50).
- Portion width may result in a surface area difference, which is proportional to the amount and rate of constituents released from the product (Ref. 51).
- Portion thickness may result in a surface area difference, which is directly proportional to the amount and rate of constituents released from the product (Ref. 51).
- Pouch material basis weight, pouch material air permeability, and pouch material caliper influences the interactions between the tobacco and oral cavity, thereby potentially affecting the amount and rate of constituents released from the product (Ref. 52).
- Pouch material nicotine dissolution rate is a function of tobacco cut size and pouch materials, thereby potentially affecting the amount and rate of constituents released from the product (Ref. 53).
- Pouch material nicotine dissolution extent is a function of the initial release and duration of the ongoing release, thereby potentially affecting the amount and rate of constituents released from the product (Refs. 52 and 54).

Table 3 in proposed § 1114.7(i)(2)(ii)(B) describes the design parameters and information on performance criteria to be provided for new roll-your-own (RYO) tobacco rolling paper products. These parameters are a necessary part of the application because they are needed to fully characterize the product and changes in these parameters may affect the rolling paper's impact on public health, as described below:

- RYO paper length and RYO paper width may alter the surface area that is available for tobacco packing, thereby affecting the smoke constituent yields (Ref. 47).
- RYO paper mass may be a result of a surface area or basis weight difference and, in turn, may affect puff count and smoke constituent yields (Refs. 41 and 47).
- RYO paper base paper basis weight may affect puff count and smoke constituent yields (Ref. 41).
- RYO paper base paper porosity may affect smoke constituent yields (Ref. 41).
- RYO paper band porosity may affect smoke constituent yields because band porosity allows for the overall assessment of the weighted change in air flow through the cigarette paper during active puffing (Ref. 42).
- RYO paper band diffusivity may affect smoke constituent yields because it mimics air flow during smoldering (Ref. 43).
- RYO paper band width may affect ventilation and, in turn, smoke constituent yields (Ref. 44).

• RYO paper band space may affect ignition propensity and, in turn, puff count (Ref. 45).

Table 4 in proposed § 1114.7(i)(2)(ii)(B) describes the design parameters and information on performance criteria to be provided for new RYO tobacco tubes. These parameters are a necessary part of the application because they are needed to fully characterize the product and changes in these parameters may affect the RYO tube's impact on public health, as described below:

• Tube mass may affect smoke constituent yields (Ref. 32).
• Tube length may alter tobacco biomarker levels (Ref. 33).
• Tube diameter may affect filter efficiency and, in turn, smoke constituent yields (Ref. 34).
• Tube paper length and tube paper width may affect smoke constituent yields (Ref. 32).
• Tube paper base paper basis weight may affect puff count and smoke constituent yields (Ref. 41).
• Tube paper base paper porosity may affect smoke constituent yields (Ref. 41).
• Tube paper band porosity may affect smoke constituent yields since band porosity allows for the overall assessment of the weighted change in air flow through the cigarette paper during active puffing (Ref. 42).
• Tube paper band diffusivity may affect smoke constituent yields because it mimics air flow during smoldering (Ref. 43).
• Tube paper band width may affect ventilation and, in turn, smoke constituent yields (Ref. 44).
• Tube paper band space may affect ignition propensity and, in turn, puff count (Ref. 45).

Table 5 in proposed § 1114.7(i)(2)(ii)(B) describes the design parameters and information on performance criteria to be provided for new RYO tobacco filtered tubes. These parameters are a necessary part of the application because they are needed to fully characterize the product and changes in these parameters may affect the filtered tube's impact on public health, as described below:

• Tube mass may affect smoke constituent yields (Ref. 32).
• Tube length may alter tobacco biomarker levels (Ref. 33).
• Tube diameter may affect filter efficiency and, in turn, smoke constituent yields (Ref. 34).
• Tube paper length directly correlates to non-filter tube length, which may affect smoke constituent yields (Ref. 32).
• Tube paper width may affect smoke constituent yields (Ref. 32).
• Tube paper base paper basis weight may affect puff count and smoke constituent yields (Ref. 41).
• Tube paper base paper porosity may affect smoke constituent yields (Ref. 41).
• Tube paper band porosity may affect smoke constituent yields since band porosity allows for the overall assessment of the weighted change in air flow through the cigarette paper during active puffing (Ref. 42).
• Tube paper band diffusivity may affect smoke constituent yields because it mimics air flow during smoldering (Ref. 43).
• Tube paper band width may affect ventilation and, in turn, smoke constituent yields (Ref. 44).
• Tube paper band space may affect ignition propensity and, in turn, puff count (Ref. 45).
• Filter efficiency may affect smoke constituent yields (Ref. 44).
• Filter diameter, filter mass, filter tow crimping index, and denier per filament may affect filter efficiency and, in turn, smoke constituent yields (Ref. 46).
• Total denier, filter density, and filter length may affect filter efficiency and, in turn, smoke constituent yields (Ref. 30).
• Filter pressure drop may affect smoke constituent yields (Ref. 47).
• Plug wrap, including length, width, basis weight, porosity, and caliper, contributes to the overall ventilation (Ref. 44).
• Tipping paper, including length, width, and basis weight, may affect smoke constituent yields (Ref. 48).
• Filter ventilation, including location and number of holes and rows, may affect smoke constituent yields (Ref. 34).

Table 6 in proposed § 1114.7(i)(2)(ii)(B) describes the design parameters and information on performance criteria to be provided for RYO tobacco. These RYO tobacco parameters are a necessary part of the application because they are needed to fully characterize the product and changes in these parameters may affect the RYO tobacco's impact on public health, as described below:

• Tobacco filler mass may affect smoke constituent yields when used with rolling paper (Ref. 32).
• Tobacco cut size alters the size of the tobacco pieces, which may result in more particulate matter (Ref. 39).
• Tobacco moisture may affect puff count when used with rolling paper (Ref. 40).

Table 7 in proposed § 1114.7(i)(2)(ii)(B) describes the design parameters and information on performance criteria to be provided for new RYO tobacco paper tips. These parameters are a necessary part of the application because they are needed to fully characterize the product and changes may affect the paper tip's impact on public health, as described below:

• RYO paper tip length and RYO paper tip width may alter the surface area that is available for tobacco packing, thereby affecting the smoke constituent yields (Ref. 47).
• RYO paper tip mass may be a result of a surface area or basis weight difference and, in turn, may affect puff count and smoke constituent yields (Refs. 41 and 47).
• RYO paper base paper basis weight may affect puff count and smoke constituent yields (Ref. 41).
• RYO paper base paper perforation may affect smoke constituent yields (Ref. 41).
• RYO paper tip ventilation may affect smoke constituent yields (Ref. 34).

Table 8 in proposed § 1114.7(i)(2)(ii)(B) describes the design parameters and information on performance criteria to be provided for filtered, sheet-wrapped cigars. These parameters are a necessary part of the application because they are needed to fully characterize the product and changes may affect the cigar's impact on public health, as described below:

• Cigar length and diameter can directly affect the amount of tobacco that is burned and, in turn, affect smoke constituent yields (Ref. 55).
• Tobacco filler mass may affect smoke constituent yields (Ref. 56).
• Tobacco rod density may modify burn properties and smoke constituent yields (Refs. 37 and 38).
• Tobacco cut size alters the size of the tobacco pieces, which may result in more particulate matter (Ref. 39).
• Tobacco moisture may affect puff count (Ref. 40).
• Cigar wrapper and binder porosity may affect smoke constituent yields (Refs. 58 and 59).
• Filter efficiency may affect smoke constituent yields (Ref. 44).
• Filter diameter and filter length may affect filter efficiency and, in turn, smoke constituent yields (Ref. 46).
• Filter pressure drop may affect smoke constituent yields (Ref. 47).
• Tipping paper length may affect smoke constituent yields (Ref. 48).
• Ventilation may affect smoke constituent yields (Ref. 56).

In addition to the parameters that would be required by the proposed rule, FDA recommends a PMTA for a filtered, sheet-wrapped cigar also contain the following additional design parameters in table 8a and is specifically requesting

public comments on whether these parameters should be required in the final rule.

TABLE 8a—ADDITIONAL DESIGN PARAMETERS RECOMMENDED TO BE PROVIDED FOR FILTERED SHEET-WRAPPED CIGARS

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Cigar mass (mg). • Cigar draw resistance (mm H_2O). • Cigar burn rate (mm/s). • Cigar wrapper length (mm). • Cigar wrapper width (mm). • Cigar wrapper basis weight (g/m^2). • Cigar binder length (mm). • Cigar binder width (mm). • Cigar binder basis weight (g/m^2). • Filter mass (mg). • Filter density (g/cm^3). • Filter tow crimping index. • Filter total denier (g/9000m). • Filter denier per filament (dpf). • Plug wrap length (mm). • Plug wrap width (mm). • Plug wrap basis weight (g/m^2). • Plug wrap porosity (CU). • Tipping paper width (mm). • Tipping paper basis weight (g/m^2). • Tipping paper perforation (CU). • Filter ventilation position of holes. • Filter ventilation number of holes. • Filter ventilation number of rows.	• Cigar mass (mg). • Cigar draw resistance (mm H_2O). • Cigar burn rate (mm/s). • Puff count. • Cigar wrapper length (mm). • Cigar wrapper width (mm). • Cigar wrapper basis weight (g/m^2). • Cigar binder length (mm). • Cigar binder width (mm). • Cigar binder basis weight (g/m^2). • Filter mass (mg). • Filter density (g/cm^3). • Filter tow crimping index. • Filter total denier (g/9000m). • Filter denier per filament (dpf). • Plug wrap length (mm). • Plug wrap width (mm). • Plug wrap basis weight (g/m^2). • Plug wrap porosity (CU). • Tipping paper width (mm). • Tipping paper basis weight (g/m^2). • Tipping paper perforation (CU).

FDA recommends including these parameters as part of the application because they may help fully characterize the product and may affect its impact on public health:

• Cigar mass reflects the amount of tobacco in a cigar, which may affect smoke constituent yields (Ref. 56).

• Cigar puff count can directly affect smoke constituent yields (Ref. 56).

• Cigar draw resistance may result in differences in the difficulty of pulling air through the tobacco rod and, in turn, affect smoke constituent yields (Ref. 36).

• Burn rate may affect puff count and, in turn, affect smoke constituent yields (Ref. 57).

• Cigar wrapper and binder basis weight may affect puff count and smoke constituent yields (Refs. 36 and 58).

• Cigar wrapper and binder length and width may directly influence the area through which air is permitted to enter the tobacco column, which, in turn, may affect puff count and smoke constituent yields (Ref. 36).

• Filter mass, filter tow crimping index, denier per filament, total denier, and filter density may affect filter efficiency and, in turn, smoke constituent yields (Ref. 46).

• Plug wrap, including length, width, basis weight, porosity, and caliper, contributes to the overall ventilation (Ref. 39).

• Tipping paper, including width, and basis weight, may affect smoke constituent yields (Ref. 48).

• Ventilation, including location and number of holes and rows, may affect smoke constituent yields (Ref. 56).

Table 9 in proposed § 1114.7(i)(2)(ii)(B) describes the design parameters and information on performance criteria to be provided for unfiltered, sheet-wrapped cigars. These parameters are a necessary part of the application because they are needed to fully characterize the product and changes may affect the cigar's impact on public health, as described below:

• Cigar mass reflects the amount of tobacco in a cigar, which may affect smoke constituent yields (Ref. 56).

• Cigar length and diameter can directly affect the amount of tobacco that is burned and, in turn, affect smoke constituent yields (Ref. 55).

• Tobacco filler mass may affect smoke constituent yields (Ref. 56).

• Cigar wrapper porosity may affect smoke constituent yields (Refs. 58 and 59).

• Cigar tip dimensions directly influence the overall cigar draw resistance and in turn, puff count (Ref. 60).

In addition to the parameters that would be required by the proposed rule, FDA recommends a PMTA for an unfiltered, sheet-wrapped cigar also contain the following additional design parameters as described in Table 9a and is specifically requesting public comments on whether these parameters should be required under the final rule.

TABLE 9a—ADDITIONAL DESIGN PARAMETERS RECOMMENDED TO BE PROVIDED FOR UNFILTERED SHEET-WRAPPED CIGARS

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Cigar draw resistance (mm H_2O). • Cigar burn rate (mm/s). • Tobacco rod density (g/cm^3). • Tobacco cut size (mm). • Tobacco moisture (%).	• Cigar draw resistance (mm H_2O). • Cigar burn rate (mm/s). • Puff count. • Tobacco rod density (g/cm^3). • Tobacco cut size (mm).

TABLE 9a—ADDITIONAL DESIGN PARAMETERS RECOMMENDED TO BE PROVIDED FOR UNFILTERED SHEET-WRAPPED CIGARS—Continued

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Cigar wrapper length (mm). • Cigar wrapper width (mm). • Cigar wrapper basis weight (g/m^2). • Cigar binder length (mm). • Cigar binder width (mm). • Cigar binder basis weight (g/m^2). • Cigar binder porosity (CU). • Cigar tip mass (mg) (if applicable).	• Tobacco moisture (%). • Cigar wrapper length (mm). • Cigar wrapper width (mm). • Cigar wrapper basis weight (g/m^2). • Cigar binder length (mm). • Cigar binder width (mm). • Cigar binder basis weight (g/m^2). • Cigar binder porosity (CU). • Cigar tip mass (mg) (if applicable).

FDA recommends including these parameters as part of the application because they may help fully characterize the product and changes may affect its impact on public health:

• Cigar puff count can directly affect smoke constituent yields (Ref. 56).

• Cigar draw resistance may result in differences in the difficulty of pulling air through the tobacco rod and, in turn, affect smoke constituent yields (Ref. 36).

• Burn rate may affect puff count and, in turn, affect smoke constituent yields (Ref. 57).

• Tobacco rod density may modify burn properties and smoke constituent yields (Refs. 37 and 38).

• Tobacco cut size alters the size of the tobacco pieces, which may result in more particulate matter (Ref. 39).

• Tobacco moisture may affect puff count (Ref. 40).

• Cigar wrapper and binder basis weight may affect puff count and smoke constituent yields (Refs. 36 and 58).

• Cigar wrapper and binder length and width may directly influence the area through which air is permitted to enter the tobacco column, which, in turn, may affect puff count and smoke constituent yields (Ref. 36).

• Cigar binder porosity may affect smoke constituent yields (Refs. 58 and 59).

Table 10 in proposed § 1114.7(i)(2)(ii)(B) describes the design parameters and information on performance criteria to be provided for leaf-wrapped cigars. These parameters are a necessary part of the application because they are needed to fully characterize the product and changes may affect the cigar's impact on public health, as described below:

• Cigar mass reflects the amount of tobacco in a cigar, which may affect smoke constituent yields (Ref. 56).

• Cigar length and diameter can directly affect the amount of tobacco that is burned and, in turn, affect smoke constituent yields (Ref. 55).

• Tobacco moisture may affect puff count (Ref. 40).

In addition to the parameters that would be required by the proposed rule, FDA recommends a PMTA for a leaf-wrapped cigar also contain the following additional design parameters as described in Table 10a. FDA is gaining experience reviewing the design parameters of deemed tobacco products and is specifically requesting public comments on whether these parameters should be required under the final rule.

TABLE 10a—ADDITIONAL DESIGN PARAMETERS RECOMMENDED TO BE PROVIDED FOR LEAF-WRAPPED CIGARS

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Cigar draw resistance (mm H_2O). • Cigar burn rate (mm/s). • Tobacco filler mass (mg). • Tobacco rod density (g/cm^3). • Tobacco cut size (mm). • Cigar wrapper length (mm). • Cigar wrapper minimum width (mm). • Cigar wrapper maximum width (mm). • Cigar wrapper basis weight (g/m^2). • Cigar wrapper porosity (CU). • Cigar binder length (mm). • Cigar binder minimum width (mm). • Cigar binder maximum width (mm). • Cigar binder basis weight (g/m^2). • Cigar binder porosity (CU).	• Cigar draw resistance (mm H_2O). • Cigar burn rate (mm/s). • Puff count. • Tobacco filler mass (mg). • Tobacco rod density (g/cm^3). • Tobacco cut size (mm). • Cigar wrapper length (mm). • Cigar wrapper minimum width (mm). • Cigar wrapper maximum width (mm). • Cigar wrapper basis weight (g/m^2). • Cigar wrapper porosity (CU). • Cigar binder length (mm). • Cigar binder minimum width (mm). • Cigar binder maximum width (mm). • Cigar binder basis weight (g/m^2). • Cigar binder porosity (CU).

FDA recommends including these parameters as part of the application because changes they may help fully characterize the product and may affect its impact on public health as follows:

• Cigar draw resistance may result in differences in the difficulty of pulling air through the tobacco rod and, in turn, affect smoke constituent yields (Ref. 36).

• Burn rate may affect puff count and, in turn, affect smoke constituent yields (Ref. 57).

• Filler mass (mg) may affect smoke constituent yields (Ref. 56).

• Tobacco rod density may modify burn properties and smoke constituent yields (Refs. 37 and 38).

• Tobacco cut size alters the size of the tobacco pieces, which may result in more particulate matter (Ref. 39).

• Cigar wrapper and binder basis weight may affect puff count and smoke constituent yields (Refs. 36 and 58).

• Cigar wrapper and binder porosity may affect smoke constituent yields (Refs. 58 and 59).

• Cigar wrapper and binder length, minimum width, and maximum width may directly influence the area through which air is permitted to enter the tobacco column, which, in turn, may affect puff count and smoke constituent yields (Ref. 36).

Table 11 in proposed § 1114.7(i)(2)(ii)(B) describes the design parameters and information on performance criteria to be provided for cigar tobacco. These parameters are a necessary part of the application because they are needed to fully characterize the product and changes may affect its impact on public health, as described below:

• Tobacco cut size alters the size of the tobacco pieces, which may result in more particulate matter (Ref. 39).

• Tobacco moisture may affect puff count (Ref. 40).

In addition to the parameters that would be required by the proposed rule, FDA would recommend applicants include filler mass (mg) as additional design parameter in a PMTA for cigar tobacco because it may affect smoke constituent yields (Ref. 56). FDA is gaining experience reviewing the design parameters of cigar tobacco and other deemed tobacco products and is specifically requesting public comments on whether this parameter should be required in the final rule.

Table 12 in proposed § 1114.7(i)(2)(ii)(B) describes the design parameters and information on performance criteria to be provided for a cigar wrapper. These parameters are a necessary part of the application because they are needed to fully characterize the product and changes may affect its impact on public health, as described below:

• Cigar wrapper length, and its minimum width and maximum width may directly influence the area through which air is permitted to enter the tobacco column, which, in turn, may affect puff count and smoke constituent yields (Ref. 36).

In addition to the parameters that would be required by the proposed rule, FDA also recommends a PMTA for a cigar wrapper also contain the following additional design parameters as described in Table 12a and is specifically requesting public comments on whether these parameters should be required under the final rule.

TABLE 12a—ADDITIONAL DESIGN PARAMETERS RECOMMENDED TO BE PROVIDED FOR CIGAR WRAPPERS

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Cigar wrapper basis weight (g/m^2). • Cigar wrapper porosity (CU).	• Cigar wrapper basis weight (g/m^2). • Cigar wrapper porosity (CU).

FDA recommends including these parameters as part of the application because changes they may help fully characterize the product and may affect its impact on public health as follows:

• Cigar wrapper basis weight may affect puff count and smoke constituent yields (Refs. 36 and 58).

• Cigar wrapper porosity may affect smoke constituent yields (Refs. 58 and 59).

Table 13 in proposed § 1114.7(i)(2)(ii)(B) describes the design parameters and information on performance criteria to be provided for a waterpipe. The number of hoses and the waterpipe bowl volume are a necessary part of the application because they are needed to fully characterize the product.

In addition to the parameters that would be required by the proposed rule, FDA recommends a PMTA for a waterpipe also contain the following additional design parameters as described in Table 13a and is specifically requesting public comments on whether these parameters should be required under the final rule.

TABLE 13a—ADDITIONAL DESIGN PARAMETERS RECOMMENDED TO BE PROVIDED FOR WATERPIPES

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Hose length (mm). • Hose material (mm). • Hose internal diameter (mm). • Stem length (mm). • Stem internal diameter (mm). • Hose Permeability (CU). • Bowl diameter (mm). • Bowl shape. • Pressure drop (mm H_2O). • Water filter efficiency (%). • Foil length (mm). • Foil width (mm). • Ventilation hole distribution. • Number of ventilation holes. • Ventilation (%). • Heating source type.	• Hose length (mm). • Hose internal diameter (mm). • Stem length (mm). • Stem internal diameter (mm). • Hose Permeability (CU). • Bowl diameter (mm). • Pressure drop (mm H_2O). • Water filter efficiency (%). • Foil length (mm). • Foil width (mm). • Ventilation (%).

The parameters included in table 13 apply to waterpipes generally. For products that contain a heating source or waterpipe tobacco, applications should specify information regarding the heating source and waterpipe tobacco as described in tables 14 and 15. FDA recommends including these parameters as part of the application

because they can help fully characterize the product and changes may affect its impact on public health:

- Hose dimensions (length and diameter) are directly proportional to air infiltration and affects toxicant yields (Ref. 61).
- Hose material may affect hose permeability, which may affect smoke constituent yields (Ref. 61).
- Water filtering efficiency is directly proportional to mainstream smoke and can increase exposure to HPHCs (Ref. 62).
- Pressure drop may result in differences in the difficulty of pulling air through the waterpipe and, in turn, affect smoke constituent yields (Ref. 36).
- Waterpipe components or parts, including stem, bowl, windscreen (foil), and purge valve, impact puffing behavior and toxicant exposure; therefore, the foil dimensions and ventilation may affect smoke constituent yields (Ref. 63).
- The diameter of the flow path is directly related to the resistance to draw, which may affect smoke constituent yields (Ref. 63).
- The aluminum foil perforation pattern (size, number and distribution of holes) impacts the path of hot gases through the tobacco mixture, which may affect smoke constituent yields (Ref. 63).

Table 14 in proposed § 1114.7(i)(2)(ii)(B) describes the design parameters and information on performance criteria to be provided for waterpipe tobacco. These parameters are necessary to fully characterize the product and changes may affect its impact on public health as follows:

- Tobacco cut size alters the size of the tobacco pieces, which may result in more particulate matter. Finer tobacco cut size may result in a decrease in filling power and in turn, a larger amount of tobacco in the bowl (Refs. 39 and 40).
- Tobacco moisture may affect puff count. Moisture contributes to packing density, thus decreasing void volume (Ref. 40).

In addition to the parameters that would be required by the proposed rule, FDA is recommending PMTAs for a waterpipe tobacco also include the filler mass (mg) because it may affect smoke constituent yields (Ref. 56) and is specifically requesting public comments on whether this parameter should be required in the final rule.

Table 15 in proposed § 1114.7(i)(2)(ii)(B) describes the design parameters and information on performance criteria to be provided for a waterpipe heating source. These parameters are necessary to fully characterize the product and changes may affect its impact on public health because when combusted, heating sources such as charcoal or wood cinders expose the user to high yields of toxicants such as carbon monoxide and polycyclic aromatic hydrocarbons. Therefore, the heating source temperature may affect smoke constituent yields (Ref. 64).

In addition to the parameters that would be required by the proposed rule, FDA recommends a PMTA for a waterpipe heating source also include the additional design parameters as described in Table 15a and is specifically requesting public comments on whether these parameters should be required under the final rule.

TABLE 15a—ADDITIONAL DESIGN PARAMETERS RECOMMENDED TO BE PROVIDED FOR WATERPIPE HEATING SOURCES

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Charcoal burn rate (mm/s) (if applicable).	• Charcoal temperature (°C) (if applicable).
• Charcoal mass (mg) (if applicable).	• Charcoal burn rate (mm/s) (if applicable).
• Charcoal density (g/cm^3) (if applicable).	• Charcoal mass (mg) (if applicable).
• Electrical heater coil resistance (ohms) (if applicable).	• Charcoal density (g/cm^3) (if applicable).
• Number of coils (if applicable).	• Electrical heater coil resistance (ohms) (if applicable).
• Coil configuration (if applicable).	• Coil diameter (gauge) (if applicable).
• Coil diameter (gauge) (if applicable).	• Coil failure testing (if applicable).
• Coil failure testing (if applicable).	• Battery mAh rating (mAh) (if applicable).
• Battery mAh rating (mAh) (if applicable).	• Battery voltage operating range (volts) (if applicable).
• Battery voltage operating range (volts) (if applicable).	• Battery current operating range (amps) (if applicable).
• Battery current operating range (amps) (if applicable).	• Power delivery unit (PDU) voltage operating range (volts) (if applicable).
• Power delivery unit (PDU) voltage operating range (volts) (if applicable).	• PDU current operating range (amps) (if applicable).
• PDU current operating range (amps) (if applicable).	• PDU wattage operating range (watts) (if applicable).
• PDU wattage operating range (watts) (if applicable).	• PDU temperature cut-off (°C) (if applicable).
	• PDU wattage deviation (watts).
	• PDU temperature control deviation (°C).

FDA recommends including these parameters (as applicable to the heating source) as part of the application because they may help fully characterize the product and changes may affect its impact on public health:

- When combusted, heating sources such as charcoal or wood cinders expose the user to high yields of toxicants such as carbon monoxide and polycyclic aromatic hydrocarbons. Therefore, the heating source mass, density, temperature, and burn rate may affect smoke constituent yields (Ref. 64).

Table 16 in proposed § 1114.7(i)(2)(ii)(B) describes the design parameters and information on performance criteria to be provided for waterpipe foil. The waterpipe foil length and width are necessary to fully characterize the product and changes may affect its impact on public health because waterpipe components or parts windscreen (foil) impact smoke's puffing behavior and toxicant exposure. Therefore, the foil dimensions may affect smoke constituent yields. (Ref. 63).

In addition to the parameters that would be required by the proposed rule, FDA recommends a PMTA for waterpipe foil also include the following additional design parameters as described in Table 16a and is specifically requesting public comments on whether these parameters should be required under the final rule.

TABLE 16a—ADDITIONAL DESIGN PARAMETERS RECOMMENDED TO BE PROVIDED FOR WATERPIPE FOIL

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Foil length (mm). • Foil width (mm). • Ventilation hole distribution. • Number of ventilation holes. • Ventilation (%).	• Foil length (mm). • Foil width (mm). • Ventilation (%).

FDA recommends including these parameters as part of the application because they may help fully characterize the product and changes may affect its impact on public health:

• Waterpipe components or parts, including the windscreen (foil) impact smoke's puffing behavior and toxicant exposure. Therefore, the foil dimensions and ventilation may affect smoke constituent yields (Ref. 63).

• The aluminum foil perforation pattern (size, number and distribution of holes) impacts the path of hot gases through the tobacco mixture, which may affect smoke constituent yields (Ref. 63).

Table 17 in proposed § 1114.7(i)(2)(ii)(B) describes the design parameters and information on performance criteria to be provided for a pipe. The bore diameter, bit length and diameter, and stem length and diameter are design parameters are necessary to fully characterize the product.

In addition to the parameters that would be required by the proposed rule, FDA recommends a PMTA for a pipe also include the following additional design parameters as described in Table 17a. FDA is issuing this list of pipe parameters, which are based upon similar parameters in other categories of tobacco products, for consideration and public comment. We are particularly interested in scientific investigations that support keeping or removing these parameters, or adding different parameters to the table.

TABLE 17a—ADDITIONAL DESIGN PARAMETERS RECOMMENDED TO BE PROVIDED FOR PIPES

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Moisture drain volume (ml). • Moisture drain location. • Bowl chamber cover outer diameter (mm). • Bowl chamber cover inner diameter (mm). • Draught hole diameter (mm). • Bottom screen. • Draught hole shape. • Draught hole location. • Bowl chamber diameter (mm). • Bowl chamber hole shape. • Bow chamber volume (cm^3). • Pipe pressure drop (mm H_2O). • Two-phase smoke flow (cc/min). • Airway volume (cm^3). • Filter length (mm). • Filter pressure drop (mm H_2O). • Filter efficiency (%). • Pipe ventilation (%).	• Moisture drain volume (ml). • Bowl chamber cover outer diameter (mm). • Bowl chamber cover inner diameter (mm). • Draught hole diameter (mm). • Bowl chamber diameter (mm). • Bow chamber volume (cm^3). • Pipe pressure drop (mm H_2O). • Two-phase smoke flow (cc/min). • Airway volume (cm^3). • Filter length (mm). • Filter pressure drop (mm H_2O). • Filter efficiency (%). • Pipe ventilation (%).

Table 18 in proposed § 1114.7(i)(2)(ii)(B) describes the design parameters and information on performance criteria to be provided for pipe tobacco. Tobacco cut size and moisture are design parameters that are necessary to fully characterize the product.

In addition to the parameters that would be required by the proposed rule, FDA recommends a PMTA for pipe tobacco also include filler mass (mg). FDA recommends the inclusion of this pipe tobacco parameter based upon similar parameters in other categories of tobacco products for consideration and public comment. We are particularly interested in scientific investigations that support keeping or removing this parameter, or adding different parameters.

Table 19 in proposed § 1114.7(i)(2)(ii)(B) describes the design parameters and information on performance criteria to be provided for an ENDS. These parameters are a necessary part of the application because they are needed to fully characterize the product and changes may affect its impact on public health, as described below.

• The air flow rate of the ENDS can affect the coil temperature, e-liquid consumption, and aerosol characteristics such as particle number concentration, count median diameter, and $PM_{2.5}$, which impact aerosol exposure (Ref. 65).

• Coil resistance may affect overall heating element resistance, thereby influencing heating element temperature. The heating element temperature may affect toxicant emissions and nicotine delivery (Refs. 66–70).

• Coil resistance and battery output voltage determine PDU wattage. PDU wattage determines the amount of heat produced by the atomizer. PDU wattage or wattage operating range may affect the heating element temperature, thereby affecting toxicant emissions (Refs. 68 and 70).

• An increase in battery capacity (mAh rating) can increase the number of puffs the e-cigarette can deliver per vaping session. Longer vaping sessions

may lead to greater exposure to toxicant emissions (Ref. 69).

• The temperature of the coil can affect the chemical and physical characteristics of the aerosol delivered to the user. An increase in coil temperature can increase HPHC levels in the aerosol, therefore, maximum coil temperature and temperature control deviation from this maximum coil temperature can affect toxicant emissions and nicotine delivery (Refs. 67–70).

In addition to the parameters that would be required by the proposed rule, FDA recommends a PMTA for an ENDS also include the following additional design parameters as described in Table 19a and is specifically requesting public comments on whether these parameters should be required under the final rule.

TABLE 19a—ADDITIONAL DESIGN PARAMETERS RECOMMENDED TO BE PROVIDED FOR ENDS

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Draw resistance (mm H_2O).	• Draw resistance (mm H_2O).
• Puff count (for full tank/cartridge) (dimensionless).	• Puff count (for full tank/cartridge) (dimensionless).
• Atomizer tank/cartridge volume (mL).	• Atomizer tank/cartridge volume (mL).
• Number of coils (dimensionless).	• Coil diameter (gauge).
• Coil diameter (gauge).	• Coil failure testing (cycles to failure).
• Coil failure testing (cycles to failure).	• Mass of wicking material (mg).
• Mass of wicking material (mg).	• Wicking rate (mm/min).
• Wicking rate (mm/min).	• Battery voltage operating range (V).
• Battery voltage operating range (V).	• Battery current operating range (mA).
• Battery current operating range (mA).	• PDU voltage operating range (V).
• Power Delivery Unit (PDU) voltage operating range (V).	• PDU current operating range (mA).
• PDU current operating range (mA).	• PDU wattage deviation (W).

FDA recommends including these parameters (as applicable to the ENDS product) as part of the application because they may help fully characterize the product and changes may affect its impact on public health:

• Coil and solder, as well as coil coatings, can transfer to the e-liquid and lead to increased toxicant emissions (Refs. 71 and 72).

• Number of coils present can affect overall atomizer resistance and distribution of heat dissipation (Ref. 73).

• The position of the coil can increase the possibility of dry puff conditions and subsequent increased toxicant emissions (Ref. 68).

• E-liquid absorbency of the wick and wicking rate can lead to dry puff conditions and increased toxicant emissions (Ref. 73 and 74).

• Wicking materials can transfer to the e-liquid and lead to increased toxicant emissions (Ref. 72).

• Atomizer and cartridge components of e-cigarettes may be heated repeatedly and aerosolized and can contribute to increased toxicant emissions (Ref. 66).

• Puff count can differ depending on other puff topography (*e.g.,* puff duration and puff flow rate), e-cigarette and atomizer design, and e-liquid parameters. Puff count can also affect total puff volume, which in turn can affect total toxicant emissions (Ref. 74).

• E-liquid capacity of the atomizer tank/cartridge can affect total puff volume, which in turn can affect total toxicant emissions (Refs. 74 and 75).

• Battery/PDU voltage or voltage operating range may affect the heating element temperature, thereby affecting toxicant emissions and nicotine delivery (Refs. 67–70).

• Battery wattage or wattage operating range may affect the heating element temperature, thereby affecting toxicant emissions (Refs. 68 and 70).

• Coil resistance and battery output voltage determine PDU wattage. PDU wattage determines the amount of heat produced by the atomizer. PDU wattage or wattage operating range may affect the heating element temperature, thereby affecting toxicant emissions (Refs. 68 and 70).

• Atomizer coil temperature (heating element temperature) may affect toxicant emissions and nicotine delivery (Refs. 67–70).

• PDU wattage deviation may influence heating element temperature, thereby affecting toxicant emissions (Refs. 68 and 70).

• The temperature of the coil can affect the chemical and physical characteristics of the aerosol delivered to the user. An increase in coil temperature can increase HPHC levels in the aerosol, therefore, maximum coil temperature and temperature control deviation from this maximum coil temperature can affect toxicant emissions and nicotine delivery (Refs. 67–70).

• Coil resistance, number of coils, coil gauge, and coil configuration may affect overall heating element resistance, thereby influencing heating element temperature. The heating element temperature may affect toxicant emissions and nicotine delivery (Refs. 66–70).

• Battery type, battery current operating range, battery failure safety features, battery conformance to standards, and PDU current operating range are necessary for evaluating battery and PDU safety. Risks of e-cigarette battery explosion, leakage, fire, or overheating are a safety concern (Refs. 66 and 76).

• Battery power impacts the delivery of nicotine and the total emissions of volatile aldehydes (Refs. 77 and 78).

• Battery and PDU voltage impacts the amount of e-liquid consumed, the vapor temperature, and the total emissions of volatile aldehydes (Ref. 78).

• The type and amount of wicking material can affect the e-liquid absorbency of the wick and wicking rate, possibly leading to dry puff conditions and increased toxicant emissions (Refs. 73 and 74).

• The draw resistance of the ENDS impacts the ease of drawing air into the ENDS to produce aerosol, which can affect nicotine and other toxicant delivery to the user (Ref. 79).

Table 20 in proposed § 1114.7(i)(2)(ii)(B) describes the design parameters and information on performance criteria to be provided for an e-liquid. These parameters are a necessary part of the application because they are needed to fully characterize the product and changes may affect its impact on public health, as described below:

• The e-liquid volume can affect the delivery of nicotine and other toxicants to the user (Ref. 74 and 75).

In addition to the parameters that would be required by the proposed rule, FDA recommends a PMTA for an e-liquid also contain the following additional design parameters as described in Table 20a and is specifically requesting public comments on whether these parameters should be required under the final rule.

TABLE 20a—ADDITIONAL DESIGN PARAMETERS RECOMMENDED TO BE PROVIDED FOR E-LIQUIDS

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• E-liquid boiling point (°C). • E-liquid viscosity (at 20 °C) • E-liquid volume (ml). • Particle number concentration (#/cm^3). • Count median diameter (nm). • $PM_{2.5}$ (μg/m^3).	• E-liquid boiling point (°C). • E-liquid viscosity (at 20 °C). • E-liquid volume (ml). • Particle number concentration (#/cm^3). • Count median diameter (nm). • $PM_{2.5}$ (μg/m^3).

These parameters are a necessary part of the application because they may help fully characterize the product and changes may affect the its impact on public health:

• E-liquid solvent composition can cause variations in e-liquid boiling point. E-liquid composition, and subsequently e-liquid boiling point, can affect aerosol particle size distribution and amount of aerosol produced (Ref. 80).

• Aerosol parameters such as particle number concentration, count median diameter, and $PM_{2.5}$ are used to characterize the amount and size of particles to which the user is exposed. Epidemiological and clinical studies have shown that exposure to large amounts of small particles can impair lung function and is correlated with cardiovascular disease (Refs. 81 and 82).

• E-liquid viscosity and boiling point impact the proportion of nicotine that is aerosolized (Ref. 83). E-liquid viscosity can also affect the e-liquid absorbency through the wick and wicking rate, possibly leading to dry puff conditions and increased toxicant emissions. Also, the e-liquid viscosity can affect the electronic cigarette nicotine and other toxicant delivery to the user (Refs. 73 and 74).

• The e-liquid volume can affect the delivery of nicotine and other toxicants to the user (Refs. 74 and 75).

iv. Function. The proposed rule would require the application to contain a description of how the product is intended to function. For example, this could include a description of how the energy or heating source is used in or with the product, and how the delivery of the product's output (*e.g.,* smoke, aerosol, nicotine) is controlled. This information can be critical to FDA's review of a tobacco product, including whether the product functions as intended and whether the application contains data and information that is relevant to the way in which it is intended to function. For example, if an applicant states that a product heats or aerosolizes, but does not combust tobacco or an e-liquid, it would assist FDA in determining whether the information in the PMTA shows the product functions as intended and whether the application contains appropriate information regarding this function (*e.g.,* data regarding relevant HPHCs).

v. pH of product and nicotine formulation. The proposed rule would require the PMTA to specify the pH of the product. The pH of the product is important for FDA to review as part of a PMTA because it can affect the amount of unprotonated nicotine delivered to the user (Refs. 84 and 85).

The proposed rule would also require the PMTA to specify the formulation of the nicotine in the product. The nicotine formulation would be required to state the type(s) and quantity of nicotine in the product. Type(s) of nicotine include, but are not limited to, unprotonated nicotine and nicotine salts (*e.g.,* nicotine lactate, nicotine benzoate, nicotine pyruvate). The quantity of unprotonated nicotine is important for FDA to review because the amount and speed of nicotine delivered by a tobacco product is related to the proportion of nicotine in a tobacco product that is unprotonated (Refs. 86 and 87). The types and quantities of nicotine salts in the product are important for FDA to review because nicotine salt complexes can substantially increase nicotine delivery relative to free-base nicotine in ENDS products (Refs. 88–90).

vi. Fermentation process. For those products that contain fermented tobacco, the proposed rule would require an application to contain information on the fermentation process. The proposed rule would require this information because the fermentation process can result in different degrees of change in the chemical constituents of the tobacco (Ref. 91 and 92) and also affect the type and number of microorganisms in the final product, (Ref. 93) which could potentially affect the levels of TSNAs and stability of the products during storage. In addition, the type and amount of the fermentation inoculum can change the product as a result of directed fermentation (Ref. 94). Therefore, the application must contain the following information regarding the fermentation process:

• Composition of the inoculum (starter culture) with genus and species name(s) and concentration(s) (if applicable).

• Any step(s) taken to reduce microbes present during product processing (*e.g.,* cleaning of product contact surfaces);

• Specifications and test data for pH, temperature, moisture content, and water activity;

• Frequency of aeration or turning (if applicable);

• Duration of fermentation;

• Added ingredients; and

• Method used to stabilize or stop fermentation (if applicable), including parameters of the method (*e.g.,* length of treatment, temperature) and method validation data to demonstrate that fermentation is adequately suppressed to preclude further in-package fermentation that could lead to increases in TSNAs and microbial content in the final product. Having a process in place to suppress microbial activity to preclude further in-package fermentation is important because failing to do so could result in a product that may have different constituent levels than are specified in the application; and

• Storage conditions of the fermented tobacco prior to packaging and duration of storage (if applicable).

vii. Storage and stability information. The proposed rule would also require a PMTA to contain product storage and stability information that establishes the microbial and chemical stability of the product throughout the stated shelf life. Product storage and stability information is important for FDA's review of a tobacco product because

bacterial communities and constituents in tobacco products can change over time. Information obtained through stability testing could be used to ensure that the tobacco product is chemically and microbiologically stable during the expected product storage period and does not result in changes that could affect the product's potential health risks. If no shelf life is indicated, an applicant should provide details of stability over a specified amount of time and justify why that time period is appropriate. For example, if an applicant believes that 2 years after the date of manufacture is an appropriate time because that is the typical period of time in which their product is sold to consumers, an applicant should describe such.

The proposed rule would require this stability testing information because product stability is affected by factors such as the fermentation and stabilization processes (if applicable), addition of chemical additives to control microbial activity (*e.g.,* preservatives, metabolic inhibitors, humectants), and water activity (a_w) of the product (Refs. 91 and 95–98). Additionally, factors such as nitrate/nitrite concentrations, moisture content, microbial content, storage temperature, and pH are reported to influence the microbial stability and TSNA formation during storage of tobacco products (Refs. 99–104).

An application would be required to contain the following storage and stability information:

- A description of how the shelf life is indicated on the tobacco product, if applicable. The proposed rule would not require a tobacco product to indicate the product's shelf life; however, if it is indicated on the product, the PMTA must describe how it is indicated. For example, if the tobacco product labeling has a 'use by,' 'best by,' or expiration date, a PMTA would have to describe how the date is determined (*e.g.,* a certain number of days after packaging).
- Testing on the tobacco product in the same container closure system that will be used if granted a marketing order performed at the beginning (zero time), middle, and end of the expected storage time for the chemical and microbial endpoints for the following items:
  - Microbial content data, including total aerobic microbial count and total yeast and mold count, along with identification of detected microbiological organisms by genus and species names (if applicable);
  - pH;
  - moisture content;
  - water activity;
  - TSNAs. The data specifying TSNAs would be required to be reported as separate amounts for a total TSNAs, NNN, and NNK.
  - nitrate and nitrite levels;
  - preservatives and microbial metabolic inhibitors (if any); and
  - method of heat treatment or pasteurization used to reduce microbial loads.

Accelerated studies, combined with basic stability information on the components or parts and container closure system (separately), or the tobacco product (as a whole) may be used to support tentative expiration dates provided full shelf life studies are not available and are being conducted. Where data from accelerated studies are used to project a tentative expiration date that is beyond a date supported by actual shelf life studies, stability studies must be conducted, including tobacco product testing at appropriate intervals, until the tentative expiration date is verified or the appropriate expiration date is determined.

As would be required by proposed § 1114.7(i)(4), the reported stability testing would need to be performed on test samples that reflect the final tobacco product composition and design (including the container closure system), and be conducted using a sufficient sample size and number of replicates to substantiate the results of the type of testing conducted. Proposed § 1114.7(i)(4) would also require the test data to contain:

- The name and location of the testing laboratory or laboratories and documentation showing that the laboratory or laboratories is (or are) accredited by a nationally or internationally recognized external accreditation organization;
- The length of time between dates of manufacture and date(s) of testing;
- The storage conditions of the tobacco product before it was tested;
- The number of samples and measurement replicates for each sample; and
- A description of method procedure, method validation information and rationale for selecting each test method, including relevant voluntary testing standard; and
- Reports of product formulation testing that include test protocols, quantitative acceptance criteria, line data, and a summary of the results, for each applicable parameter.

viii. Product and packaging design risks and misuse hazards. This section of an applicant's PMTA is required to contain a review and assessment of reasonably foreseeable risks associated with the design of the tobacco product and its packaging that may occur during normal use of the tobacco product or during any foreseeable misuse of the product, including user error, which may cause illness, injury, or death not normally associated with the use of the tobacco product. The review and assessment would be required to identify the measures taken to reduce or eliminate each risk associated with the design of the tobacco product and packaging. Examples of these design risks include, but are not limited to: Defects in the air permeability of fire standards compliant banding on cigarette paper that is intended to allow cigarettes to self-extinguish when left unattended, software errors or flaws (*i.e.,* bugs) that occasionally result in the product performing differently than designed; failure of a safety switch to shutoff a product if it exceeds a certain temperature; and the failure of a battery design feature to prevent battery from overcharging. The PMTA would have to contain a review and assessment of each defect, describing the potential to cause illness, injury, or death and the measures taken to reduce or eliminate the defects and their potential impact. FDA is requiring this information under section 910(b)(1)(G) of the FD&C Act because the potential for the product design or foreseeable misuse to cause illness, injury, or death provides information that informs FDA's determination of whether permitting the marketing of the product would be APPH.

FDA is requesting public comment regarding the scope of design risks and misuse hazards that would be required to be included in this section. Specifically, FDA is requesting input regarding whether the design risks or misuse hazards for which an application would be required to contain a review and assessment should be (1) those not normally associated with the tobacco product, (2) those not normally associated with the category of tobacco products; or (3) those not normally associated with all tobacco products generally.

10. Principles of Operation

Proposed § 1114.7(i)(3) describes FDA's interpretation of the full statement of the principle or principles of operation required by section 910(b)(1)(B) of the FD&C Act and would require the PMTA to contain full narrative descriptions of:

- The way in which a typical consumer will use the new tobacco product. This includes, for example:
- A description of how a consumer operates the product;

• Where applicable, whether and how a consumer can change the product design and add or subtract ingredients, such as:

○ E-cigarettes that allow users to change performance features, such as the temperature, voltage, or wattage;

○ E-cigarettes that allow users to add or subtract e-liquid ingredients, such as liquid nicotine and flavoring, including instances where such manipulation is not intended by the manufacturer (*e.g.,* ways to misuse the product);

○ E-cigarettes that allow users to add, subtract, or substitute components or parts other than identical replacement parts; and

○ Waterpipes that allow users to add, subtract, or substitute components or parts other than identical replacement parts, such as stems and hoses;

• The length of time it takes for a user to consume a single unit of the product. This may be characterized in multiple ways depending on the product type, for example, a single unit may include, but not be limited to one cigarette, one tobacco pouch, or a specified volume of e-liquid used. FDA requests public comment on appropriate metrics for determining what should constitute a single unit for various product types and also whether FDA should require the average time for all users to consume a single unit, the median time to consume a single until, or the range of time it takes users to consume a single unit of the product; and

• Whether the product incorporates a heating source and, if it does, a description of the heating source.

11. Product Testing and Analysis Information

Proposed § 1114.7(i)(4) requires that all testing and analyses of the tobacco product required in § 1114.7(i) be performed on test samples that reflect the final tobacco product composition and design, and that they be conducted using a sufficient sample size and number of replicates to substantiate the results of the type of testing conducted. FDA is proposing this requirement under its authority in 910(b)(1)(G) because the testing requirements described in this section are relevant to the subject matter of the application in that it helps FDA determine whether the product testing and analyses are accurate and reliable. If the product that is the subject of the PMTA is a component or part, testing and analyses of the product should be performed with a range of other components or parts with which a consumer is expected to use the product (*e.g.,* an e-liquid should be tested in a representative sample of e-cigarettes in which it is may be used). FDA notes that the sample size and number of replicates necessary to substantiate the type of testing may vary according to the type of testing. FDA recommends that a PMTA contain an explanation of why the applicant believes the sample size and number of replicates used is sufficient to support the reliability of the results. Additionally, the applicant would be required to provide the following information about the testing and analysis:

• The name and location of the testing laboratory or laboratories and documentation showing that the laboratory is (or laboratories are) accredited by a nationally or internationally recognized external accreditation organization;

• The length of time between dates of manufacture and date(s) of testing;

• The storage conditions of the tobacco product before it was tested;

• The number of samples and measurement replicates for each sample;

• Description of method procedure, method validation information and rationale for selecting each test method, including relevant voluntary testing standards;

• Reports of all product formulation testing, including line data, test protocols, quantitative acceptance criteria, and a summary of the results, for each applicable parameter. Please note that an applicant would be required to retain source data under proposed § 1114.45; and

• Complete descriptions of any smoking or aerosol-generating regimens used for analytical testing that are not standardized or widely accepted by the scientific community, if applicable. Where the applicant is not using a widely recognized and standardized regimen, such as the ISO or HCI regimens, the PMTA would need to contain complete description of the regimen.

12. Manufacturing

Section 910(b)(1)(C) of the FD&C Act requires a PMTA to contain full descriptions of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, the tobacco product. Proposed § 1114.7(j) provides FDA's interpretation of this requirement, together with its authority under section 910(b)(1)(G) of the FD&C Act, stating that these descriptions must include information regarding all manufacturing facilities, include descriptions of design controls, and be sufficiently detailed to demonstrate that the product meets manufacturing specifications and can be manufactured in a manner consistent with the information submitted in the PMTA.

Additionally, because FDA must, under section 910(c)(2)(B) of the FD&C Act, deny a PMTA that does not demonstrate compliance with regulations issued under section 906(e) of the FD&C Act, the descriptions contained in the manufacturing section must demonstrate the means by which the processes comply with any applicable tobacco product manufacturing practices regulation issued under section 906(e). FDA has not yet issued a regulation under section 906(e) of the FD&C Act, so demonstrating compliance with such regulations is not currently required; however, FDA intends to issue regulations under section 906(e), and once such regulations are effective, applicants must demonstrate that their methods, facilities, and controls comply with that rule to receive a marketing order under section 910(c)(1)(i)(A) of the FD&C Act.[11] Until a final rule issued under section 906(e) of the FD&C Act is effective, FDA will evaluate the manufacturing process information and consider whether the product can be manufactured in a manner consistent with the information submitted within the application as part of its determination of whether the marketing of the new tobacco product would be APPH. As part of this evaluation, FDA may conduct inspections as described in proposed § 1114.27 to verify the information and data submitted in the application.

The process by which a tobacco product is manufactured is important to FDA's determination of whether a new tobacco product is APPH because it demonstrates the likelihood that a tobacco product will be manufactured in accordance with the specifications set forth in the PMTA. A tobacco product that fails to conform to the PMTA's specifications, referred to as a ''nonconforming tobacco product,'' could result in a defective product and increase the product's risk compared to what would normally be expected from

[11] In establishing the effective date of a regulation under section 906 of the FD&C Act, FDA must provide for a ''reasonable period of time for . . . manufacturers to conform to good manufacturing practices,'' and small tobacco product manufacturers will have at least 4 additional years to comply. See section 906(e)(1)(B) of the FD&C Act. FDA anticipates that manufacturers preparing PMTA applications before any regulation under 906(e) is finalized will have sufficient time to prepare applications that demonstrate that their methods, facilities, and controls comply with such a rule before the applicable effective date. For PMTA applications submitted before any regulation under 906(e) is finalized, FDA generally expects the review of such applications will be concluded prior to the effective date.

use of the product as characterized in the PMTA. Additionally, a nonconforming tobacco product constitutes a different tobacco product than the one authorized in the marketing order, which would render a nonconforming tobacco product adulterated under section 902(6)(B) of the FD&C Act. A nonconforming tobacco product can be the result of a number of issues, including design defects, failures of or problems with purchasing controls, inadequate process controls, improper facilities or equipment, inadequate training, inadequate manufacturing methods and procedures, or improper handling of the tobacco product.

Nonconforming tobacco products have been highlighted in the news. For example, in 2017, a manufacturer of smokeless tobacco products issued a voluntary recall of certain products after receiving complaints of foreign metal material, including sharp metal objects, in its smokeless tobacco products. After the recall, the manufacturer investigated whether the contamination was a result of the manufacturing practice or a deliberate act by an individual to contaminate the product. FDA is also aware of other instances where smokeless tobacco products contained rocks or metal shavings as well as other nontobacco related materials (NTRMs) (*e.g.,* glass, nails, pins, wood, dirt, sand, fabric, cloth, and plastics) in finished tobacco products. These NTRMs can cause cuts or lacerations to the lips and gums or result in broken teeth. This proposed regulation provides requirements for how manufacturers would be required to handle complaints in similar situations, as well as the subsequent investigation, evaluation, and corrective and preventive actions they would need to take to address such issues.

FDA also has observed during inspections that tobacco product manufacturers have received complaints regarding nonconforming tobacco products that contain contaminants and hazards such as biological materials (*e.g.,* mold, mildew, hair, fingernails) and chemical hazards (*e.g.,* ammonia, cleaning agents, and kerosene). Caustic cleaning chemicals may cause the consumer to experience adverse health effects not normally associated with tobacco use, such as vomiting, nausea, allergic reactions, dizziness, numbness, or headaches.

Nonconforming tobacco products may also contain higher levels of a constituent than the consumer is expecting and that the product is supposed to have as characterized by the PMTA. For example, FDA is aware of the variability of nicotine among certain ENDS products and that the labeling may not accurately reflect the actual levels of nicotine in those products. In one study, researchers found that actual nicotine amounts differed from labeled amounts by more than 20 percent in 9 out of 20 original e-cigarette cartridges tested, and in 3 out of 15 refill cartridges tested (Ref. 105). FDA has observed on inspections that some e-liquid manufacturers do not have established procedures to conduct activities or maintain records of their manufacturing processes, including but not limited to calibration of equipment, documenting the identity or purity of their ingredients, and testing final product to confirm that it meets established specifications such as the concentration of nicotine. A finished ENDS that contains a nicotine concentration higher than the established specification can be more addictive (Refs. 106 and 107). Similarly, a cigarette that does not conform to its pH specification can deliver nicotine in a different speed and amount to the user which can impact the tobacco product's toxicity and addictiveness (Ref. 45). Exposure to nonconforming products in this circumstance can result in user exposure to increased levels of nicotine, which can lead to increased addictiveness.

Nonconforming products may also contain defects that can cause the tobacco product to be more harmful. For example, an ENDS product may have a defect that contributes to an increased risk of fire and/or explosion. The ENDS product, during use or foreseeable misuse, can expose consumers to increased harm if the device catches fire or explodes resulting in serious burns that would not be expected from use of the product (*e.g.,* Ref. 108).

Given the dangers associated with nonconforming (including contaminated) tobacco products, FDA is proposing to evaluate an applicant's manufacturing process information to help determine whether the marketing of a new tobacco product would be APPH, specifically considering whether the manufacturer explains controls it would establish and maintain to prevent the manufacture and distribution of nonconforming products that may have an adverse effect on public health.

The manufacturing section of a PMTA must contain the following information in the manufacturing section to meet the requirements of proposed § 1114.7(j) and to help FDA determine if it conforms to the requirements of section 906(e) of the FD&C Act:

- A listing of all manufacturing, packaging, storage, and control facilities for the product, including the name, address, and FEI number for each facility, if applicable, and a contact name and telephone number for a representative from each facility;
- A narrative description, accompanied by a list and summary of all standard operating procedures (SOPs) and examples of relevant forms and records for the following categories of information for all manufacturing, design controls, packing, and storage for the tobacco product:
  - Manufacturing and production process activities at each establishment, including a description of each establishment, all production steps, process controls, process specifications with relevant acceptance criteria, and monitoring and acceptance activities;
  - Managerial oversight and employee training related to the manufacture, processing, packing, and installation of the tobacco product, as applicable;
  - Monitoring procedures and manufacturing controls for product design, product characteristics, and changes in products, specifications, methods, processes, or procedures, including a hazard analysis that details the correlation of the product design attributes with public health risk, as well as any mitigation strategies implemented;
  - Activities related to identifying and monitoring suppliers and the products supplied (including, for example, purchase controls and product acceptance activities);
  - Handling of complaints, nonconforming products and processes, and corrective and preventative actions;
  - Testing procedures carried out before the product is released to market, including:
    - A list and summary of any standards used for all testing methods;
    - Validation or verification activities for all test methods used to ensure that the tobacco product meets specifications;
    - Documentation of accreditation information for all testing laboratories;
    - Complete description of smoking or aerosol-generating regimes used for analytical testing, if any;
    - Tobacco product specifications (including any physical, chemical, and biological specifications) and acceptance criteria for those specifications; and
    - Reports of release testing performed on finished products to demonstrate conformity with established specifications, including test protocols, line data, and a summary of the results for each applicable testing.

13. Health Risk Investigations

Under section 910(b)(1)(A) of the FD&C Act, a PMTA must contain full reports of all information, published or known to, or which should be reasonably known to, the applicant concerning investigations which have been made to show the health risks of the tobacco product and whether the tobacco products present less risk than other tobacco products. Proposed § 1114.7(k) sets forth FDA's proposed interpretation of this requirement, together with its authority in section 910(b)(1)(G), in three parts: (1) The types of investigations that would be considered investigations into the health risks of the product and whether the tobacco product presents less risk than other products; (2) the documentation an application would be required to contain to demonstrate that the application contains all published investigations; and (3) the information that would constitute a full report of an investigation.

a. Types of investigations and analyses. FDA interprets the information required under section 910(b)(1)(A) of the FD&C Act, together with its authority under section 910(b)(1)(G) of the FD&C Act, to include the health risk investigations specified in proposed § 1114.7(k)(1). Under the proposed rule, applicants would be required to submit full reports (as described in proposed § 1114.7(k)(3)) of all information published or known to, or which should reasonably be known to, the applicant regarding the types of investigations described in proposed § 1114.7(k)(1). Applicants would be required to submit full reports of these investigations, regardless of whether they support or are adverse to the application, or are conducted within or outside the United States.

Proposed § 1114.7(k)(1) requires an application to contain health risk investigations that are published, known to, or should reasonably be known to an applicant. This proposed requirement would ensure that FDA understands the full scope of the health risk investigations for a new tobacco product. It does not require a PMTA to contain each type of health risk investigation described in this section beyond what is published, known to, or should reasonably be known to, an applicant and, applicants should not interpret this proposed section to be a list of investigations that it must conduct to receive a marketing order. While a PMTA must contain substantive information regarding certain categories of information set forth in § 1114.27(b)(i)(ii) to be filed by FDA as described in section VIII.B., an applicant has some flexibility in determining how to use existing information to support a PMTA for their product and what types of additional investigations it may need to conduct to provide FDA with information that demonstrates that permitting the marketing of its new tobacco product would be APPH. Applicants may want to review the areas of scientific investigation listed in this proposed section in an effort to determine whether there are gaps in the existing scientific information regarding its product that it may need to fill by conducting a new study regarding its tobacco product. As discussed in the description of § 1114.31 in section VIII.D., acceptance and filing of a PMTA does not mean that it has sufficient scientific information necessary to obtain a marketing order.

An applicant may choose to conduct one of the health risk investigations described in § 1114.7(k)(1) to help demonstrate the health risks of a new tobacco product; however, it should be clear that the proposed rule is not requiring applicants to conduct these studies beyond what may be necessary to generate substantive information to meet the filing requirements set forth in proposed § 1114.27(b)(1)(ii). While the proposed rule is not requiring applicants to conduct studies beyond what may be necessary to generate substantive information to meet the filing requirements set forth in § 1114.27(b)(1)(ii), if such studies, together with other information in the PMTA, do not show that permitting the marketing of the new tobacco product would be APPH, FDA would issue an no marketing order. Applicants have some flexibility in the particular studies that they may conduct; an application would not necessarily need to contain each type of study described in § 1114.7(k) for filing or to receive an order.

Proposed § 1114.7(k) would interpret section 910(b)(1)(A) broadly to ensure FDA has a complete understanding of the existing information about a new tobacco product; it does not set requirements for specific studies that must be contained in every single PMTA. The description of the issuance of no marketing orders (proposed § 1114.33) in section VIII.E. describes circumstances where FDA intends to issue a no marketing order. The description of the issuance of marketing order (proposed § 1114.31) in section VIII.D. contains information regarding FDA's determination of whether there is a showing that the marketing of a new tobacco product would be APPH.

The proposed rule would not require an applicant to conduct any of its own studies for the purposes of the proposed application acceptance and filing requirements in § 1114.27, except as would be necessary to meet the filing requirements of proposed § 1114.27(b)(2)(ii). Should an applicant choose to do so, FDA is providing proposed, recommendations for consideration throughout this section of the preamble. In addition to proposed recommendations for specific types of studies that follow, FDA is making proposed recommendations for three general topics related to health risk investigations that may help an applicant prepare a PMTA in some instances: Bridging data from an investigation conducted using a different product to the product that is the subject of the application, choosing appropriate comparison products, and using foreign data.

- *Bridging.* FDA recognizes that in preparing the health risk investigations section of a PMTA, an applicant may choose to use data from a study conducted using a different tobacco product in an attempt to demonstrate the health risks of the product that is the subject of the application. The submission of studies using different products is optional and is not required under the proposed rule. Ideally, a PMTA will contain studies conducted with respect to the new tobacco product itself, but the bridging of data from a different product to the new tobacco product that is the subject of the application may be feasible for a subset of products or for certain types of studies. If an applicant lacks data on the product from one or more of the types of studies listed in this section, the applicant could bridge data regarding another product, or an earlier version of the product where appropriate. For example, ''X-flavor'' e-liquids with nicotine concentrations ranging from 1 milligram per milliliter (mg/mL) to 24 mg/mL may be able to show the health risks of each of the e-liquids without having to conduct a unique study for each nicotine concentration of the ''X-flavor'' product if data from a subset of nicotine concentrations (*e.g.,* low, middle, high) of ''X-flavor'' products may be bridged to other nicotine concentrations of ''X-flavor'' products. Other examples where data from studies on a smaller number of products could potentially be bridged to a larger number of products include smokeless tobacco products available in various pouch sizes or e-liquids available in various container volumes. If an applicant chooses to bridge data from a

studied tobacco product to the subject new tobacco product, FDA recommends that the application contain the rationale and justification to support the use of bridging studies.

Where an applicant chooses to bridge to data from a general study or a study conducted using a different tobacco product, it should provide a scientific rationale to justify why the study findings apply to its new tobacco product and any study limitations that may be relevant. Failure to provide a sufficient justification that such data can be used to evaluate the new tobacco product would result in FDA being unable to rely upon it in evaluating the PMTA. There may be circumstances when an applicant would need to submit additional substantive information, including bridging studies, as appropriate, to justify that the results of a general study or a study using a different tobacco product is relevant to evaluation of its new tobacco product. Where an applicant seeks to use information from a study conducted using a different tobacco product in the same product category, it may need to provide comparative product information or potentially a bridging study to show the results apply to its specific new tobacco product. For instance, if an applicant wants to use the results of an abuse liability study that was conducted on a different product, an applicant should justify how key similarities between the products (*e.g.,* product design, nicotine formulation and content) demonstrate the results of the study apply to its tobacco product. As another example, national surveys, such as the NYTS, provide information about trends in tobacco product use by youth and typically do so for product categories as a whole, rather than specific products. If an applicant intends to use such survey data to help show the likelihood of youth initiation with its product, it would need to explain why results about a product category in general would apply to its specific product.

Another example of when a justification or a bridging study may be needed is when the location or region of a study differs from the intended locations or regions where the product will be used, which is further described in the foreign data section below.

• *Comparison Products.* As part of FDA's consideration under 910(c)(4) of the FD&C Act of the risks and benefits of the marketing of the new tobacco product to the population as a whole, including users and nonusers of tobacco products, FDA reviews the health risks associated with changes in tobacco product use behavior (*e.g.,* initiation, switching, poly use, cessation) that may occur with the marketing of the new tobacco product. We recommend an applicant compare the health risks of its product to both products within the same category and subcategory, as well as products in different categories as appropriate. It is helpful for FDA to understand applicant's rationale and justification for comparators chosen whether within the same category or different categories of tobacco products. This comparative health risk data is an important part of the evaluation of the health effects of product switching. As set forth in proposed § 1114.27(b)(1)(ii), a PMTA would be required to contain substantive information regarding comparative health risks to be filed for review.

Information about tobacco products in the same category or subcategory is important to FDA's evaluation of a tobacco product's potential effect on public health because current users may switch to other products within the same category. When determining an appropriate comparison product within the same category or subcategory of product, FDA recommends applicants consider products consumers are most likely to consider interchangeable between your proposed product and other similar products. For example, for a PMTA for an e-liquid, FDA recommends the product be compared to other e-liquids used in a similar manner. This comparison is not meant to be a 1:1 comparison as in a substantial equivalence report under section 905(j), rather, it is meant to demonstrate how the proposed new product may be evaluated in relation to similar products.

Information about tobacco products in different categories is important to FDA's evaluations because it can help demonstrate the changes in health risks current tobacco users could face if they switched to your new tobacco product or use it in conjunction with their current tobacco product. For tobacco products that are not in the same tobacco product category, but that may be appropriate for examining health risk, FDA recommends determining the likely users of the proposed new product to justify appropriate comparison products. For example, if an applicant submitting a PMTA for an ENDS believes that current users of cigarettes and ENDS will use its product, it would be appropriate to compare the health risks of the ENDS to both cigarettes and other similar ENDS products. Polytobacco use risks should also be considered.

• *Foreign Data.* An application may contain health risk investigations conducted outside of the United States. If the study data concern a demographic that is different from the United States, the applicant should provide a scientific rationale for why the results of the study can be generalized to other demographic groups that are representative of the U.S. population as whole.[12] This could include a discussion of the factors that would be expected to influence study findings and whether they vary significantly across the U.S. population. The applicant should also clearly describe any reasons why study findings may not be generalized to the broader U.S. population.

Foreign clinical studies should be performed by clinical investigators so that the rights, safety, and welfare of human subjects have been protected in accordance with ethical principles acceptable to the international community, such as those reflected in the International Council for Harmonisation (ICH) Good Clinical Practice standards.

An application may be required to contain full reports of foreign investigations even if they do not meet these criteria because of the requirements of proposed § 1114.7(k) that an application contain all published studies regarding a new tobacco product. This could include, for example, a published health risk investigation regarding the product conducted outside the United States by someone other than the applicant. Where data do not meet the recommendations described in the preceding paragraph, an application should contain a description of the ways in which the foreign data fails to meet those criteria and, if applicable, describe whether FDA should still consider the data to be valid.

i. Health risks of the product. Proposed § 1114.7(k)(1)(i)(A) would require a PMTA to contain full reports of all investigations, published or known to, or which should reasonably be known to, the applicant regarding the potential health effects of their product. This would include full reports of investigations on the constituents, including HPHCs, in the specific product or formed during use of the product, and at the quantitative levels that would be delivered to both users and nonusers under the range of conditions under which the specific product may be used. FDA is proposing to include these investigations under its interpretation of the requirements of

[12] For a discussion of both intrinsic and extrinsic factors in foreign data that might need to be addressed, please see the International Council for Harmonisation (ICH) E5 guidance: Ethnic Factors in the Acceptability of Foreign Clinical Data.

section 910(b)(1)(A) of the FD&C Act because the health effects of constituents at the levels delivered to both users and nonusers help demonstrate the overall health risks of the product. Types of investigations into the health effects of constituents that applicants would be required to submit as part of a PMTA if published or known to, or which should reasonably be known to an applicant include human exposure studies, in silico computational toxicology techniques, risk assessments, in vitro toxicology studies, published reports of in vivo toxicology studies, and, if necessary, new in vivo toxicology studies.

The proposed rule would not require an applicant to conduct any particular type of studies regarding the health risks of the constituents for the purposes of application acceptance and filing; however, as set forth in proposed § 1114.27(b)(1)(ii) and described in section VIII.B., an application would be required to contain substantive information regarding the health risks of the new tobacco product to be filed. Where an applicant chooses to conduct its own investigations, FDA is providing the following discussion of non-binding recommendations for consideration.

The health effect evaluation of tobacco constituents, including HPHCs, in a PMTA should begin with an assessment of human exposure. For tobacco product users, this assessment should include direct measurements of exposure, estimates of exposure from analytical studies of the tobacco product and its smoke or aerosol, or investigations that combine both approaches. For nonusers of the tobacco product, exposure estimates would include analytical studies. One source of this information can be the HPHC data that would be required by proposed § 1114.7(i)(1)(v). FDA recommends that these investigations specifically assess the levels of each HPHC to which users and nonusers could be exposed and that direct measurements or estimates of exposure use the same route of administration (*e.g.,* inhalation, ingestion, dermal contact) as the tobacco product they evaluate. Other aspects of the exposure that FDA would recommend applicants define in the tobacco constituent exposure assessment include exposure duration, inhalation rate, consumption rate, body mass, and other similar relevant measures.

Study reports regarding the health effects of product constituents at both the exposure ranges estimated for user and nonuser exposure and higher exposures are important in the toxicological evaluation of a PMTA because it allows for a more thorough dose-response assessment. Higher exposures may provide indication of toxicity potential from lower exposure levels over longer exposure times. FDA recommends including dose-response assessments across a range of exposures. For noncarcinogenic constituents, FDA recommends including study reports that define the threshold of toxicity, especially those that identify the no-observable-adverse effect level and lowest-observable-adverse-effects-level. For carcinogenic constituents, if only high-exposure studies are available, an assumption of linearity should be made for low-dose extrapolation. For both carcinogenic and noncarcinogenic constituents, user and nonuser exposures should be compared to available dose response information.

FDA supports reducing the reliance on animal testing where adequate and scientifically valid non-animal alternatives can be substituted. FDA encourages sponsors to meet with CTP early in the development process to discuss what, if any, animal testing is appropriate and the suitability and acceptability of non-animal tests for their specific new tobacco product. When animal-based nonclinical laboratory studies are conducted, investigators should use appropriate animal models and adhere to the best practices of refinement, reduction, and replacement of animals in research and to applicable laws, regulations, and policies governing animal testing, such as the Animal Welfare Act (7 U.S.C. 2131 *et seq.*) and the Public Health Service Policy of Humane Care and Use of Laboratory Animals (available at *https://olaw.nih.gov/policies-laws/phs-policy.htm*).

Under proposed § 1114.7(k)(1)(i)(B), a PMTA would be required to contain all investigations, published or known to, or which should reasonably be known to, the applicant regarding the toxicological profile of the new tobacco product related to the route of administration, including, but not limited to, the genotoxicity, carcinogenicity, respiratory toxicity, cardiac toxicity, reproductive and developmental toxicity, and chronic (repeat dose) toxicity of the new tobacco product relative to other tobacco products. The toxicological profile also includes information regarding the ingredients, additives, and HPHCs, relative to the route of administration and the range of the potential levels of exposure resulting from the use of or other exposure to the product. While FDA is aware of the risk of harm posed by HPHCs generally, understanding the toxicological effects of HPHCs in the product is important to FDA's review because the levels and combinations of HPHCs to which a consumer may be exposed can determine whether, and the severity with which, a user may experience harm. For example, some constituents may only cause harm above certain levels of exposure, while others may have no safe level of exposure. Additionally, since there are potential complex interactions between HPHCs and each tobacco product can produce a different mixture of these HPHCs, FDA needs to determine the toxicity of the specific mixture of HPHCs in a tobacco product in order to compare that tobacco product to other similar products on the market place and to use this comparison in the decision about whether permitting the marketing of the product would be APPH. The toxicological profile investigations covered by the proposed rule would also include studies that discuss the toxicological effects of any leachables and extractables from the container closure system and the ingredient mixture, such as additive or synergistic effects.

FDA is proposing to include the toxicological profile of the tobacco as part of its interpretation of the health risk investigations required under section 910(b)(1)(A) of the FD&C Act, where published, known to, or which should reasonably be known to an applicant, because it identifies the hazardous or harmful effects of product constituents and allows for product comparisons that estimate the impact of the assessed tobacco product on the health of both users and nonusers of the tobacco product.

The types of toxicological information or data regarding a tobacco product that a PMTA would be required to contain if published or known to, or should reasonably be known to, an applicant would generally include the characterization of toxic effects of HPHCs to which users and nonusers may be exposed. This evaluation can include identification of the organs affected by constituents; the cancer and noncancer effects of the constituents; dose response relationships between exposure to constituents and health effects; and, when appropriate, threshold levels of exposure above which noncancer effects occur. The toxicological assessment of the product that is the subject of a PMTA should focus on the HPHCs reported in proposed § 1114.7(i)(1)(v), the constituent reporting section. The types of studies or information required by the proposed rule, if published or known to, or should reasonably be known to an applicant, include toxicological

assessments conducted in terms of both the whole tobacco product and the individual HPHCs that the product contains or delivers to users and nonusers.

Because different tobacco products contain different ingredients and additives, they may also have different HPHC yields. A tobacco product that would result in increased exposure to a potent HPHC or set of HPHCs, for example, may present higher health risks to users. However, important aspects such as dose-response and whether the end organ toxicity is carcinogenic or noncarcinogenic in nature could affect whether this higher exposure results in an estimate of increased risk. The information generated from the toxicological assessment of tobacco products is part of the information that the applicant should use in product comparisons to estimate the impact of the assessed tobacco product on the public health.

The toxicological profile includes information about, or investigations into, the potential for a tobacco product or its constituents to cause toxicity. For the specific toxicological profile of a new tobacco product or constituents in or formed during use of the new tobacco product, the applicant should address known tobacco target organs of toxicity, as appropriate for the product and/or route of administration. The profile should include data and thorough literature reviews of the following health effects known to be caused by tobacco products as applicable such as:

- Genotoxicity (the ability of a chemical agent to damage DNA within a cell, causing mutations that may lead to cancer);
- Carcinogenicity (the ability of a chemical agent to directly cause cancer in humans or animals after exposure);
- Cardiovascular toxicity (the ability of a chemical agent to cause adverse effects on the cardiovascular system (*i.e.,* heart and blood vessels));
- Respiratory toxicity (the ability of a chemical agent to cause adverse effects on the respiratory system, which comprises the nasal passages, pharynx, trachea, bronchi, and lungs);
- Reproductive toxicity (the ability of a chemical agent to cause adverse effects on the male or female reproductive systems such that normal reproduction is impaired);
- Developmental toxicity (the ability of a chemical agent to interfere with the development of the embryo or fetus); and
- Other diseases associated with use.

While not required for application acceptance or filing under proposed § 1114.33, FDA recommends that an application contain a discussion of the toxicological potential for the tobacco product to cause additional chronic toxicities, other than those listed above, such as any end-organ toxicity or route of administration effects. These end-organ toxicities include, but are not limited to, the potential toxicity on the liver, kidneys, immune system, digestive system, and neurological system. An example of route of administration effects that FDA recommends be addressed is the toxic potential of a smokeless tobacco product to the oral cavity, including teeth.

FDA also recommends the application address acute toxicity, which concerns the ability of a chemical agent to cause adverse effects after either a single exposure or multiple exposures in a short period of time (usually less than 24 hours). If there are known acute toxicities for product constituents at the levels to which an individual may be exposed (*e.g.,* carbon monoxide poisoning from waterpipe use, the ingestion of nicotine contained in e-liquids) including through accidental or unintended exposures, an applicant should justify how the product could contain such constituents and how permitting its marketing would be APPH. This could include a description of the design features, such as child-resistant packaging for e-liquids, that would prevent exposures to constituents that could result in acute toxicity as part of proposed § 1114.7(i)(1)(vi)(B). See the discussion in section VII.B.9.a.vi. for more information about protective packaging.

FDA recommends that an applicant compare the toxicity of its product to the toxicity of other products in the same product category or subcategory. Additionally, FDA recommends that applicants consider use exposure in conjunction with the hazards posed by a particular product to determine the most appropriate group of comparator products.

While applicants are not required to conduct toxicological analyses under the proposed rule, if an application does not contain substantive information regarding either the health risks of the new tobacco product or a comparison of the health risks compared to other tobacco product categories, FDA intends to refuse to file a PMTA as set forth in proposed § 1114.27(b)(1)(ii) and described in section VIII.B.. Information about the product's toxicity and a comparison of its toxicity to other tobacco products could satisfy this threshold information requirement for filing; however, it should be noted that information from nonclinical studies alone, including a product's toxicological profile, is generally not sufficient to support a determination that permitting the marketing of the product would be APPH. An applicant should also consider the existing valid scientific evidence regarding its new tobacco product to determine whether it would need to conduct and submit a full report of toxicological analyses to demonstrate the potential health risks of the new tobacco product as part of its PMTA. If an application does not contain sufficient information about the health risks of the new tobacco product to allow FDA to make a determination regarding the potential risks and benefits to the population as a whole under section 910(c)(4) of the FD&C Act, FDA will issue a no marketing order for the new tobacco product.

Under proposed § 1114.7(k)(1)(i)(C), a PMTA would be required to contain all studies concerning the pharmacological profile of the new tobacco product that are published or known to, or which should reasonably be known to, the applicant, including investigations into the pharmacokinetics, pharmacodynamics, metabolism, and elimination profile, of each of the ingredients, additives, and HPHCs for the range of potential levels of exposure resulting from the use of or exposure to the product relative to other tobacco products. The applicant would also be required to specify whether the studies were conducted in vitro, in vivo, ex vivo, or in silico. The pharmacological profile of the product and its constituents are important for FDA to consider when evaluating the relationship between the dose of the product and the body's response. FDA is proposing to include the pharmacological profile of the tobacco product as part of the information required under section 910(b)(1)(A) of the FD&C Act because it provides important information regarding how the product constituents and human body interact with each other, which directly impacts whether and what health impacts the constituents can have on users and nonusers of the product.

The types of pharmacological information that the applicant would be required to include in a PMTA if published or known to, or which should reasonably be known to, the applicant include pharmacokinetics and pharmacodynamics. Pharmacokinetics concern the movement of a constituent into, through, and out of the body. Types of pharmacokinetic information that an application would be required to contain if published or known to, or which should reasonably be known to, the applicant include absorption (the

rate and movement of a constituent into the bloodstream after administration), bioavailability (the extent to which the constituent reaches the site of action), distribution (the transfer of a constituent from one location in the body to another), metabolism (the breaking down of a constituent), and excretion (the elimination of a constituent). Pharmacodynamics refers to the effects of the constituent on the body including physiological (*e.g.,* changes in blood pressure and heart rate) and subjective effects (*e.g.,* whether the product is ''liked'' or produces other changes in affect). Types of pharmacodynamic information that an applicant would be required to submit in a PMTA if published or known to, or which should reasonably be known to, the applicant include physiological and subjective effects data and information regarding drug-receptor interactions, chemical interactions, and dose-response relationships.

The pharmacological profile of the product provides important information about the health risks of the product because it is directly related to the health risks of the product as well as its risk relative to other products. The pharmacological profile of nicotine, for example, is particularly important for assessing product health risk because its pharmacokinetic properties can enhance or reduce the product's associated health risks. In general, the abuse potential of nicotine increases when absorption is rapid because the rewarding properties of the compound increase, and suppression of withdrawal symptoms occurs more quickly. Nicotine's pharmacological profile impacts use behavior that can then affect the overall exposure of the user to HPHCs and other constituents in the product. Changes in use behavior may result from the pharmacokinetic properties of the nicotine and can result in increased or decreased exposure to the constituents within a product. (Refs. 109–112).

Under proposed § 1114.7(k)(1)(i)(D), a PMTA would be required to contain full reports of all investigations published or known to, or which should reasonably be known to the applicant concerning the health risks of the tobacco product compared to other tobacco products on the market, never using tobacco products, quitting tobacco product use, and using the tobacco product in conjunction with other tobacco products. Under section 910(b)(1)(A) of the FD&C Act, an applicant must submit investigations that have been made to show whether the tobacco product presents less risks than other tobacco products. FDA is proposing under section 910(b)(1)(G) of the FD&C Act to require applicants to submit investigations that have been made to show whether the tobacco product has the same or different potential health risks (not just less potential health risks) than other tobacco products to capture investigations that could potentially show a range of risks compared to other tobacco products. FDA is proposing that applicants include comparisons between the health risks of the tobacco product and never using tobacco product under the authority of section 910(b)(1)(A) and (G) of the FD&C Act because this information is relevant to determining the health risks faced by nonusers who initiate tobacco use with the tobacco product.

FDA is also proposing to require that an application contain, if published, known to or which should be reasonably known to the applicant, comparisons between the health risks of the tobacco product and using the tobacco product in conjunction with other tobacco products as part of the required information because existing data indicates that a significant number (approximately 40 percent or more by some estimates) of individuals who currently use tobacco products use more than one type of tobacco product (Refs. 113 and 114). This information is important in determining the health risks faced by individuals that may use the new tobacco product in conjunction with other tobacco products because research indicates that individuals who use a tobacco product with lower health risks in conjunction with a tobacco product with potentially higher health risks may continue to face the potentially higher health risks of the more dangerous product above a certain threshold of usage (Refs. 115 and 116).

The types of investigations that a PMTA would be required to contain if published or known to, or which should reasonably be known to the applicant in this section include, for example:

- Cross sectional and longitudinal surveys (such as market analyses or publicly available national surveys such as NYTS);
- epidemiologic studies that are descriptive (which describe the occurrence of a prespecified or unknown outcome), such as case reports and case series; and
- analytic studies (which describe the association between exposure and outcome) such as randomized controlled clinical trials, cohort studies, and case control studies.

Additionally, clinical studies that employ surrogate endpoints (*e.g.,* biomarker studies) may be used to draw conclusions regarding the effects of the product on a clinical benefit endpoint and patient reported outcome data (*i.e.,* report of the status of health that comes directly from the subject without interpretation from the subject's response by a clinician) may be used as supportive evidence for health outcomes or effects.

For determining the health risks that are posed to a typical user of a tobacco product for the purposes of comparison, FDA recommends using an average of light, moderate, and heavy users. FDA also recommends including evidence and a description supporting the range of light, moderate, and heavy use an applicant includes in its PMTA, including how they relate to the exposures in the submitted toxicology studies. Where an applicant does not have data regarding light, moderate, or heavy product use because the product has not been commercially marketed, including outside the United States, an applicant could, where applicable, bridge to data regarding a similar tobacco product or conduct clinical studies under ad libitum (*i.e.,* unrestricted use) conditions.

As set forth in proposed § 1114.27(b)(1)(ii) and described in section VIII.B, for an application to be filed it must contain substantive information comparing the new tobacco product's health risks to those generally presented by the same product category and at least one different product category that is used by the consumers an applicant expects to use their new tobacco product. An applicant should consider the appropriate comparative health information a PMTA may need beyond this threshold requirement to provide FDA with a full understanding of the potential risk and benefits to current tobacco users. If a PMTA lacks sufficient information to demonstrate the changes in risk to which current users of tobacco products would potentially be exposed if they switched to the new tobacco product or began using it in conjunction with their current product, FDA intends to issue a no marketing order for the new tobacco product.

For demonstrating the health risks that are posed by the product in comparison to using other tobacco products, FDA recommends a comparison to both products that are within the same category or subcategory of tobacco product and also to other categories of tobacco products currently on the market, as appropriate. As described in section VII.B.13.a., when determining an appropriate comparison product within the same category or subcategory of product, FDA recommends applicants consider

products that consumers are most likely to consider interchangeable between your proposed product and other similar products. For example, for a PMTA for an e-liquid, FDA recommends the product be compared to other e-liquids likely to be used in the same manner. When determining appropriate comparator products that are not in the same tobacco product category, FDA recommends comparing the health risks of the product to categories of products that have a substantial market share (*e.g.,* cigarettes, smokeless tobacco, cigars). Because it is expected that current consumers of products that are in the same category may switch products and consumers of different categories of tobacco product may also switch products or use a new product in conjunction with their current product, this comparative health risk data is an important part of the evaluation of whether switching could potentially result in a lower or higher population health risks.

ii. Impacts on tobacco use behavior of tobacco product users. FDA interprets health risk investigations under section 910(b)(1)(A) of the FD&C Act to include the effect of the product and its label, labeling, and advertising on tobacco use behavior and tobacco use topography because use behavior and topography are directly related to levels of exposure to HPHCs, which, in turn, impacts health risks. For example, changes in tobacco product use behavior and topography that result in more frequent or intense use of the product will result in greater exposure to HPHCs and may result in increased health risks. Aspects of a product that could result in more frequent or intense use compared to currently marketed products can include differences in the appeal and design of the product, including ingredients; flavors; alteration in the amount or delivery of nicotine; physical differences such as changes in the velocity of the inhaled particles, the effort required to inhale, or the density of the smoke, vapor, or aerosol; or other changes which similarly affect user behavior (*e.g.,* ventilation, filter density).

Proposed § 1114.7(k)(1)(ii)(A) would require a PMTA to contain full reports of investigations into the abuse liability of the new tobacco product that are published or known to, or which should reasonably be known to the applicant. However, as set forth in proposed § 1114.27(b)(1)(ii) and described in section VIII.B., if a PMTA does not contain substantive information regarding the abuse liability of a new tobacco product, FDA may refuse to file the application. This means where there is no published information regarding the abuse liability or information that is otherwise known to the applicant, including information from investigations using other products that an applicant could bridge to its product, an applicant would need to conduct its own investigation and include a full report of the results in its PMTA for filing.

Abuse liability refers to the potential of a substance to result in addiction and be used repeatedly or even sporadically resulting in undesirable effects. The abuse liability of a new tobacco product is important for FDA to evaluate because it indicates the degree to which users of the tobacco product are likely to use and develop an addiction to the product. Abuse liability may result in compulsive and continued use despite harm or risk of harm, and craving of the product. FDA proposes to require the submission of abuse liability information under its interpretation of section 910(b)(1)(A) of the FD&C Act because it indicates the likelihood of users to become addicted to the product and face the health risks posed by product use over the long term, and may provide insight into the use and adoption of the product, which is an important part of FDA's assessment of the health risks of the new tobacco product as part of its determination of the risks and benefits to the population as a whole under section 910(c)(4) of the FD&C Act. If FDA lacks sufficient information regarding the potential abuse liability of the new tobacco product, it intends to issue a no marketing order for the new tobacco product.

The types of investigations that inform an evaluation of a product's abuse liability can be wide ranging and are likely to overlap with data submitted elsewhere as part of the PMTA, including data regarding product chemistry, pharmacology, and pharmacokinetic characteristics. Where the data are included elsewhere in a PMTA, FDA recommends including content in this section by cross-reference to the full reports of relevant investigations in other sections. Applicants should analyze the results of all investigations included in the application that impact the abuse liability of the product and synthesize the findings in this section.

While applications need to contain only a threshold amount of abuse liability information under proposed § 1114.27(b)(2)(ii) to be filed, the abuse liability of a tobacco product is an important part of FDA's finding of whether permitting the marketing of the new tobacco product would be APPH and applicants would want to consider conducting an abuse liability study if they do not believe there is sufficient existing data regarding their product. The ''standard'' abuse liability study is a double-blind, placebo-controlled, within-subject study comparing several doses of a new product to a comparator product with a known abuse liability. Generally, the primary outcome measure is peak ''liking'' (Emax) as reported via a visual analog scale. Applicants that wish to conduct abuse liability studies examining tobacco products may utilize a similar framework with additional assessments, although evaluating multiple doses may not be applicable to some tobacco products. These assessments may include use topography, and pharmacokinetics and pharmacodynamics assessments under both prescribed and ad libitum (*i.e.,* unrestricted) use conditions. Real world, actual use data may also provide outcomes relevant to the products' abuse liability, including misuse. Abuse liability conclusions should be considered as an integral assessment of all outcome measures important to understanding the abuse liability of the new tobacco product both independently and relative to other tobacco products with a known abuse liability. FDA generally expects abuse liability studies to contain a comparison to one or more tobacco products and applicants seeking to market a new tobacco product for which little abuse liability data has been established should ensure FDA has sufficient information to understand how the abuse liability of such a product compares to other relevant categories of tobacco products.

Section 1114.7(k)(1)(ii)(B) of the proposed rule would require a PMTA to contain investigations published or known to, or which should reasonably be known to the applicant into how consumers actually use the product, including use topography, the product use frequency, use trends over time, and how such use affects the health risks of the product to individual users. FDA is proposing to require this information because the ways in which consumers actually use the product, instead of relying only on how manufacturers intend the product to be used, help to demonstrate the levels of constituents to which the users will be exposed. Under proposed § 1114.27(b)(1)(ii), FDA may refuse to file a PMTA that does not contain substantive information regarding how consumers actually use the product, including use topography, product use frequency, use trends over

time, and how such use affects the health risks of the product to individual users. This means where there is no published information regarding actual use or information that is otherwise known to the applicant, including information from investigations using other products that an applicant could bridge to its product, an applicant would need to conduct its own investigation and include a full report of the results in its PMTA for filing.

An actual use study can include the use of actual product in either a simulated use setting or in a real use environment. Actual use studies are important to the evaluation of a PMTA because they provide information regarding whether consumers will use the product as intended. In addition, actual use studies help demonstrate whether consumers are likely to misuse the product, including in ways that may change the health risks that the product poses to users and nonusers. For example, ENDS users have applied e-liquid directly onto an exposed heater coil, a process known as dripping, which can lead to greater exposure to volatile aldehyde and a resulting change in the health risks of using the product. (Ref. 69). Actual use studies may be conducted using outpatient protocols so that results are as close to actual use as possible. The format of the study should reflect the goals of the study and how the applicant believes the information will inform FDA's decision.

Use topography measures the way in which users consume a product. Use topography is an important measure to consider in assessing a product's health risk and abuse liability because the volume, frequency, and duration of product use determines the amount of, and manner in which, a user is exposed to HPHCs in a product and, consequently, affects the health risks of the product. For combusted or inhaled products, use topography could include measurements of the number of puffs taken, puff duration, puff volume, duration of use, and other relevant measures. For smokeless tobacco, use topography could include measures such as the number of smokeless tobacco tins used per week, the total dips per day, and the dip duration.

Section 1114.7(k)(1)(ii)(C) of the proposed rule would also require the PMTA to contain full reports of all investigations, published or known to, or which should reasonably be known to the applicant, regarding the likelihood that users will use the product in conjunction with other tobacco products. Data indicate that a substantial number of tobacco product users are poly-users of tobacco products (Ref. 113 and 114). FDA is proposing to require information regarding the likelihood of dual or poly-use because such use may increase or decrease known health risks and may pose risks that are not currently known (Refs. 115 and 116). The likelihood of tobacco product users using the new tobacco product in conjunction with another tobacco product, when considered with the health effects resulting from such poly use, will help FDA determine the health risks that poly users may encounter.

Section 1114.7(k)(1)(ii)(D)–(F) of the proposed rule would also require the PMTA to contain full reports of investigations published or known to, or which should reasonably be known to the applicant, regarding the likelihood that current tobacco product users:

- Will start using the product;
- will starting using the product exclusively and then switch to or switch back to other tobacco products that may present increased risks to individual health; and
- will start or continue to use the product when they otherwise would have quit using tobacco products.

While proposed § 1114.7(k)(1)(ii)(c)–(f) would require a PMTA to contain only information published, known to, which would reasonably be known to the applicant, as set forth in proposed § 1114.27(b)(1)(ii), if a PMTA does not contain a threshold amount of information regarding likelihood of changes to tobacco use behavior of current tobacco users, FDA intends to refuse to file the application. This means where there is no published information regarding the likelihood of changes in tobacco use behavior by current users of tobacco products or information that is otherwise known to the applicant, including information from investigations using other products that an applicant could bridge to its product, an applicant would need to conduct its own investigations and include a full report of the results in its PMTA to meet this requirement for application filing. And while the rule would not require an applicant address each potential change in tobacco product use behavior for the purposes of filing, FDA must be able to determine the potential risks and benefit to the population as a whole, including each of the potential risks and benefits associated with changes in tobacco product use behavior by current tobacco product users in order to issue a marketing order for the product. If a PMTA lacks sufficient information needed for FDA to make these determinations, FDA intends to issue a no marketing order for the new tobacco product.

FDA is proposing to require information regarding the tobacco use behavior of current tobacco product users because these behavior patterns affect the health risks posed to those individuals. Current tobacco product users who start using the product may be switching from a product that may present greater, lower, or equal levels of individual health risk. Current tobacco product users that adopt the product may not continue use of the product in the future, so FDA seeks information regarding whether they are likely to switch back or switch to a product that may present higher levels of individual risk. Finally, current tobacco product users who otherwise would have otherwise quit using tobacco may use the new tobacco product instead, exposing them to health risks to which they might not have otherwise been exposed. FDA is also proposing to require information regarding current tobacco product user behavior because to determine whether the product is appropriate for the protection of public health, FDA must under section 910(c)(4)(A) of the FD&C Act take into account the increased or decreased likelihood that current tobacco product users will stop using tobacco products. The types of studies that will likely fall into this category can include actual use studies and national survey databases that could be used to bridge general data to the specific product. Ideally, the studies would look at past, present, and likely future behaviors of the tobacco product users.

iii. Impacts on tobacco use initiation by nonusers, including youth and young adults. The proposed rule would also require a PMTA to contain full reports of investigations published or known to, or which should reasonably be known to the applicant, regarding the likelihood that consumers who have never used tobacco products, particularly youth and young adults, will initiate use of the tobacco product and the likelihood that consumers who have never used tobacco products and adopt use of the tobacco product will switch to other tobacco products that may present higher levels of individual health risk however, as set forth in proposed § 1114.27(b)(1)(ii), if a PMTA does not contain a threshold amount of information regarding the likelihood of changes to tobacco use by current nonusers of tobacco products, FDA intends to refuse to file the application. This means that where there is no published information or information that is otherwise known to the applicant regarding the likelihood of changes in

tobacco use behavior by current nonusers of tobacco products, including information from investigations using other products that an applicant could bridge to its product, an applicant would need to conduct its own investigations and include a full report of the results in its PMTA for filing. And while the rule would not require an application to contain more than a threshold amount of relevant information for filing, FDA must be able to determine the potential risks and benefit to the population as a whole, including the potential risks and benefits associated with changes in tobacco product use behavior by current tobacco product users in order to issue a marketing order for the product. If FDA lacks sufficient information to make these determinations, it intends to issue a no marketing order for the new tobacco product.

FDA is proposing to require information regarding likelihood of tobacco use initiation and switching to potentially more harmful tobacco products, including among youth and young adults, as part of its interpretation of the requirements of section 910(b)(1)(A) of the FD&C Act because it will help FDA determine the number of current nonusers who will likely be exposed to the health risks presented by the tobacco product, as well as the risks posed by potentially more harmful products that individuals may go on to use. The information regarding initiation and switching by current nonusers of tobacco products is also being required under section 910(b)(1)(G) because FDA must take into account the increased or decreased likelihood that those who do not use tobacco products will start using tobacco products under section 910(c)(4)(A) of the FD&C Act. The types of studies that would likely fall into this category include survey studies and focus groups. In order to assess whether permitting the marketing of a proposed product would be APPH, FDA will need to understand how youth may use or intend to use the proposed product because youth are a population of particular concern for initiating tobacco use. However, FDA does not require research to be conducted on youth. Inferences regarding youth may potentially be extrapolated from young adults, as well as derived from existing sources of data, reviews of published scientific literature, and/or bridging information obtained from other sources. Providing data from the published literature or marketing information in your application with appropriate bridging information may be one useful approach. If you take such an approach, FDA recommends that you clearly explain how such data can be extrapolated to the target population or populations of interest, including youth, for the product that is the subject of the PMTA.

If an applicant chooses to conduct a study in the United States using minors, they must use appropriate parental consent procedures, as well as follow the requirements of the Children's Online Privacy and Protection Act (15 U.S.C. 6501–6505), the Pupil Rights Amendment (20 U.S.C. 1232h), and their implementing regulations (*see* 16 CFR part 312 and 34 CFR part 98, respectively). FDA strongly recommends that any studies conducted outside of the United States are designed so that the rights, safety, and welfare of human subjects, including minors, have been protected in accordance with ethical principles acceptable to the international community, such as those reflected in the ICH Good Clinical Practice standards.

Regardless of where a study is conducted, any studies using minors should have a narrow research scope and be as focused as possible given sensitivities around the conduct of research in youth populations. Specifically, research priorities for youth should be focused on key questions relating to use (*e.g.,* prevalence of use, characteristics of users, and patterns of use), risk perception, and intention to use/susceptibility among non-users. Studies conducted among youth focusing on issues beyond these key questions (*e.g.,* exposing youth to advertisements or marketing material for tobacco products) would warrant a very strong justification to demonstrate that the risks of conducting the research are minimal and do not outweigh the potential benefits of collecting such information.

The proposed rule would also require a PMTA to contain full reports of investigations published or known to, or which should reasonably be known to the applicant, regarding the likelihood that former users of tobacco products will re-initiate use with the tobacco product. FDA is proposing to include information regarding likelihood of re-initiation by former users as part of its interpretation of the requirements of section 910(b)(1)(A) of the FD&C Act and under its authority of 910(b)(1)(G) of the FD&C Act because it will help FDA determine the health risks to which these former users may be exposed if they begin using the new tobacco product. Survey studies are one type of investigation that is likely to fall into this category.

iv. Perceptions and use intentions. The proposed rule would require a PMTA to contain full reports of investigations published or known to, or which should reasonably be known to the applicant, regarding tobacco product perceptions and use intentions, including the impact of the product and its label, labeling, and advertising on individuals' perception of the risks of the product, and the ability of individuals to understand the labeling and instructions for use and use the product in accordance with those instructions; however, as set forth in proposed § 1114.27(b)(1)(ii), if a PMTA does not contain substantive information regarding the potential impact of the product and its label, labeling, and advertising on individuals' perception of the product, and their use intentions, FDA intends refuse to file the application. This means where there is no published information or information that is otherwise known to the applicant regarding the potential impact of the product and its label, labeling, and advertising on individuals' perception of the product, and their use intentions, including information from investigations using other products that an applicant could bridge to its product, an applicant would need to conduct its own investigations and include a full report of the results in its PMTA for filing. And while the rule would not require an application to contain more than a threshold amount of relevant information for filing, FDA must be able to determine the potential risks and benefit to the population as a whole, including the potential risks and benefits associated with changes in tobacco product use behavior by current tobacco product users in order to issue a marketing order for the product. As described in section VII.B.6., because the advertising, marketing, and promotion of a tobacco product can have a significant impact on the potential for tobacco product initiation, especially by youth, where FDA is unable to determine the impact that the labeling, advertising, marketing, and promotion of the new tobacco product may have on consumer perceptions and use intentions, FDA intends to issue a no marketing order for the new tobacco product.

FDA is proposing to include perception and use intention studies as part of its interpretation of the requirements of section 910(b)(1)(A) and under its authority of 910(b)(1)(G) of the FD&C Act because perception of the risk of the product may influence decisions to use the product and the resultant

exposure to the health risks presented by the product (Ref. 117). If an applicant uses advertising as stimuli in a tobacco product perception and use intention study, the PMTA would be required to indicate, as part of the full report of the study under proposed § 1114.7(k)(3), whether it is representative of advertising that the applicant intends to use in marketing the product that is required by proposed § 1114.7(f)(2). If the advertising is not representative of the advertising an applicant intends to use in marketing the product, the applicant would be required to indicate whether the study results are still relevant to the likely impact of product advertising on tobacco product perceptions and use intentions.

Additionally, information about individuals' understanding regarding the labeling is also relevant to determining whether the labeling is misleading, which is a reason for which FDA would have to deny an application under section 910(c)(2)(C) of the FD&C Act, and also may provide information on the likelihood of individuals using the product. Additionally, whether consumers understand the instructions for use and use the product in accordance with those instructions can help show whether consumers will be exposed to potentially greater health risks by using the product improperly. Topics that should be examined in tobacco product perception and intention investigations overlap with the topics identified in the human factors section that follows.

v. Human factors. The proposed rule would also require a PMTA to contain full reports of investigations, published or known to, or which should reasonably be known to, the applicant regarding human factors that influence the health risks of the product, which includes use conditions, use environments, use related hazards, estimated use error risk, potential unintended uses, risk controls to ensure that harms and unintended consequences are minimized, and adverse experiences related to such uses; however, as set forth in proposed § 1114.27(b)(1)(ii), if a PMTA does not contain a threshold amount of information regarding the potential impact of human factors on the health risks of the product, FDA intends to refuse to file the application. This means where there is no published information or information that is otherwise known to the applicant regarding the potential impact of human factors on product risk, including information from investigations using other products that an applicant could bridge to its product, an applicant would need to conduct its own investigations and include a full report of the results in its PMTA for filing. And while the rule would not require an application to contain more than a threshold amount of relevant information for filing, FDA must be able to determine the potential risks and benefits of the new tobacco product to the population as a whole. If FDA lacks sufficient information to make this determination, it intends to issue a no marketing order for the new tobacco product. FDA is proposing to require human factors information as part of its interpretation of the requirements of section 910(b)(1)(A) of the FD&C Act because it provides an assessment of use-related health hazards for the tobacco product.

In situations where it is critical for the end user to have instructions on how to properly use the product, it is important for applicants to demonstrate that the instructions for use are adequate. FDA recommends that human factors studies focus on the particular aspects of labeling that provide instructions for use. For example, it may be appropriate for a human factors study to evaluate the tobacco product user's:

- Ability to select the appropriate task from a set of instructions that include different options;
- Understanding of how to identify a defective or expired product;
- Awareness and understanding of the safety information provided in the instructions for use;
- Recognition of any potential harms or dangers that would signify the need to seek medical attention, such as shortness of breath, allergic reaction, weakness, increased heart rate; and
- Understanding of diagrams, if provided as part of the product labeling (which may overlap with investigations regarding consumer perception and understanding).

Analyzing use-related risks is a critical step in identifying use related hazards associated with the product and in characterizing high-risk hazards so that they can be mitigated or eliminated. FDA recommends that a PMTA contain a use-related risk analysis to help identify critical tasks that should be evaluated in human factors studies and inform the priority of testing the tasks in a human factors study, and determine if there are specific use scenarios to include in testing. If an applicant conducts human factors testing to determine use related risks, FDA recommends that the test considers potential users of the product, use environments, similar products used within the environments, and any associated medical factors or health conditions that may affect whether users may experience serious or unexpected adverse experiences. An applicant may also want to include information on known use related problems with similar products or previous versions of the product.

As part of the risk analysis, FDA recommends that an application first identify all users and use environments for the product, as well unintended users who are likely to use the product and unintended environments in which the product is likely to be used. For example, intended users may be characterized within the application according to their respective experience levels, skills, age ranges, and use responsibilities. Use environments are an important factor to consider because they can have diverse characteristics that affect the users' interactions with the product. In some cases, use of the product may actually be prohibited (*e.g.,* laws prohibiting use of a product in the workplace, public spaces, airplanes).

FDA recommends that human factors investigations be conducted in the form of actual use studies. Because it may be difficult in some cases to simulate the conditions of use, physical characteristics of the product, or environment of use, actual use studies allow for better assessment of how users interface with the product. If errors or failures or new findings are identified in the human factors validation study, then these problems should be evaluated to determine the root cause(s), potential for harm, and additional measures to eliminate or mitigate risk.

b. Literature search. Proposed § 1114.7(k)(2) would require an applicant to conduct a literature search for each type of information described in proposed § 1114.7(k)(1) and require the application to contain a description of the literature search performed, including the databases searched and the date searched, search terms, reasons for inclusion or exclusion of documents, and the strategy for study quality assessment. The PMTA would also be required to contain a bibliography of all published studies and articles referenced in the application. If a literature search was performed and resulted in no information found, the application would also be required to contain a statement to that effect. FDA is proposing to require that an application contain the bibliography and literature search information because section 910(b)(1)(A) of the FD&C Act requires (in part) that a PMTA contain full reports of all published health risk investigations. FDA is also proposing to include these requirements in the rule under authority of sections

701(a) and 910(b)(1)(G) of the FD&C Act because it would help FDA to determine whether the application contains reports of all published investigations in an efficient manner by helping FDA determine whether the application contains all relevant published studies, rather than having to follow up with the applicant about the inclusion or exclusion of specific studies. FDA must determine whether the application contains all published investigations because FDA needs to ensure it has all relevant health risk data to determine whether permitting the marketing of the product would be APPH. The description of the reasons for inclusion or exclusion of documents, in particular, will facilitate FDA's review of an application because it will explain, if applicable, why some investigations that initially appear relevant were excluded from the application and also why some investigations that do not initially appear to be relevant were included in the application. For ease of review, FDA recommends that an applicant include internal hyperlinks to, or otherwise reference, the location of published studies that are included in an application. If applicable, it is also recommended that an application explain why an investigation that was conducted using a product other than the one that is the subject of the PMTA is relevant to the application to inform FDA's review of the PMTA.

c. Study reports. Proposed § 1114.7(k)(3) would set requirements for the full report of each investigation that must be included as part of an application. An application would be required to contain each type of documentation listed in proposed § 1114.7(k)(3) to the extent that it is applicable to the type of investigation and to the extent that it is reasonably available to the applicant. FDA considers a document to be reasonably available unless it does not exist or obtaining the document is unduly burdensome due to the effort or expense involved. Where an applicant considers a document that would be required by this section to not be reasonably available, the application would be required contain an explanation in the full report that describes the actions taken to obtain the document and specifies why the document is not reasonably available. It is important to note that failure to submit documents may affect the extent to which FDA is able to rely upon an investigation's findings during substantive application review. A full report of the investigation would be required to contain:

i. Full copies of any published articles and other reference materials. FDA is proposing to require that an application contain full copies of published articles and other reference materials to facilitate the review process. FDA is proposing this requirement to enable it to review an application more quickly.

ii. Documentation of all actions taken to ensure the reliability of the study. The requirements for this item would differ based upon whether the investigation is a clinical investigation or a nonclinical laboratory investigation. For nonclinical laboratory investigations, an application would be required to include documentation demonstrating all actions taken to ensure the reliability of the study, including whether the investigation was conducted using good laboratory practices (GLPs), such as those specified in part 58 (21 CFR part 58). FDA considers GLPs to be those that support the quality, reliability, and integrity of nonclinical laboratory investigations. FDA is proposing this requirement to help enable it to determine whether the study's findings are accurate and reliable. While this rule on its own would not require compliance with the GLP regulations found in part 58,[13] FDA would consider a nonclinical laboratory investigation that contains the documentation required by part 58 to satisfy the requirements of proposed § 1114.7(k)(3)(ii).

FDA recommends that an application contain a final report of each nonclinical laboratory investigation that contains the following items, at minimum, to show that the study was accurate and reliable:

- Name and address of the facility performing the study and the dates on which the study was initiated and completed;
- Objectives and procedures stated in the approved protocol, including any changes in the original protocol;
- Statistical methods employed for analyzing the data;
- The test and control articles identified by name, chemical abstracts number or code number, strength, purity, and composition or other appropriate characteristics;
- Stability of the test and control articles under the conditions of administration;
- A description of the methods used;
- A description of the test system used. Where applicable, the final report should include the number of animals used, sex, body weight range, source of supply, species, strain and substrain, age, and procedure used for identification;
- A description of the dosage, dosage regimen, route of administration, and duration;
- A description of all circumstances that may have affected the quality or integrity of the data;
- The name of the study director, the names of other scientists or professionals, and the names of all supervisory personnel, involved in the study;
- A description of the transformations, calculations, or operations performed on the data, a summary and analysis of the data, and a statement of the conclusions drawn from the analysis;
- The signed and dated reports of each of the individual scientists or other professionals involved in the study;
- The locations where all specimens, raw data, and the final report are stored;
- The statement prepared and signed by the quality assurance unit, if any, a description of the quality control review performed and its results;
- The study director's signature and date upon completion of the final report; and
- Any corrections or additions to a final report, clearly identifying the part of the final report that is being added to or corrected and the reasons for the correction or addition, and bearing the dated signature of the person responsible.

The proposed rule would require full reports of investigations (both clinical and nonclinical) to contain, to the extent reasonably available, a certification that the investigators do not have, or documentation fully disclosing, any potential financial conflicts of interest, such as the financial arrangements specified in the financial disclosure by clinical investigators regulation in part 54 (21 CFR part 54). While FDA does not currently require compliance with part 54 for tobacco product investigations, complying with those requirements for both clinical and nonclinical investigators would satisfy the financial disclosure requirements of the proposed rule. Financial conflicts information is important for FDA to consider because it addresses a potential source of bias in investigations. Applicants would be able to use these disclosures as well as appropriate procedures in the design and conduct of the study to demonstrate that a potential bias that may affect the results of the investigation has been minimized. FDA would use the information contained in

[13] It is important to note that in the **Federal Register** of August 24, 2016 (81 FR 58341), FDA issued a proposed rule that, when finalized, would require laboratory investigations regarding tobacco products to comply with the requirements of part 58.

these disclosures, in conjunction with information about the design and purpose of the study, as well as on-site inspections (if necessary) in its assessment of the reliability of the data.

The investigator financial arrangements that the applicant should disclose and describe, include:

- Any financial arrangement entered into between the sponsor of the study and the investigator involved in the conduct of a clinical trial, whereby the value of the compensation to the investigator for conducting the study could be influenced by the outcome of the study;
- Any significant payments of other sorts from the sponsor of the study, such as a grant to fund ongoing research, compensation in the form of equipment, retainer for ongoing consultation, or honoraria;
- Any proprietary interest in the tested product held by any investigator involved in a study;
- Any significant equity interest in the sponsor of the study held by any investigator involved in any clinical study; and
- Any steps taken to minimize the potential for bias resulting from any of the disclosed arrangements, interests, or payments.

iii. A copy of all protocols and amendments that were used in the study;

iv. Copies of all investigator instructions, if any were produced in addition to the protocol;

v. The statistical analysis plan. The statistical analysis plan, including a detailed description of the statistical analyses used (including all variables, confounders, and subgroup analyses), the scientific rationale for the choice of sample sizes, and any amendments to the plan;

FDA is proposing to require the protocol, investigator instructions, and statistical analysis plan as part of the full report of a study because they would enable FDA to understand a study's design, conduct, and analysis in its entirety and to evaluate the validity of a study.

vi. Line data. To facilitate FDA's review, the application should contain line data in SAS-transport file in XPT format, created by a procedure that allows the files to be readily read by the JMP software. FDA also recommends that an application contain data definition files that include the names of the variables, codes, and formats used in each dataset, and copies of SAS programs and necessary macro programs used to create derived datasets and the results reported in the study reports. Such data are important for FDA to replicate applicant findings or conduct alternative statistical analyses. FDA intends to provide technical specifications on its website for submitting information, such as line data, in an electronic format that FDA can review, process, and archive (*e.g.,* method of transmission, media, file formats, preparation, organization of files, accompanying metadata) (*https://www.fda.gov/tobacco-products*);

vii. Sites and clinical investigators. A list of sites and clinical investigators that conducted the study, including contact information and physical address(es);

viii. The location of all source data. If the site that conducted the study has not maintained all of the source data, indicate where the data are located;

ix. Format. The format of the records and data (*e.g.,* electronic or hard copy);

x. Early termination sites. A list of all sites that had early termination and the reason for early termination, along with any audit certificates and inspection results, if applicable;

xi. Contractors. A list of contractors who participated in the study, the role of each contractor, and the initiation and termination dates of the participation of each contractor;

xii. Signed report. A signed full report of all findings; and

xiii. Study materials and case report forms. For human subject studies, all versions of study materials and case report forms used, and all individual case report forms associated with participant deaths, other serious and unexpected adverse experiences, withdrawals, and discontinuations from the study. The proposed rule would require the application to contain one blank copy of each version of the study materials (including, but not limited to, consent forms, questionnaires, and stimuli) and case report form, and only those completed individual case report forms regarding deaths, serious and unexpected adverse experiences, withdrawals, and discontinuations for individuals that were exposed to the tobacco product, or for individuals who were exposed to a similar or related product that the applicant is using to help demonstrate the health effects of its product. An example of where such case report forms from a study regarding a similar product would be required is where a clinical biomarker study on a product that is similar to the proposed product in terms of design, ingredients, and HPHCs is used to provide information about the anticipated health risks of the proposed product. As described in proposed § 1114.45, applicants would be required to keep each questionnaire and case report form from the study as part of its own internal records, which FDA may inspect, as described in proposed § 1114.27, or request that the applicant submit to facilitate its review of an application. If an applicant fails to keep such records, FDA may be unable to rely upon an investigation's findings during substantive application review.

Additionally, while clinical investigations for tobacco products are not required to be conducted in accordance with the requirements for the protocol and procedures implemented to protect human subjects in the Institutional Review Boards regulation in part 56 (21 CFR part 56) and the Protection of Human Subjects regulation in part 50 (21 CFR part 50), FDA plans to issue regulations requiring compliance with those parts for tobacco products. Until FDA takes such action, FDA strongly encourages applicants to follow the requirements of parts 50 and 56 or take sufficient actions to ensure that the investigation is conducted in a manner that comports with the ethical and moral considerations involved with conducting studies using human subjects. Each clinical investigation included in the PMTA should have been reviewed and approved by an Institutional Review Board (IRB) operating to safeguard the rights, safety, and well-being of all trial subjects, with special attention being paid to vulnerable subjects. FDA recommends applicants retain documentation concerning efforts related to the protection of human subjects, including documents related to the IRB, such as:

- Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects;
- Minutes of IRB meetings in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution;
- Records of continuing review activities;
- Copies of all correspondence between the IRB and the investigators;
- A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each

member and the institution (*e.g.,* full-time employee, part-time employee, a member of governing panel or board, stockholder, paid or unpaid consultant);

- Written procedures for the IRB; and
- Statements of significant new findings provided to subjects, such as those discussed in § 50.25.

FDA also recommends, but does not currently require, maintaining documentation of the protocol and procedures implemented to protect human subjects, such as those set forth in the protection of human subjects regulation in part 50. Each clinical investigation included in the PMTA should have been conducted using only human subjects who gave their informed consent to participate in the study. As described in § 50.20, informed consent is consent that is obtained from the subject or the subject's authorized representative under circumstances that provide the prospective subject or representative with sufficient opportunity to consider whether to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the subject's representative should be in language understandable to the subject or the representative. The informed consent should not include any exculpatory language through which the subject or representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

xiv. Perception and use intention studies. For perception and use intention studies that use a label, labeling, or advertising as stimuli, the proposed rule would require the full report of the study to contain a statement regarding whether the label, labeling, or advertising used is representative of advertising that the applicant intends to use in marketing the product. If the advertising used as stimuli is not representative of the advertising an applicant intends to use in marketing the product, the applicant would be required to indicate whether and how the study findings are still relevant to the likely impact of product advertising on consumer tobacco product perceptions and use intentions. For more information about tobacco product perception and use intention studies, please see the description of proposed § 1114.7(k)(1)(iv) in section VII.B.13.a.iv.

d. The effect on the population as a whole. The proposed rule would require a PMTA to contain an in-depth analysis and discussion of how the data and information contained in the application establish that the proposed product is appropriate for the protection of public health. This discussion must include the effect that the new tobacco product may have on the health of the population as a whole by integrating all of the information (both qualitative and quantitative as available) regarding the product, its potential effects on health, as well as tobacco use behavior, including likelihood of cessation and initiation, to provide an overall assessment of the potential effect that the marketing of the tobacco product may have on overall tobacco-related morbidity and mortality. Relevant outcomes measures could include reductions in serious medical conditions and premature mortality and gains in life-years lived in the population. FDA is proposing this requirement because it directly informs FDA's determination under section 910(c)(2)(A) of the FD&C Act of whether permitting the marketing of the new tobacco product would be APPH.

e. Certification statements. Proposed § 1114.7(m) would require that the application contain a specific statement certifying that the applicant would maintain all records to substantiate the accuracy of the application consistent with the record retention requirements in proposed § 1114.45, that the information and accompanying submission are true and correct, that no material fact has been omitted, that the signer is authorized to submit the information on the applicant's behalf, and that the signer understands that anyone who knowingly and willfully makes a materially false, fictitious, or fraudulent statement to the Government of the United States is subject to criminal penalties under 18 U.S.C. 1001. This certification would help ensure that the applicant understands the responsibilities related to the application (including the potential consequences of submitting false information to the U.S. Government), the applicant intends to submit the PMTA, and the PMTA is ready for review.

C. Amendments (Proposed § 1114.9)

FDA generally expects that when an applicant submits a PMTA, the submission will include all information required by section 910(b)(1) of the FD&C Act and proposed part 1114 to enable FDA to determine whether it should authorize the marketing of a new tobacco product. However, FDA recognizes that additional information may be needed to complete the review of a PMTA and, therefore, is proposing § 1114.9 to allow the submission of amendments to a pending application.

Proposed § 1114.9 provides that FDA may request, and an applicant may submit, an amendment to a pending PMTA together with the appropriate form (Ref. 11). Because FDA tracks PMTAs using the STN, an amendment must specify the STN that is assigned to the PMTA. An amendment would also be required to include the certification statement set forth in § 1114.7(m), with the appropriate information inserted, and signed by an authorized representative of the applicant. FDA may, at any time after it receives and before it acts on an application, request that an applicant submit additional information that is necessary to complete the review of a PMTA. Similarly, an applicant may submit an amendment on its own initiative that is necessary for FDA to complete its review of the pending PMTA. These amendments may include information such as newly completed or published studies that are relevant to the PMTA, clarifications, or a transfer in ownership of the PMTA as described in proposed § 1114.13.

Proposed § 1114.9(b) describes how the submission of an amendment may affect the time required for the review (as described in proposed § 1114.27(c)(1)) of the application. FDA intends to notify applicants regarding changes to the review period, including pausing, resuming, and resetting the review period for amendments as described in this section. If the applicant submits a major amendment to an application, either at FDA's request or on its own initiative, FDA may restart the 180-day review period. FDA considers major amendments to be those that will require substantial FDA review time. Examples of major amendments include substantial new data from a previously unreported study, detailed new analyses of previously submitted data or substantial new manufacturing information. When an applicant submits a major amendment, FDA would consider the applicant to have submitted a new PMTA with the review period beginning on the date which FDA receives the amendment. Because section 910(c)(1) of the FD&C Act requires FDA to complete its review of an application meeting the requirements of section 910(b)(1) within 180 days of its receipt, under proposed § 1114.9(b)(1) a new 180-day review period would begin on the date FDA receives a major amendment.

Proposed § 1114.9(b)(2) describes the effect that minor amendments would have on the 180-day review period. FDA

considers minor amendments to be any amendments that are not major amendments. Minor amendments can be clarifications or other information that FDA needs to complete its review of a PMTA, but will not require substantial review time. If FDA determines that a minor amendment is necessary to complete its review of a pending submission and requests that the applicant submit the amendment, FDA may pause the review period on the date that it issues the amendment request to the applicant. FDA will resume the review period on the date that it receives a written response from the applicant either submitting the requested information or declining to submit the amendment. For example, if FDA requests a minor amendment on day 80 of its review, the date FDA receives the amendment would be day 81, even though weeks or months may have passed from the date of request to receipt. An applicant may notify FDA that it is declining to submit an amendment; however, if an applicant declines to submit an amendment to FDA, and FDA is not be able to determine whether the PMTA meets the requirements to receive a marketing order without the amendment, it would issue a no marketing order.

If FDA requests an amendment, either major or minor, and the applicant neither submits the amendment nor notifies FDA that it is declining to submit the amendment within 180 days of FDA's request, FDA may, as described in proposed § 1114.9(c), consider the applicant to have submitted a request to voluntarily withdraw its PMTA and issue an acknowledgement letter stating that the application has been withdrawn under § 1114.11. FDA will consider requests for more time to submit an amendment and may grant reasonable requests. FDA is proposing § 1114.9(c) under authority of section 701(a) of the FD&C Act to efficiently enforce section 910 of the FD&C Act because it would allow FDA to dedicate its resources to reviewing PMTAs that are more likely to receive a marketing order, rather than continuing to review a PMTA submitted by a nonresponsive applicant that is unlikely to provide FDA with the information it needs to complete its review.

If an application has been closed under § 1114.29 or withdrawn under § 1114.11, proposed § 1114.9(d) would prevent the applicant from amending the application. If an applicant wishes to make changes to an application after it is closed or withdrawn, it would have to do so through submission of a new application.

D. Withdrawal by Applicant (Proposed § 1114.11)

Proposed § 1114.11 discusses the ability of an applicant to withdraw a pending PMTA. At any time prior to FDA acting on the application (*i.e.,* taking one of the actions described in proposed § 1114.29), the applicant may request to withdraw its application by using the appropriate form (Ref. 11) to specify the name of the new tobacco product, the STN of the application, and stating whether the withdrawal request is related to a health concern. If the request is related to a health concern, the applicant must describe the concern(s), including the extent, duration, and frequency of the health effects, and identify what gave rise to the concerns, such as adverse experience reports. FDA would require information about health concerns under authority of section 909 of the FD&C Act because the information would help FDA protect the public health (*e.g.,* identifying a problem that could be present in similar currently marketed products) and section 701(a) of the FD&C Act because it would allow FDA to efficiently enforce provisions of the FD&C Act (*e.g.,* more quickly ensure an identified health concern was addressed if an application for the same product is submitted again). Once FDA receives and processes the withdrawal request, it would issue an acknowledgment letter to the applicant, at which time the application would be considered withdrawn. Withdrawing an application would not prejudice a future submission.

The application is an Agency record even if withdrawn. Thus, under proposed § 1114.11(c), FDA would retain the withdrawn application consistent with Agency record retention schedules and policies and, under the Agency's public information regulations in 21 CFR part 20 (part 20), would provide a copy to the applicant upon request subject to § 20.45.

E. Change in Ownership of an Application (Proposed § 1114.13)

Proposed § 1114.13 describes the steps that an applicant would be required to take when it transfers ownership of a PMTA. This proposed section is intended to facilitate transfers of ownership and help ensure that FDA has current information regarding the ownership of a PMTA. An applicant may transfer ownership of its PMTA at any time, including when FDA has yet to act on it. Under proposed § 1114.13, at the time of the transfer, the new and former applicants (or owners) of the PMTA would be required to use the appropriate form (Ref. 11) and submit certain information to the Agency. First, the former applicant would be required to submit a notice to FDA identifying the new applicant and stating that all rights to the PMTA have been transferred to the new applicant. Second, the new applicant would be required to submit a signed notice to FDA containing the following information:

- To the extent applicable, the new applicant's commitment to agreements, promises, and conditions made by the former applicant and contained in the PMTA (*e.g.,* certifications, proposed restrictions on the sales and distribution of the tobacco product);
- The date that the change in ownership is effective;
- Either a statement that the new applicant has a complete copy of the PMTA (including any amendments, or any records required to be kept under proposed § 1114.45); or a statement of intent to request a copy of the PMTA filed with FDA under the Freedom of Information Act (FOIA) (FDA's implementing regulations are in part 20); and
- A certification that no modifications have been made to the new tobacco product since the PMTA was submitted to FDA.

Although FDA expects that the new applicant would have a copy of the PMTA from the former applicant, if the new applicant requests a copy of the PMTA filed with FDA, FDA would provide a copy to the new applicant, subject to the FOIA requirements as implemented by FDA at part 20 and under the fee schedule in § 20.45.

The new applicant also would be required to make available all required records upon inspection by FDA (proposed § 1114.45 would impose a recordkeeping requirement).

F. Supplemental Application Submission (Proposed § 1114.15)

Proposed § 1114.15 discusses the availability of supplemental PMTAs. Supplemental PMTAs are an alternative format of submitting a PMTA that meets the requirements of proposed § 1114.7 that would reduce the burden associated with the submission and review of an application. Specifically, supplemental PMTAs are a standardized cross-referencing format that FDA would implement under its authority of section 701(a) of the FD&C Act to efficiently enforce section 910 of the FD&C Act for submissions that are based on a PMTA that FDA has previously reviewed. Applicants that have received a marketing order would be able to submit a supplemental PMTA to seek marketing

authorization for a new tobacco product that results from a modification or modifications to the original tobacco product that received the marketing order. The applicant would be able to submit a supplemental PMTA only for a modification or modifications that require the submission of limited information or revisions to the PMTA to make it apply to the modified tobacco product. FDA is proposing to restrict the use of supplemental PMTAs to only changes that require the submission of limited information or revisions to ensure that FDA is able to efficiently review the application. An applicant would also be able to submit a supplemental PMTA for modifications made to comply with a product standard issued under section 907 of the FD&C Act where FDA specifies that the submission of supplemental PMTAs would be appropriate.

As discussed in proposed § 1114.15(a), an applicant would not be able to submit a supplemental PMTA where the modifications to the original tobacco product require the submission of new information or revisions to the extent that review of the PMTA for the new tobacco product in the supplemental PMTA format would be confusing, cumbersome, or otherwise inefficient and submitting a standard PMTA under § 1114.7(b) would better facilitate review. Because supplemental PMTAs are based on a cross-referencing system that is supposed to reduce the burden of preparing and reviewing a PMTA, FDA is proposing this limitation to ensure PMTAs are submitted in the format that is the easiest to review, process, and archive. Changes that require multiple, sweeping, or difficult-to-trace changes to the PMTA for the original tobacco product would be more efficient to review in the full text format of § 1114.7.

Applicants that have questions about whether it would be appropriate to submit a supplemental PMTA for the modifications they are seeking to implement should contact FDA for more information. To further illustrate when a supplemental PMTA could be submitted, FDA has prepared the following examples of modifications to ENDS products that are likely appropriate to be submitted using the supplemental PMTA format and likely not appropriate to be submitted using the supplemental PMTA format.

Potentially Appropriate for Supplemental PMTA Format

• Changes in connection type/thread size (*e.g.,* 510).
• Minor Software Changes not affecting device functionality.
  ○ Changes to user interface.
  ○ Changes in recording/data capture properties.
• Minor changes in e-liquid volume, viscosity or boiling temperature.
• Minor changes in draw resistance.
• Minor changes in air flow rate.
• Changes to coil configuration if number of coils, coil gauge, material, and overall coil resistance remain unchanged.
• Changes to amount of wicking material.
• Minor changes in wick ignition temperature.

Likely Not Appropriate for Supplemental PMTA Format
• Any modification that might increase risk of harm to individual health from the product. • Modifications that may alter tobacco product use behavior and initiation, such as modifications that have strong youth appeal. • Design modifications that change the category or subcategory of the product (*e.g.,* modifying a closed e-cigarette to be an open e-cigarette).

Additionally, FDA is proposing two other limitations on the submission of a supplemental PMTA. Under proposed § 1114.15(a), a supplemental PMTA could not be submitted where the marketing order for the original tobacco product has been withdrawn or has been temporarily suspended or is the subject of temporary suspension or withdrawal proceedings by FDA, except where authorized by FDA in writing following a presubmission meeting. FDA is proposing to restrict the submission of supplemental PMTAs in this situation because it can signal that the PMTA for the original tobacco product contains information that is not sufficient or reliable such that a marketing order could be issued. If the reason for the temporary suspension or withdrawal is unrelated to the sufficiency or reliability of information contained in a PMTA, an applicant may request, and FDA may grant, authorization to use a supplemental PMTA under these circumstances.

1. Required Format

Under proposed § 1114.15(b) the supplemental PMTA format would be the same as the format for standard PMTAs submitted under § 1114.7(b), except that applicants would be required to include content in a supplemental PMTA by cross-referencing content in the PMTA and postmarket reports for the original tobacco product. FDA believes that including content in an application by cross-referencing to a PMTA for the original tobacco product is appropriate for supplemental applications because the referenced information will be presented in the proper context and format, and will facilitate application review.

2. Required Content

The required content for a supplemental PMTA is divided into two general categories: New content sections and content sections cross-referenced from the PMTA for the original tobacco product. A supplemental PMTA must contain the full text or a cross-reference to text in a master file for the following new content sections under proposed § 1114.15(c)(1):

- General information (as described in § 1114.7(c));
- New product information (as described in § 1114.15(c));
- Statement of compliance with 21 CFR part 25 (as described in § 1114.7(g));
- Labeling (as described in § 1114.7(f)) if the labeling is not identical to the labeling submitted in the PMTA or postmarket reports for the original tobacco product;
- Postmarket information (as described in § 1114.15(d)); and
- Certification statement (as described in § 1114.15(e)).

A supplemental PMTA must also contain application sections that comprise information included by cross-reference to the PMTA for the original tobacco product. It is important to note that these cross-referenced sections must be accompanied by the full text of any updates or supplemental information that are necessary to tailor this information to the new tobacco product. These updates or supplemental

information should consist of changes to application content that is not otherwise included as part of the new product information section. For example, if a new health risk investigation on the product is published and it is not contained in the new product information section, a full report (as described in § 1114.7(k)(3)) of the investigation must be included in full text together with a cross-reference to the health risk investigations section in the PMTA for the original tobacco product. The cross-reference-based sections that must be included under proposed § 1114.15(c)(2) are:

- Descriptive information (as described in § 1114.7(d));
- Product samples (as described in § 1114.7(e)). Please note, however, that FDA may, request the submission of product samples after receipt of a supplemental PMTA;
- Labeling (as described in § 1114.7(f)) if the labeling is identical to the labeling submitted in the PMTA or postmarket reports for the original tobacco product;
- Summary of all research findings (as described in § 1114.7(h));
- Product formulation (as described in § 1114.7(i));
- Manufacturing (as described in § 1114.7(j)); and
- Health risk investigations (as described in § 1114.7(k)).

3. New Product Information

Under proposed § 1114.15(d), the application must contain the following information concerning modifications to the original tobacco product, including:

- Full descriptions of the modification(s) to the original tobacco product and comparisons of such modification(s) to the unmodified version(s) described in the PMTA for the original tobacco product.
- A statement as to whether the new tobacco product is intended to replace the original tobacco product if the new product receives a marketing order, is intended to be a line extension of the original tobacco product, or is intended to be introduced as an additional product by the same manufacturer.
- All data and information relating to the modification(s) that would be required in an application under § 1114.7. This is data and information that can span across a number of application sections. A change in the connection type or thread size for an ENDS product, for example, may require a change in the design parameters and the manufacturing sections.
- A concluding summary of how the new tobacco product meets the requirements to receive a marketing order. This summary must describe how the data and information concerning the product modification when viewed together with the information cross-referenced from the previously submitted PMTA demonstrate that the new tobacco product meets the requirements of section 910(c) of the FD&C Act to receive a marketing order.

4. Postmarket Information

Under proposed § 1114.15(e), a supplemental PMTA would be required to contain postmarket information. Where an applicant has submitted postmarket reports for the original tobacco product, it must incorporate those reports by cross-reference. Where an applicant has yet to submit a postmarket report for the original tobacco product, it must submit a report as part of the supplemental application that contains all the information that would otherwise be required in a report under proposed § 1114.41, covering the period in time from when it received its marketing order for the original tobacco product to when it submitted the supplemental PMTA. Because information that is contained in a postmarket report is likely to be required content of a standard PMTA for the modified tobacco product, FDA is allowing applicants to cross-reference this content to avoid the burden of resubmitting information that FDA has previously reviewed.

5. Certification Statement

Proposed § 1114.15(f) would require the application to contain a specific certification statement signed by an authorized representative that, in addition to the certification required under § 1114.7(m) for a standard PMTA, certifies that the modifications identified in the certification are the only modification(s) to the original tobacco product.

G. Resubmissions (Proposed § 1114.17)

Proposed § 1114.17 describes resubmissions, which are an alternative format for submitting an application that meets the requirements of § 1114.7(b) or § 1114.15 to seek a marketing order for a tobacco product by responding to the deficiencies outlined in a no marketing order. An applicant may submit a resubmission for the same tobacco product that received a no marketing order or for a different new tobacco product that results from changes necessary to address the deficiencies outlined in a no marketing order. This application format allows an applicant to address the deficiencies described in a no marketing order without having to undertake the effort of submitting a standard PMTA. The resubmission format is available to resubmit an application that received a no marketing order because FDA has completed its review of such PMTAs and can rely on the findings of these reviews to save time when reviewing a resubmission. The resubmission format is not available for PMTAs that FDA refused to accept, refused to file, cancelled, or administratively closed, or that the applicant withdrew, because FDA has not previously completed reviews of such applications upon which it can rely, and such applications may need significant changes to be successfully resubmitted. It is important to note that, as discussed in section VIII.E regarding proposed § 1114.33, while FDA will identify the deficiencies that resulted in the no marketing order, the deficiencies specified in the order might not be an exhaustive listing of all deficiencies contained in the PMTA.

Similar to a supplemental PMTA, an applicant would not be able to submit a resubmission to the extent that review would be confusing, cumbersome, or otherwise inefficient and submitting a standard PMTA under § 1114.7 would better facilitate review. Where responding to the deficiencies outlined in the no marketing order would require broad or sweeping changes to the original PMTA, an applicant would need to submit a standard PMTA under § 1114.7 to better facilitate review. Where possible, FDA will specify in the no marketing order if an applicant may not pursue a resubmission to address the identified flaws.

1. Format

Under proposed § 1114.17(b) the resubmission format requirements would be the same as the format in § 1114.7(b) for standard PMTAs, except that applicants would be required to include content in a resubmission by cross-referencing content in the PMTA. FDA believes that including content in a PMTA by cross-referencing to a PMTA for the original tobacco product is appropriate for resubmissions applications because the referenced information will be presented in the proper context and format, and will facilitate application review.

2. Content

The required content for resubmission is divided into two general categories: new content sections and cross-referenced content sections. The resubmission must contain the full text or cross-referenced text from a master file of the following new content sections under proposed § 1114.17(c)(1):

- General information (as described in paragraph § 1114.7(c));
- Response to deficiencies (as described in § 1114.17(d)); and
- Certification statement (as described in § 1114.17(e)).

A resubmission must also contain application sections that comprise information included by cross-reference to the PMTA for the original tobacco product. It is important to note that these cross-referenced sections must be accompanied by the full text of any updates or additional information that are necessary to tailor this information to the new tobacco product. These updates or additional information should consist of changes to application content that is not otherwise included as part of the response to deficiencies section. This information could include, for example, full reports of health risk investigations published after the applicant submitted the PMTA that received the no marketing order. The cross-reference-based sections that must be included under proposed § 1114.17(c)(2) are:

- Descriptive information (as described in § 1114.7(d));
- Product samples (as described in § 1114.7(e)). Please note that FDA may require the submission of product samples after it has received your application;
- Labeling (as described in § 1114.7(f)), together with updates to the labeling made by the time of submission, if any;
- Statement of compliance with 21 CFR part 25 (as described in § 1114.7(g));
- Summary of all research findings (as described in § 1114.7(h));
- Product formulation (as described in § 1114.7(i));
- Manufacturing (as described in § 1114.7(j)); and
- Health risk investigations (as described in § 1114.7(k)).

3. Response to Deficiencies

As described in proposed § 1114.17(d), the application must contain a section that lists and provides a separate response to each deficiency described by FDA in the no marketing order, including all data and information necessary to complete each response, as well as any applicant-identified deficiencies. The deficiencies should be addressed in the order in which they are listed in the no marketing order, followed by applicant-identified deficiencies. Where an applicant modifies the original tobacco product to address the deficiencies outlined in the no marketing order, the applicant must also include: (a) A full description of each modification to the product and comparisons of that change to the original version described in the PMTA for the original tobacco product; and (b) all data and information relating to each modification to the product that would be required in an application under § 1114.7.

4. Certification Statement

Proposed § 1114.17(e) would require the applicant to include one of two certification statements signed by an authorized representative that, in addition to the certification required under § 1114.7(l) for standard PMTA, certifies either: (a) That the application addresses all deficiencies specified in the no marketing order and is being submitted for a tobacco product that is identical to the product for which FDA issued a no marketing order or (b) the application addresses all deficiencies and the tobacco product is distinct from the original tobacco product, but the only modifications to the original tobacco product are those identified in the certification.

5. Resubmission Meeting

Under proposed § 1114.17(f), applicants may request a meeting with FDA prior to submitting a resubmission to determine whether it may utilize the resubmission format and to discuss any issues related to the application, such as application organization and format. For example, applicants that have questions about whether it would be appropriate to pursue a resubmission for the modifications they are seeking to implement to respond to deficiencies identified in a no marketing order may contact FDA for more information.

VIII. FDA Review (Proposed Part 1114, Subpart C)

A. Communications Between FDA and Applicants (Proposed § 1114.25)

Proposed § 1114.25 would set forth general principles for the communications between FDA and applicants and is intended to provide more information to applicants about FDA communications. Proposed § 1114.25 explains that during the course of FDA's review of an application, FDA may seek to communicate with applicants about relevant matters including scientific, medical, and procedural issues that arise during the review process. Communications regarding human risk issues may arise if adverse experience reports exist for the tobacco product. FDA may use a variety of methods to communicate with applicants such as telephone conversations, letters, emails, or face-to-face meetings depending on the circumstances and issues. FDA would document any communications regarding a PMTA in accordance with 21 CFR 10.65. While applicants may contact FDA with questions, as a general matter, FDA does not provide applicants with predecisional details about an ongoing application review, such as whether an initial submission is sufficient to receive a marketing order or the date and time at which FDA will act on an application.

B. Review Procedure (Proposed § 1114.27)

Proposed § 1114.27 describes the procedures by which FDA would review a PMTA. When an applicant submits a PMTA, FDA performs an acceptance review of the submission. Currently, FDA performs it acceptance review of all premarket submissions based upon the criteria set forth in § 1105.10. The proposed rule would incorporate and build upon these general criteria to set PMTA-specific acceptance criteria. Under the proposed rule, FDA may refuse to accept an application for further review if, upon initial review, it:

- Does not comply with the applicable format requirements for the type of PMTA (*i.e.,* § 1114.7(b) for a standard PMTA, § 1114.15 for a supplemental PMTA § 1114.17 for a resubmission);
- Is not administratively complete because it does not appear to contain the information required by the applicable application content requirements section. This means that the content required for the type of PMTA must be readily and easily identifiable as part of a cursory review of the application (*i.e.,* a standard PMTA must appear to contain information required by § 1114.7, a supplemental PMTA must appear to contain information required by § 1114.15, and a resubmission must appear to contain information required by § 1114.17). The acceptance review would assess the facial completeness of a submission only, and would not be an in-depth, technical review. Examples of submissions that FDA would refuse to accept under this rule include, but are not limited to, applications that do not appear to contain:
  - Labeling (as required by § 1114.7(f));
  - Design parameter information (as required by § 1114.7(i)(2)(ii));
  - An environmental assessment (as required by § 1114.7(g)); or
  - A literature search (as required by § 1114.7(k)(2)).
- Does not pertain to a tobacco product that is subject to chapter IX of

the FD&C Act, as required by § 1105.10(a)(1). Under this provision FDA would refuse to accept the PMTA if it does not pertain to a product that is subject to the jurisdiction of CTP. CTP has premarket review jurisdiction over products that meet the definition of ''tobacco product'' in section 201(rr) of the FD&C Act and are subject to chapter IX of the FD&C Act either in section 901(b) of the FD&C Act or by regulation. This means that FDA will refuse to accept submissions for a product that is a drug under the definition in section 201(g)(1), a device under section 201(h), a combination product as described in section 503(g) of the FD&C Act, or otherwise does not meet the definition of a tobacco product.

• May otherwise be refused under § 1105.10.

Once FDA has completed its acceptance review under proposed § 1114.29(a)(1), FDA will issue a letter to the applicant informing it of FDA's decision. If FDA accepts the application for further review, it will issue an acceptance letter to the applicant that specifies the STN for the PMTA. If FDA refuses to accept the application, it will issue a letter to the applicant that identifies the reasons, where practicable, that prevented FDA from accepting the application. The applicant may, after FDA has refused to accept a PMTA, correct the deficiencies and submit a new PMTA under proposed § 1114.7. Because FDA is not issuing a no marketing order under § 1114.33 when it refuses to accept a submission, an applicant would not be able to utilize the resubmission format described in proposed § 1114.17 to address the flaws outlined by FDA.

FDA is proposing to implement the acceptance review procedures under authority of sections 701(a) and 910 of the FD&C Act. The content, format, and jurisdiction requirements that an application would have to meet to be accepted for review will ensure that FDA will be able to efficiently review applications and consider only applications that meet quality and content standards. By refusing to accept submissions that have clear deficiencies, FDA will be able to focus its resources on those submissions that are more likely to be filed for substantive review.

After FDA accepts a PMTA for review, FDA may request product samples as described in § 1114.7(e) and will conduct a filing review to determine whether the application contains sufficient information to permit a full substantive review of the application. FDA may refuse to file a PMTA if:

• The PMTA does not include sufficient information required by section 910(b)(1) of the FD&C Act and by §§ 1114.7, 1114.15, or 1114.17, as applicable, to permit a substantive review of the application. These requirements include a sufficient EA for each type of PMTA, the absence of which is an existing reason for which FDA may refuse to file an application under § 25.15. The filing requirements would also include product samples if required by FDA after application acceptance. FDA's filing review is an examination of the submission to ensure it contains adequate technical information for FDA's substantive review of the application to proceed. Unlike the acceptance review, which considers whether a submission meets quality elements and appears to be facially complete, the filing review is a more in-depth review to ensure the technical elements contain sufficient information for initiating substantive review. For example, during acceptance review, FDA would check whether the PMTA appears to contain product design parameters, but during filing review, FDA would review to determine whether it contains the correct design parameters for the product category and has a value for each design parameter required by § 1114.7(i)(2)(ii). FDA is proposing to conduct the filing review under authority of section 701 of the FD&C Act to improve the efficiency of the PMTA review process. By determining whether a PMTA contains sufficient technical information prior to conducting substantive review, FDA can commit the considerable resources necessary to conduct substantive review of a PMTA to only those submissions that are prepared for review;

• The application does not contain substantive information regarding certain specified broad categories of information that must be addressed in every PMTA for FDA to determine whether permitting the marketing of the new tobacco product would be APPH. FDA considers substantive information to be information that is relevant to the subject it claims to support and has evidentiary support. Bare statements that the marketing of the tobacco product is unlikely to result in tobacco product initiation or that it has no abuse liability without supporting information would not constitute the types of substantive information necessary for application filing. This information can come from a variety of sources including investigations conducted by the applicant, investigations conducted using a different product that the applicant can bridge to its new tobacco product (as described in section VII.B.13.a.), or published reports of investigations that apply to, or are bridged to, the new tobacco product (such as those found in the literature search that would be required by proposed § 1114.7(k)(2)). Proposed § 1114.27(b)(1)(ii) would require a PMTA to contain substantive information regarding certain categories of investigations described in proposed § 1114.7(k)(1). While FDA retains discretion to file applications as set forth in proposed § 1114.27(b)(1), we generally intend to refuse to file each application that does not meet the information threshold requirement in paragraph (ii). Where there is no substantive information that is published or known to an applicant regarding any of the categories of information outlined in this section, including information in scientific literature or an investigation that an applicant could bridge to its product, an applicant would be required to conduct its own investigations and include the resulting full report in its PMTA in order to meet the requirements for filing. In general, FDA expects that manufacturers seeking to market a new product in accordance with the requirements of the statute will have access to information to meet these requirements for filing.[14]

FDA is proposing this application filing requirement under its authority in sections 910(b)(1)(G) and 701(a) of the FD&C Act. As described in section VIII.D., FDA needs information regarding the potential health risks of the new tobacco product, the likelihood of changes in tobacco product use behavior, and the potential health consequences associated with those changes in behavior to determine the potential risk and benefits to the population the health of the population under section 910(c)(4) of the FD&C Act. Refusing to file PMTAs that contain no information regarding these broad categories of information would allow FDA to efficiently enforce the premarket review requirements of section 910 of the FD&C Act by avoiding the significant expenditure of resources it would otherwise commit to the substantive review of applications that clearly lack sufficient information to receive a marketing order. FDA expects that this efficiency would significantly

[14] Information that is available to applicants includes, for example, the studies FDA has funded, published, and made available to the public, which are consolidated FDA's our website. This database includes many ENDS related studies and can be searched by key terms (*e.g.,* e-cigarettes): *https://www.fda.gov/tobacco-products/research/ctp-supported-tobacco-regulatory-research-projects.*

benefit those applicants seeking timely consideration of complete, high-quality applications.

Proposed § 1114.27(b)(1)(ii) would require PMTAs to contain substantive information regarding:

- The health risks of the new tobacco product (as described in § 1114.7(k)(1)(i)(A)–(C)). Information regarding the health risks of the new tobacco product is a basic piece of information that FDA needs to determine the potential risks and benefits to the population as a whole associated with changes in tobacco use behavior.
- The health risks of the new tobacco product compared to the health risks that are generally presented by both tobacco products in the same category and tobacco products in at least one different category that are used by the consumers an applicant expects to use their new tobacco product (as described in portions of § 1114.7(k)(1)(i)(D)). This would require a comparison to the risks generally presented by a product category as a whole. However, a comparison to specific products that are generally representative of the risks of the product category as a whole (*e.g.,* products that represent a significant share of the market for the product category) would also be sufficient. Comparative health risk information is a required part of FDA's review of an application because, as described in section VII.B.13.a., it can demonstrate the potential risks and benefits that current tobacco users could face if they switched to the new tobacco product or use it in conjunction with their current tobacco product.
- The abuse liability of the new tobacco product (as set forth in § 1114.7(k)(1)(ii)(A)). Information regarding abuse liability indicates the likelihood of users to become addicted to the product and face the health risks posed by product use over the long term, and may provide insight into the use and adoption of the product, which FDA must consider as part of its determination of the risks and the benefits of the marketing of the new tobacco product to the population as a whole under section 910(c)(4) of the FD&C Act.
- How consumers actually use the product, including use topography, product use frequency, use trends over time, and how such use affects the health risks of the product to individual users (as set forth in § 1114.7(k)(1)(ii)(B)). Information regarding how consumers will actually use the new tobacco product is necessary to FDA's review of a PMTA because it helps demonstrate the health risks of the new tobacco product by showing the levels, and frequency, of exposure to HPHCs and other toxic substances contained in and delivered from the new tobacco product.
- The potential impact that the marketing of the new tobacco product would have on the likelihood that current tobacco product users would start using the new tobacco product, use the product in conjunction with other tobacco products, and, after using the product, switch to or switch back to other tobacco products that may present increased risks to individual health (as described in § 1114.7(k)(1)(ii)(C)–(F)). Information regarding potential changes to tobacco product use of current tobacco product users is a required basis for FDA's findings under 910(c)(4)(A).
- The potential impact that the marketing of the new tobacco product would have on tobacco product initiation by current nonusers of tobacco products (as described in § 1114.7(k)(1)(iii)). Information regarding potential impact that the marketing of the new tobacco product would have on tobacco product initiation by current nonusers of tobacco products is a required basis for FDA's findings under 910(c)(4)(B).
- The potential impact of the product and its label, labeling, and advertising on individuals' perception of the product, and individuals' use intentions (as described in § 1114.7(k)(1)(iv)). This information is important to FDA's review of a PMTA because perceptions of the health risk of the product can influence decisions to use the product and, as described in section VII.B.6., exposure to advertising can have a significant impact on the likelihood that nonusers of tobacco products, particularly youth, will initiate tobacco product use. Without information regarding perceptions and use intentions, FDA will be unable to complete its required determination under section 910(c)(4)(B) of the FD&C Act of the increased or decreased likelihood that nonusers of tobacco products will initiate tobacco product use.

FDA invites comment on the information threshold requirements in proposed § 1114.27(b)(1)(ii), including comments on: Whether the information would be best included in the final rule as a request or a requirement; whether FDA should request or require additional information as a threshold for filing and the basis for any such additional provisions; and how these and other potential requests or requirements related to the information threshold requirement for filing relate to specific provisions of the FD&C Act, as well as other applicable law(s).

- The PMTA contains a false statement of material fact; or
- The PMTA is a supplemental PMTA that does not comply with § 1114.15 or the PMTA is a resubmission that does not comply with § 1114.17. FDA may refuse to file a supplemental PMTA or a resubmission that, although administratively complete, does not meet the requirements for when a supplemental PMTA or a resubmission may be submitted. For both supplemental PMTAs and resubmissions, this could occur when, as discussed in §§ 1114.15(a) and 1114.17(a), the modifications to the original tobacco product are not appropriate to review in these formats. As described in proposed § 1114.15(a), FDA may also refuse to file a supplemental PMTA where the marketing order for the original tobacco product has been temporarily suspended (except where authorized in writing by FDA) or has been withdrawn. As described in proposed § 1114.17(a), FDA would refuse to file a resubmission where the no marketing order for the original tobacco product states that the applicant may not use the resubmission format. If FDA refuses to file an application, it will send a letter to the applicant identifying, where practicable, the deficiencies that prevented FDA from filing the application.

After FDA files an application, it will begin its substantive review of the PMTA. Within 180 days after receipt of an application described in section 910(b)(1) of the FD&C Act, FDA intends to complete its review of a PMTA and, as described in proposed § 1114.29, act on the application, except as described in proposed §§ 1114.9 and 1114.27(c)(4) & (5). To determine when the 180-day period begins, FDA generally relies on the date the last piece of information necessary to complete the submission is received by CTP's Document Control Center or the FDA laboratory (for product samples), not the date that the applicant sent it. It is important to note the event that starts the 180-day review clock is the receipt of an application that meets the requirements of section 910(b)(1) of the FD&C Act which would also include information required by the proposed rule including product samples if required. Because the proposed rule would require the submission of samples in accordance with FDA instructions that are likely to be issued after a PMTA is accepted by FDA, the review clock would begin, at the earliest, when FDA receives product samples if it has required samples and those samples are the last piece needed

to complete an application. Similarly, if an application is missing other pieces of required information, the review clock would begin only upon receipt of that information. FDA intends to provide applicants with notice of the date on which the 180-day review period begins, as well as notice of when it is paused, resumed, or reset.

FDA is proposing four instances in which the 180-day review period after receipt of a complete PMTA would not run over a period of 180 consecutive calendar days. First, as described in § 1114.9, the submission of or request for amendments may result in changes to the number of calendar days in the review period. Where FDA requests a minor amendment, the issuance of this request would result in a pause of the review period and receipt of the amendment would resume the review period. As described in section VII.C., the submission of a major amendment would be considered to be the submission of a new PMTA, which would reset the 180-day review clock.

The second instance in which FDA's 180-day review period would not run over 180 consecutive calendar days after receipt of a complete PMTA is where a new tobacco product, if introduced or delivered for introduction into interstate commerce, would be adulterated or misbranded due to the domestic manufacturer or importer being in violation of the user fee requirements of part 1150 (21 CFR part 1150).[15] Situations in which a new tobacco product would be adulterated or misbranded for failure to comply with user fee requirements are described in § 1150.17(a) and (b), which include failure to pay user fee assessments and failure to submit required reports. In this situation, FDA intends to pause the 180-day review clock until any violation of the user fee requirement of part 1150 is resolved. FDA is proposing this provision under its section 701(a) authority to issue regulations for the efficient enforcement of the FD&C Act. It would be inefficient for FDA to expend the significant resources necessary to review an application for a product that could not be legally marketed. It would also not be reasonable for FDA to complete its review and issue a marketing order for a product that, if it is put into interstate commerce, would immediately be adulterated or misbranded and subject to FDA enforcement action. While FDA would not refuse to accept or refuse to file an application on the basis that the product would be adulterated for failure to pay user fees, FDA would not complete its review of a PMTA until the applicant is in compliance with part 1150. FDA is proposing this action, rather than refusing to accept or refusing to file an application because noncompliance with the requirements of part 1150 can often be resolved quickly.

The third instance in which FDA's 180-day review period would not run over 180 consecutive calendar days after the receipt of a complete PMTA is where FDA is prevented from scheduling or conducting inspections of the manufacturing sites and the sites and entities involved with the clinical and nonclinical research (including third parties and contract research organizations) that would prevent FDA from completing its review of the PMTA in a timely manner. Where this occurs, FDA may pause the 180-day review period for the number of days necessary to complete the inspection after a delay occurs. FDA has experienced delays in both scheduling and conducting inspections, which results in FDA not having the information it needs to complete its required review in 180 calendar days.

The fourth instance in which FDA's 180-day review period may not run over 180 consecutive calendar days after the receipt of a complete PMTA is where FDA determines after application filing that the applicant has not submitted an adequate EA. NEPA and regulations issued by the Council on Environmental Quality (42 U.S.C. 4332(2); 40 CFR parts 1500 to 1508) require FDA to assess, as an integral part of its decision-making process, the environmental impacts of any proposed Federal action to ascertain the environmental consequences of that action on the quality of the human environment and to ensure that the interested and affected public is appropriately informed. FDA has implemented the NEPA and CEQ requirements in 21 CFR part 25. Under § 25.15(a), failure to submit an adequate EA is grounds for refusing to file or authorize an application. Consistent with § 25.15(a), FDA would refuse to authorize the marketing of a new tobacco product where a PMTA contains an inadequate EA.

As described in proposed § 1114.27(c)(4), FDA may conduct inspections of the applicant's manufacturing sites, and sites and entities involved with clinical and nonclinical research (including third parties and contract research organizations) to support FDA's review of the PMTA. Inspecting the facilities and controls described in the application will allow FDA to ensure the applicant can manufacture the product in accordance with the manufacturing practices described in the application and would help FDA determine under section 910(c)(2) of the FD&C Act whether such practices conform to an applicable product standard issued under section 907 of the FD&C Act or tobacco product manufacturing practice requirement issued under section 906(e) of the FD&C Act. Inspecting sites and entities involved with clinical and nonclinical research, including their records (such as those required to be kept under proposed § 1114.45), will allow FDA the opportunity to verify the study findings and data that the applicant relies upon in the PMTA to demonstrate that the new tobacco product should receive a marketing order. Under proposed § 1114.33, failure to grant FDA access at a reasonable time and in a reasonable manner, an opportunity to inspect these sites and have access to, copy, and verify all records pertinent to the application may result in the issuance of a no marketing order because FDA would not be able to determine whether permitting the marketing of the new tobacco product would be APPH. During an inspection, an applicant should ensure that:

- All pertinent records can be viewed;
- documents written in a language other than English can be translated into English, if requested. Documents that have been translated from another language into English should be accompanied by a signed statement by an authorized representative of the manufacturer certifying that the English language translation is complete and accurate, and a brief statement of the qualifications of the person that made the translation; and
- if the tobacco product is in production (domestic or foreign) and is intended for US commercial distribution, FDA can view the product being manufactured.

C. FDA Action on an Application (Proposed § 1114.29)

Proposed § 1114.29 lists six actions that FDA may take after receiving an application:

- First, FDA could refuse to accept the application, as described in § 1114.27(a);
- Second, FDA could issue a letter administratively closing the application. This could occur where an applicant

[15] Currently, only the manufacturers of cigarettes, cigars, snuff, chewing tobacco, pipe tobacco, and roll-your-own tobacco are subject to the requirements of part 1150. See the final rule, Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Cigars and Pipe Tobacco (81 FR 28707) (May 10, 2016), for more information.

fails to respond to a request for an amendment within 180 days under § 1114.9(b) or requests to withdraw an application under § 1114.11;

- Third, FDA could issue a letter canceling the application if FDA finds it mistakenly acknowledged the application (*e.g.,* the application does not pertain to a new tobacco product, or the application was submitted in error);
- Fourth, FDA could refuse to file the application as described in § 1114.27(b);
- Fifth, FDA could issue a marketing order as described in § 1114.31; or
- Sixth, FDA could issue a no marketing order as described in § 1114.33.

D. Issuance of a Marketing Order (Proposed § 1114.31)

Under section 910(c)(1)(A)(i) of the FD&C Act, FDA will issue a marketing order for a new tobacco product after its review of a PMTA if it finds that none of the grounds for denial specified in section 910(c)(2) of the FD&C Act applies to the application. This means that in order for FDA to issue a marketing order for a new tobacco product, FDA must be able to determine the following:

1. There is a showing that permitting the marketing of the new tobacco product would be APPH.

Under section 910(c)(4) of the FD&C Act, FDA's finding that permitting the marketing of a new tobacco product would be APPH must be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of tobacco products, and taking into account:

- The increased or decreased likelihood that existing users of tobacco products will stop using such products; and
- the increased or decreased likelihood that those who do not use tobacco products (including youth and young adults) will start using such products.

Finding that there is a showing that permitting the marketing of a new tobacco product would be APPH is a complex determination that must be made with respect to risks and benefits to the population as a whole, considering the likelihood of changes in tobacco product use behavior (including initiation and cessation) caused by the marketing of the new tobacco product. When determining whether the marketing of a particular new tobacco product would be APPH, FDA will evaluate the factors in light of available information regarding the existing tobacco product market, tobacco use behaviors, and the associated health risks at the time of review. As described in section 910(c)(5) of the FD&C Act, the types of scientific data that FDA will consider in making its determination can include well-controlled investigations and, where appropriate, other valid scientific evidence that FDA determines to be sufficient to evaluate the tobacco product. FDA will consider the information supplied in the application together with any other relevant sources of information, including a report or recommendation from TPSAC, when applicable, in making its determination.

Section 910(c) of the FD&C Act requires FDA to consider an array of potential risks and benefits of each new tobacco product with respect to the population as a whole when determining whether permitting the marketing of a new tobacco product would be APPH. As set forth in the marketing order withdrawal criteria in section 910(d)(1)(A) of the FD&C Act, FDA must continue to find the product meets the APPH standard over time. Generally, FDA intends to consider the marketing of a new tobacco product to be APPH where a PMTA contains sufficient valid scientific evidence to demonstrate that the potential risks and benefits of the marketing of the new tobacco product would have a net positive effect on the health of the population as a whole. Because the APPH standard requires a balancing of product-specific potential risks and benefits, the factors that could help demonstrate that the marketing of a particular new tobacco product would be APPH might not support the marketing of a different new tobacco product. As a general example, if an application demonstrates that using a new tobacco product would present significantly less toxicological risk to individual health than cigarettes in a marketplace where many addicted users currently smoke cigarettes, it could potentially receive an order where the PMTA demonstrates that the vast majority of individuals who would use the product would be current users of cigarettes who otherwise would not have quit and would switch to using the new product exclusively. On the other hand, where a PMTA for the same new tobacco product shows that individuals that would use the new tobacco product are predominately current users of tobacco products that have less toxicological risk to individual health, including products within the same product category, the application could potentially result in the issuance of a no marketing order because the product is not likely to have a net benefit to the population as a whole.

Additionally, the factors that could demonstrate the marketing of a new tobacco product would be APPH at one point in time might not support the same determination with respect to a similar product in the future. FDA makes its APPH determination in consideration of the existing market (*e.g.,* the products on the market, tobacco product use behaviors) at the time the determination is made. As the tobacco product market changes over time, the potential risks and benefits to the population as a whole of marketing a new tobacco product might also change. A new tobacco product that receives a marketing order under the current market conditions might not receive an order at a future time in which fewer individuals are using products that present higher levels of risk to individual health or such products are no longer on the market. FDA requests comment on its interpretation of the APPH standard set forth in section 910(c) of the FD&C Act, including how it should apply the standard over time as the tobacco product marketplace and tobacco product use behaviors change.

It is important to note that in order for FDA to issue a marketing order for a new tobacco product, section 910(c)(1)(A)(i) of the FD&C Act requires FDA to find there is 'a showing' that the marketing of the new tobacco product would be APPH. FDA interprets this to mean that an applicant must submit sufficient information in its PMTA for FDA to be able to find whether the marketing of a product would be APPH. While FDA may consider outside sources of information during PMTA review, an applicant cannot rely on FDA to seek out or create additional data to fill information gaps that may exist in a PMTA. As discussed in section VIII.E. regarding proposed § 1114.33, failure to submit sufficient information that FDA needs to be able to make its required findings would result in the issuance of a no marketing order.

This proposed rule focuses primarily on PMTA review procedures and content requirements, particularly with respect to application acceptance and filing. An application may meet the acceptance and filing requirements, but still lack vital information that FDA needs to determine whether it should issue a marketing order. The proposed rule would create a requirement to submit full reports of all existing health risk investigations; however, where there is not sufficient existing evidence that an applicant may utilize to demonstrate that the marketing of a new tobacco product would be APPH, an applicant would need to conduct its

own investigations to ensure that FDA has sufficient valid scientific evidence it needs to determine whether a marketing order should be issued for the new tobacco product.

Although an applicant may submit any type of evidence to FDA in an attempt to substantiate that the new tobacco product should receive a marketing order, FDA relies upon only valid scientific evidence to determine whether the marketing of the new tobacco product would be APPH. FDA will determine whether the evidence submitted or otherwise available to FDA is valid scientific evidence for the purpose of determining the new tobacco product's impact on individual and population health, and whether the available evidence, when taken as a whole, is adequate to support a determination that permitting the new tobacco product to be marketed would be APPH.

Valid scientific evidence includes data from well-controlled investigations, as well as other sources upon which FDA may base its determinations under section 910(c)(5) of the FD&C Act. Other sources may also include partially controlled studies, studies and objective trials without matched controls, and well-documented case histories conducted by qualified experts. The other sources of study data may be considered valid scientific evidence if it has been gathered using well-established or standardized methodologies from which it can fairly and responsibly be concluded by qualified experts that there is reasonable assurance of the reliability of its findings. The evidence required may vary according to the characteristics of the tobacco product, its conditions of use, the existence and adequacy of warnings and other restrictions, and the extent of experience with its use. Isolated case reports, anecdotal experiences, reports lacking sufficient details to permit scientific evaluation, and unsubstantiated opinions are not considered valid scientific evidence.

As part of its determination of whether permitting the marketing of a new tobacco product would be APPH, FDA must be able to determine the likely health risks of the new tobacco product. While this rule does not necessarily require applicants to conduct new studies for the purposes of application acceptance and filing (beyond the requirements of proposed § 1114.27(b)(1)(ii)), FDA expects that PMTAs would provide sufficient evidence to support the issuance of a marketing order where they contain data from a variety of sources, including both clinical and nonclinical investigations that give FDA comprehensive information about the product's likely health effects in the U.S. market. Where epidemiological evidence is available and comes from an investigation using a different product or one that was conducted outside the United States, FDA would examine whether the PMTA contains sufficient information, or the applicant has conducted bridging studies when needed, to demonstrate the data is applicable to its product and the U.S. population or provides adequate justification for how the information is relevant. FDA recognizes that this type of long-term data is not available for all categories of products and does not expect that long-term clinical studies (*i.e.,* those lasting approximately 6 months or longer) will need to be conducted for each PMTA; however, in the event long-term clinical study data should become available for the new product or similar product while the application is pending, this information should be submitted to FDA in an amendment.

Where a PMTA contains no long-term epidemiological evidence regarding the product or that could be bridged to the product, FDA would consider whether there are other sources of scientific evidence that sufficiently demonstrate the potential health risks of the product, such as actual use studies (*e.g.,* clinical studies that assess real-world use conditions and health outcomes, or clinical studies that use scientifically valid endpoints as a predictor for potential long-term health effects). Where a PMTA lacks human subject study data regarding the product or that can be bridged to the product, FDA will examine how a PMTA attempts to estimate the health effects of the product on the U.S. population from the results of nonclinical investigations; however, it should be noted that information from nonclinical studies alone is generally not sufficient to support a determination that permitting the marketing of the product would be APPH.

As part of FDA's consideration of the changes in tobacco product use behavior that are likely to be caused by the marketing of the new tobacco product, FDA will examine data regarding how the product and its label, labeling, and advertising will affect the tobacco use behavior of both users and nonusers of tobacco products, including the behaviors described in § 1114.7(k)(1)(ii) and (iii). FDA needs sufficient information to determine the potential changes in tobacco product use behavior and the health risks and benefits associated with the changes in user behavior will allow FDA to make a determination of whether permitting the marketing of the new tobacco product would be APPH. Where a PMTA does not contain sufficient information for FDA to make these determinations, FDA will issue a no marketing order for the product because it would lack information necessary to determine the risks and benefits to the population as a whole as required by section 910(c)(4) of the FD&C Act.

2. The methods used in and the facilities and controls used for, the manufacture, processing, or packing of such tobacco product conform to the requirements of section 906(e) of the FD&C Act.

As discussed in section VII.B.12. regarding proposed § 1114.7(j), FDA has not yet issued a regulation under section 906(e) of the FD&C Act, so demonstrating compliance with such regulations in a PMTA is not currently required; however, FDA plans to issue proposed rulemaking(s) under section 906(e), and once such regulations are effective, applicants must demonstrate that their methods, facilities, and controls are in conformance with applicable requirements to receive a marketing order under section 910(a)(1)(i)(A) of the FD&C Act. Until such a time as a final rule issued under section 906(e) of the FD&C Act is effective, FDA will evaluate the manufacturing process and consider whether the product can be manufactured in a manner consistent with the information submitted within the application as part of its determination of whether the marketing of the new tobacco product is appropriate for the protection of public health. As part of this evaluation, FDA will consider whether the applicant would be able to consistently produce the new tobacco product as described in the PMTA. The potential for an applicant to produce nonconforming tobacco products that have higher levels of HPHCs than intended, have dangerous foreign material, or otherwise potentially presents a higher risk of harm than the product described in the PMTA may affect FDA's determination of whether the marketing of a product would be APPH.

3. Based on a fair evaluation of all material facts, the proposed labeling is not false or misleading in any particular.

4. The tobacco product is shown to conform in all respects to a tobacco product standard in effect under section 907 of the FD&C Act or there is adequate information to justify a deviation from such standard.

A PMTA submitted under the proposed rule would be required by proposed § 1114.7(d)(2) to contain a

statement identifying all tobacco product standards issued under section 907 of the FD&C Act that are applicable to the new tobacco product and a brief description of how the new tobacco product fully meets the identified tobacco product standard(s) or justifies a deviation from such standards, if applicable. FDA must be able to locate the data regarding the tobacco product's compliance with the product standard and determine that the tobacco product does, in fact, meet the requirements of the applicable product standard(s) or, if applicable, deviates from such standards in a way that is justified. For example, if an applicant submitted a PMTA for a product that is subject to a product standard limiting the amount of an HPHC that may be delivered to product users, FDA would need to be able to verify though a review of the HPHC testing data contained in the product formulation section that the product complies with that product standard. Under section 910(c)(2)(D) of the FD&C Act, FDA will not issue a marketing order for a tobacco product unless a PMTA demonstrates that it meets any applicable product standard(s), or an applicant has justified the deviation from such standard, if applicable.

Proposed § 1114.31(b) describes restrictions and additional requirements that FDA may include as part of a marketing order. Under section 910(c)(1)(B) of the FD&C Act, FDA may require the sale and distribution of the tobacco product be restricted to the extent that the sale and distribution of a tobacco product may be restricted under a regulation under section 906(d) of the FD&C Act. Proposed § 1114.31(b)(1) reiterates this authority as part of the rule and proposed § 1114.31(b)(2) would allow FDA to include restrictions on sales and distribution proposed by the applicant as part of its PMTA as part of a marketing order.

Proposed § 1114.31(b)(3) would allow FDA, using its authority in section 910(f) of the FD&C Act, to require an applicant to submit postmarket reports in addition to those described in § 1114.41, as appropriate, including but not limited to, requirements that an applicant provide information such as labeling, advertising, marketing, promotional materials, or marketing plans not previously submitted to FDA, and do so at least 30 days prior to the initial publication, dissemination to consumers, or use in engaging or communicating with consumers of such materials. Similar to what is described in section VII.B.6., these items provide information that is important to FDA's determination of whether the continued marketing of the new tobacco product would be APPH or whether FDA must withdraw the marketing order under section 910(d)(1)(A) of the FD&C Act because the marketing of the new tobacco product is no longer APPH. Receiving this information in advance of its first use would allow FDA to ensure it can appropriately track and monitor the impact that the use of such information. FDA anticipates it would use this authority on a case-by-case basis, especially as it relates to novel tobacco products for which the body of knowledge is still growing.

E. Issuance of a No Marketing Order (Proposed § 1114.33)

Proposed § 1114.33 describes the circumstances under which FDA would issue a no marketing order for a new tobacco product after PMTA review. Proposed § 1114.33(a)(1) specifies that FDA would issue a no marketing order if any of the grounds for denial listed in 910(c)(2) of the FD&C Act apply to the application. As mentioned in the discussion of the issuance of a marketing order, meeting the requirements for application acceptance and filing does not mean that an application has sufficient information to receive a marketing order. For example, while FDA may accept and file an application that contains the information in proposed § 1114.7(k), FDA would not issue a marketing order unless that information also makes a showing that the marketing of a new tobacco product would be APPH. While the proposed rule does not necessarily require the applicant to conduct studies on its product, applicants would need to do so for products for which insufficient information exists to demonstrate its potential health risks or face the possibility of receiving a no marketing order. Similarly, the information required in the manufacturing section of the application is required for acceptance and filing; however, unless the manufacturing process described ensures a product will be consistently produced as described in a PMTA (*e.g.,* implementing sufficient controls), an applicant may receive a no marketing order.

Examples of when FDA would be required to issue a no marketing order for a lack of information necessary to make its required findings and determinations under sections 910(c)(2) and (c)(4) of the FD&C Act are contained throughout this document and include, but are not limited to, a lack of sufficient information regarding:

- The health risks of the new tobacco product;
- a comparison to of the new tobacco product to the health risks of other tobacco products used by individuals that the applicant expects to use the new tobacco product, including products both within and outside of the new tobacco product's product category;
- the abuse liability of the new tobacco product;
- potential changes to tobacco product use behavior of current tobacco product users;
- the increased or decreased likelihood that those who do not use tobacco products will start using tobacco products;
- the impact of the product and its label, labeling, and advertising on individuals' perception of the health risks of the product and their use intentions; and
- how human factors can influence the health risks of the new tobacco product.

Proposed § 1114.33(a) would also allow FDA to issue a no marketing order where the applicant does not permit an authorized FDA employee, at a reasonable time and a reasonable manner, an opportunity to: (1) Inspect the facilities and controls, and sites and entities involved with clinical and nonclinical research (including third parties and contract research organizations) described in the application; or (2) have access to, copy, and verify all records pertinent to the application, where such refusal prevents FDA from making the required findings in 910(c) necessary to issue a marketing order. FDA is proposing to issue a no marketing order where an applicant does not permit these inspections because the ability to access and inspect the facilities and controls and sites and entities involved with clinical and nonclinical research, as well as pertinent records, is important to FDA's ability to determine whether any of the denial criteria specified in section 910(c)(2) of the FD&C Act and proposed § 1114.33(a)(1) apply to the application. Inspecting the facilities and controls described in the application will allow FDA to ensure the applicant can manufacture the product in accordance with the manufacturing practices described in the application. Inspecting records, including those required to be kept under proposed § 1114.45, will allow FDA the opportunity to verify the study findings and data that the applicant relies upon in the PMTA to demonstrate that the new tobacco product should receive a marketing order. As stated in proposed § 1114.45, the records would be required to be legible and written in English.

If FDA issues a no marketing order, it will, where practicable, identify measures to address the reasons for which the application is being denied. While FDA will identify the deficiencies that resulted in the no marketing order, the deficiencies specified in the order might not be an exhaustive listing of all deficiencies contained in the PMTA.

F. Withdrawal of a Marketing Order (Proposed § 1114.35)

Proposed § 1114.35 describes the grounds and procedures for withdrawing a marketing order for a new tobacco product. FDA would move to withdraw an order in the following situations:

1. Any of the grounds for withdrawal under section 910(d)(1) of the FD&C Act apply. These grounds include situations in which FDA finds:

• The continued marketing of the tobacco product is no longer APPH. The marketing of a product may no longer be APPH in several situations, including, for example, where there are changes to tobacco product use behaviors that were not expected in FDA's assessment of the PMTA (*e.g.,* more nonusers of tobacco products are initiating use with the product than expected and/or fewer users of potentially more harmful products are switching to the potentially less harmful new tobacco product). Another example is where studies conducted after the issuance of the marketing order show that the product presents greater risks to health than FDA understood during application review and, as a result, the product likely has or will have a net negative impact on the health of the population as a whole.

FDA also interprets section 910(d)(1)(A) of the FD&C Act to provide for the withdrawal of a marketing order where changes to the tobacco product marketplace result in FDA finding that the marketing of a product is no longer APPH. FDA interprets the APPH standard to require ongoing consideration of the public health impact of the marketing of a new tobacco product and thus what is necessary to satisfy the standard changes with the tobacco product marketplace. Because market conditions will change over time, what might be APPH at one point in time may no longer be APPH in the future. Examples of changes that could affect FDA's determination that the marketing of the product is APPH could include FDA's implementation of a tobacco product standard pursuant to section 907 of the FD&C Act that alters the relative health risks presented by other tobacco products. For instance, if FDA issued a marketing order for a new (non-cigarette) tobacco product, in part, because it presented significantly lower risks to individual health than cigarettes, and FDA later implemented a product standard that significantly lowered the health risks of cigarettes, FDA may determine that the continued marketing of the new (non-cigarette) tobacco product is no longer APPH. If FDA were to be unable to consider changing market conditions when evaluating whether the marketing of a new tobacco product continues to be APPH after it is granted a marketing order, FDA would potentially be unable to address the continued marketing of products that have higher levels of relative health risks, thus undermining its core statutory mandate to reduce the harm caused by tobacco product use. FDA requests public comments on its interpretation of 910(d)(1)(A) of the FD&C Act. FDA requests comment on its interpretation of the APPH standard, including how it should apply the standard over time as the tobacco product marketplace and tobacco product use behaviors change.

• The application contained or was accompanied by an untrue statement of material fact;

• The applicant has failed to establish a system for maintaining records, or has repeatedly or deliberately failed to maintain records or make reports required by part 1114 or another applicable regulation under section 909 of the FD&C Act.

• The applicant has refused to permit access to, or copying or verification of, records as required by section 704 of the FD&C Act;

• The applicant has not complied with the requirements of section 905 of the FD&C Act;

• On the basis of new information before the Secretary with respect to such tobacco product, evaluated together with the evidence before the Secretary when the application was reviewed, that the methods used in, or the facilities and controls used for, the manufacture, processing, packing, or installation of such tobacco product do not conform with the requirements of section 906(e) of the FD&C Act and were not brought into conformity with such requirements within a reasonable time after receipt of written notice from the Secretary of nonconformity;

• On the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when the application was reviewed, that the labeling of such tobacco product, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary of such fact; or

• On the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when such order was issued, that such tobacco product is not shown to conform in all respects to a tobacco product standard which is in effect under section 907 of the FD&C Act, compliance with which was a condition to the issuance of an order relating to the application, and that there is a lack of adequate information to justify the deviation from such standard.

2. Any postmarket requirement imposed by the marketing order or by this part that has not been met and results in FDA finding that one or more of the grounds for withdrawal specified in section 910(d)(1) of the FD&C Act apply. FDA is proposing this requirement to allow the withdrawal of a marketing order where an applicant fails to meet requirements imposed by a marketing order or part 1114, including postmarket restrictions on the sales and distribution of the tobacco product as described in section VIII.D. and results in FDA finding one or more of the grounds for withdrawal specified in section 910(d)(1) of the FD&C Act apply.

FDA may seek advice on scientific matters from any appropriate FDA advisory committee in deciding whether to withdraw a marketing order and may use information other than that submitted by the applicant in deciding whether to withdraw a marketing order. Prior to withdrawing a marketing order, FDA will notify the holder of the marketing order of the opportunity for an informal hearing under 21 CFR part 16. If the holder of the marketing order does not request an informal hearing or if FDA decides to withdraw the marketing order after the informal hearing is held, FDA will issue an order withdrawing the marketing order. FDA will notify the public that the marketing order for the product has been withdrawn and state the basis for the withdrawal.

G. Temporary Suspension of a Marketing Order (Proposed § 1114.37)

Proposed § 1114.37 describes the grounds and procedures by which FDA will temporarily suspend a marketing order under section 910(d)(3) of the FD&C Act. FDA is required by section 910(d)(3) to initiate a temporary suspension of a marketing order when it determines that there is a reasonable probability that the continued distribution of the product will cause serious, adverse health consequences or death, that is greater than what is

ordinarily caused by tobacco products on the market. FDA interprets this language to mean serious, adverse health consequences at a rate or of a severity, or death at a rate, that is greater than what is ordinarily caused by tobacco product currently on the market. Under the proposed rule, FDA will notify the holder of the marketing order of the opportunity to hold an informal hearing. If FDA determines after the opportunity for the informal hearing that the marketing order for the tobacco product should be temporarily suspended, the Agency will issue an order temporarily suspending the marketing order. FDA recommends that the applicant submit a plan demonstrating how it intends to comply with the temporary suspension, including a description of how the applicant will ensure that the tobacco product will not cause or continue to cause the serious, adverse health consequences or death (or reasonable probability of such events) that resulted in the temporary suspension, and the steps the applicant plans to take to ensure that the product is not further distributed, imported, sold, marketed, or promoted in the United States. Once FDA temporarily suspends a marketing order, it will proceed expeditiously to initiate order withdrawal proceedings.

IX. Postmarket Requirements (Proposed Part 1114, Subpart D)

A. Postmarket Changes (Proposed § 1114.39)

Proposed § 1114.39 describes the scope of a marketing order. FDA issues marketing orders for the specific new tobacco product described in the PMTA. An applicant may not make any modification to the product that is the subject of the order, as any modification to the tobacco product would result in a new tobacco product under the definition in section 910(a)(1) of the FD&C Act. Changes that do not result in a new tobacco product, such as manufacturing process changes that do not modify the finished tobacco product, would be required to be reported under proposed § 1114.41. Applicants seeking to make modifications to the tobacco product may submit a standard PMTA, a supplemental PMTA, or a request for an exemption from substantial equivalence for the modified product, where appropriate, to FDA to seek marketing authorization for the new tobacco product, but may not market the new tobacco product until FDA has authorized the marketing of the new tobacco product. Marketing a new tobacco product without required premarket authorization would render the product adulterated under section 902(6)(A) of the FD&C Act and subject to an FDA enforcement action.

B. Reporting Requirements (Proposed § 1114.41)

Proposed § 1114.41 would require applicants that receive a marketing order to submit postmarket reports. FDA is requiring postmarket reports under the authority of section 910(f) of the FD&C Act, which requires applicants to establish and maintain records and make reports that FDA requires as necessary to determine or facilitate a determination of whether there may be grounds to withdraw or temporarily suspend a marketing order. Proposed § 1114.41 describes the reports that FDA would require through this regulation; however, FDA may require additional reporting in an individual applicant's marketing order.

Applicants would be required under proposed § 1114.41 to submit two types of reports after receiving a marketing order: Periodic reports and adverse experience reports. Applicants would need to submit periodic reports within 60 calendar days of the reporting date specified in the marketing order (or potentially sooner if they choose to use the application as the basis for a supplemental PMTA under proposed § 1114.15). FDA anticipates that the reports would be required on an annual basis, but FDA may require in a specific order that reports be made more or less frequently depending upon a number of factors (*e.g.,* the novelty of the type of product). Applicants would have to submit the following information electronically together with the appropriate form (Ref. 11) as part of each periodic report under proposed § 1114.41(a)(1):

- A cover letter that includes basic identifying information, such as the product name(s) (including the original product name, if different) and application STN;
- A description of the changes made to the manufacturing, facilities, or controls, if any, during the reporting period. This description would be required to include sufficient information for FDA to determine whether a change to the manufacturing, facilities, and controls results in a new tobacco product or could potentially require the marketing order to be withdrawn. This information would include a comparison to the manufacturing, facilities, or controls described in the PMTA, the rationale for marking the change, and an explanation of why the change does not result in a new tobacco product and why there are no grounds for FDA to withdraw or temporarily suspend the marketing order on the basis of the change (*i.e.,* the marketing of product continues to be APPH, the manufacturing process complies with the requirements of section 906(e) of the FD&C Act, and the product still conforms to any product standards under section 907 of the FD&C Act).
- An inventory of all ongoing and completed studies about the tobacco product conducted by, or on behalf of, the applicant that were not already submitted as part of the PMTA or previous postmarket reports. These reports can provide important information regarding health risks or changes in tobacco product use behavior, including initiation, which helps FDA determine whether the marketing of the product is no longer APPH under section 910(d)(1)(A) of the FD&C Act;
- Full reports of information (as described in proposed § 1114.7(k)(3)) published or known to, or which should reasonably be known to, the applicant concerning scientific investigations and literature about the tobacco product that would be required in a PMTA under proposed § 1114.7(k)(1) not previously submitted as part of the PMTA or previous postmarket reports, as well as significant findings from publications not previously reported. These reports can provide important information regarding whether the marketing of the product is no longer APPH under section 910(d)(1)(A) of the FD&C Act;
- A summary and analysis of all serious and unexpected adverse experiences associated with the tobacco product that have been reported to the applicant or that the applicant is aware of, accompanied by a statement of any changes to the overall risk associated with the tobacco product, including the nature and frequency of the adverse experience, and potential risk factors. This information can provide important information regarding whether the marketing of the product is no longer APPH under section 910(d)(1)(A) of the FD&C Act and whether the marketing order should be temporarily suspended under section 910(d)(3) of the FD&C Act;
- A summary of sales and distribution of the tobacco product, to the extent that the applicant collects or receives such data, for the reporting period, including:
  - Total U.S. sales reported in dollars, units, and volume with breakdowns by U.S. census region, major retail markets, and channels in which the product is sold. Sales and distribution information may constitute confidential commercial

information under § 20.61 that is exempt from public disclosure. See proposed § 1114.47 and 21 CFR part 20 for more information about the confidentiality of information submitted to FDA;

○ The Universal Product Code that corresponds to the product(s) identified in the PMTA; and

○ Demographic characteristics of product purchasers, such as age, gender, and tobacco use status.

FDA would require applicants to submit sales data under its authority in section 910(f) of the FD&C Act to help inform its determination of whether the product continues to be APPH. The volume of sales, demographics of purchasers, and other sales data provide information that can help indicate trends in tobacco use behavior for the product, such as whether nonusers are initiating tobacco product use with the product and current tobacco product users are using the product. These data are especially important for FDA to review because the data inform a determination of whether the marketing of the new tobacco product continues to be APPH. In particular, the data help FDA to assess whether the information regarding likely tobacco product use behavior described in the PMTA was consistent with actual use after authorization. For example, data that indicate higher rates of youth initiation with the tobacco product than anticipated in the PMTA could result in FDA finding that continued marketing of the tobacco product is no longer APPH and the marketing order should be withdrawn under section 910(d)(1)(A) of the FD&C Act.

• Specimens of all labeling that has not been previously submitted in the PMTA, prior postmarket reports, or under section 905(i) of the FD&C Act and descriptions of all labeling changes including the date the labeling was first disseminated and the date when dissemination was completely terminated. This labeling information can help FDA determine whether the withdrawal grounds under section 910(d)(1)(E) of the FD&C Act apply;

• Full color copies of all advertising, marketing, and promotional materials for the tobacco product that have not been previously submitted, the original date the materials were first disseminated, and the date when their dissemination was completely terminated. FDA is requiring applicants to submit advertising because it can indicate the potential for trends in tobacco use behavior for the product, such as whether nonusers are likely to initiate tobacco product use with the product and current tobacco product users are likely to use the product (see section VII.B.6 regarding proposed § 1114.7(f) for a discussion of the impact of advertising);

• A description of the implementation of all advertising and marketing plans, including strategic creative briefs and paid media plans (whether conducted by you, on your behalf, or at your direction) by channel and by product, and the dollar amount(s) and flighting of such plans, by channel and by product, including a description of any:

○ Use of competent and reliable data sources, methodologies, and technologies to establish, maintain, and monitor highly targeted advertising and marketing plans and media buys;

○ Targeting of specific adult audiences by age-range(s), including young adults, ages 18–24, and other demographic or psychographic characteristics that reflect the intended target audience, including a list of all data sources used to target advertising and marketing plans and media buys;

○ Actions taken to restrict youth-access and limit youth-exposure to the products' labeling, advertising, marketing, or promotion;

○ Use of owned, earned, shared, or paid media to create labeling for, advertise, market, and/or promote the products;

○ Use of partners, influencers, bloggers, or brand ambassadors to create labeling for, advertise, market, and/or promote the products;

○ Consumer engagements—whether conducted by you, on your behalf, or at your direction—including events at which the products are intended to be demonstrated; and

○ Use of earned media or public-relations outreach to create labeling for, advertise, market, or promote the products;

• A report or summary of the actual delivery of advertising impressions, by channel, by product (if applicable), and by audience demographics (*e.g.,* age, gender, race/ethnicity, geographic location), including a breakout by age-group (*i.e.,* adults, ages 25+; young adults, ages 18–24; and youth, ages 12–17 and ages 11 and under), not previously submitted. This report or summary must be verified against post-launch delivery-verification reports submitted to the tobacco product company from an accredited source; and

• An overall assessment of how the marketing of the tobacco product continues to be APPH.

Applicants would also be required to report all serious and unexpected adverse experiences associated with the tobacco product that have been reported to the applicant or of which the applicant is aware under proposed § 1114.41(a)(2). The serious and unexpected adverse experience reports must be submitted to CTP's Office of Science through the HHS Safety Reporting Portal or in another manner designated by FDA (if applicable) within 15 calendar days after receiving or becoming aware of a serious or unexpected adverse experience.

As part of its review of a postmarket report, FDA would be able to require the applicant to submit additional information to enable it to determine whether a change results in a new tobacco product, or to facilitate a determination of whether there are or may be grounds to withdraw or temporarily suspend the marketing order. FDA may notify an applicant that FDA has determined that a change described in a periodic report made under this section results in a new tobacco product outside the scope of the marketing order, requiring the submission of a new PMTA under § 1114.7 or a supplemental PMTA under § 1114.15 and issuance of a marketing order if the applicant seeks to market the new tobacco product, unless the new tobacco product can be legally marketed through a different premarket pathway. Failure to obtain marketing authorization for a new tobacco product would render it adulterated under section 902(6) of the FD&C Act and could be subject to enforcement action.

FDA notes that the proposed periodic reporting requirements in § 1114.41 apply most appropriately to new tobacco products that are being actively manufactured, sold, distributed, or consumed. Where an applicant temporarily ceases the introduction, or delivery for introduction, of its new tobacco product into interstate commerce, FDA is seeking public comment regarding whether it should include a provision in the rule that would allow: (1) An applicant to temporarily stop submitting periodic reports, upon notice to, and agreement by, FDA, during the period of time in which it does not introduce, or deliver for introduction, its new tobacco product into interstate commerce; and (2) an applicant to resume the introduction, or delivery for introduction, of is new tobacco product into interstate commerce, upon notice to, and agreement by, FDA, after submitting a periodic report to FDA meeting the requirements of § 1114.41 that covers the period in time since it last submitted a period report or received its order if reports had yet to be submitted. In this scenario, an applicant that fails to submit a

postmarket report and receive FDA agreement prior to resuming the introduction, or delivery for introduction, of its new tobacco product into interstate commerce may be marketing a product in violation of section 902(6)(B) of the FD&C Act, rendering their product adulterated and making it subject to enforcement action. FDA is specifically seeking comment on factors FDA should consider in determining whether the applicant should be allowed to temporarily cease its periodic reporting, including whether product has ceased being manufactured, sold, or distributed either in the United States or abroad.

FDA is also seeking public comment regarding whether it should, rather than creating a provision in a final rule, consider exercising enforcement discretion regarding periodic reporting requirements on a case-by-case basis after receiving the notice under 905(i)(3) of the FD&C Act. Under the requirements of section 905(i)(3), an applicant that receives a marketing order would be required to provide notice to FDA in the event that it discontinues the manufacture, preparation, compounding or processing for commercial distribution of the new tobacco product.

X. Miscellaneous (Proposed Part 1114, Subpart E)

Proposed subpart E describes other procedures and requirements related to PMTAs, including record retention, electronic submission requirements, and confidentiality considerations.

A. Record Retention (Proposed § 1114.45)

Consistent with the authority to require recordkeeping under sections 909 and 910(f) of the FD&C Act, proposed § 1114.45 would require applicants receiving a marketing order to maintain all records necessary to facilitate a determination of whether there are or may be grounds to withdraw or temporarily suspend the marketing order and ensure that such records remain readily available to the Agency upon request. The records would be required to be legible, written in English, and available for inspection and copying by officers or employees designated by the Secretary. This proposed requirement would help ensure that records are available to FDA during an inspection. Applicants that have stopped marketing a tobacco product may want to retain the records for a longer period if the product might be reintroduced in order to avoid the time and expense of having to generate the information again. FDA may, under the terms of section 910(f) of the FD&C Act, impose additional recordkeeping and reporting requirements as part of a marketing order in addition to the requirements in the proposed rule.

1. Record Retention by the Applicant

Under proposed § 1114.45(a)(1), an applicant must retain all documents submitted to FDA as part of an application and postmarket reports. An applicant must also retain any additional documentation supporting the application and postmarket reports that was not submitted to FDA. This additional documentation includes information that demonstrates:

- Nonclinical laboratory studies were conducted using laboratory practices that ensure the reliability and validity of the study. This information includes documents that were generated during the performance of nonclinical studies, but were not required to be submitted as part of a full study report under proposed § 1114.7(k)(3). One way that an applicant may satisfy this requirement is to retain all of the documentation described in part 58.
- Whether any investigators had financial conflicts of interest. One approach to satisfying this requirement is to retain all of the documentation described in part 54 for both clinical and nonclinical investigations.

Applicants would also be required to retain all other documents generated during the course of a study that are necessary to substantiate the study results (*e.g.,* certain communications, case reports) including:

- Communications related to the investigation between the investigator and the sponsor, the monitor, or FDA; and
- All source data and related summaries, including records regarding each study subject's case history and exposure to tobacco products used in the investigation, which can include, but is not limited to case report forms, progress notes, hospital records, clinical charts, X-rays, lab reports, and subject diaries.

The applicant would also be required to maintain a record of each complaint associated with the tobacco product that has been reported to the applicant as well as a summary and an analysis of all complaints associated with the tobacco product reported to the applicant. The records and analysis of complaints should reflect all reports made about the product, including those made during clinical investigations. FDA is requiring that records and analysis of such complaints be kept to demonstrate whether there are any potential issues with the product that could present health or safety issues.

2. Record Format and Availability

The proposed rule would require the applicant to maintain records that are legible and in the English language, and make them available for inspection and copying by officers or employees duly designated by the Secretary.

3. Retention Period

Applicants would have to retain the records as described in proposed § 1114.45(a)(3). Records relating to the PMTA would have to be retained for a period of no less than 4 years from the date the marketing order is issued. Records relating to the postmarket reports, including both periodic reporting and adverse experience reporting would have to be retained for a period of at least 4 years from the date the postmarket report was submitted or the date FDA inspects the records, whichever occurs sooner. FDA has selected 4 years as a means to help ensure that the records would be available for at least one biennial FDA inspection under section 704 and 905(g) of the FD&C Act.

B. Confidentiality (Proposed § 1114.47)

Proposed § 1114.47 states that FDA would determine the public availability of any part of any PMTA and other content related to a PMTA as provided under this proposed section and part 20 (Public Information). FOIA (5 U.S.C. 552), as well as certain provisions of the FD&C Act, (*e.g.,* section 301(j) (21 U.S.C. 331(j)) and section 906(c) (21 U.S.C. 387f(c))), govern the disclosure of the existence of a pending PMTA and the information contained in such a PMTA. Under FOIA, the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure. One such provision, 5 U.S.C. 552(b)(4), exempts records that are ''trade secrets and commercial or financial information obtained from a person and privileged or confidential'' from the requirement of mandatory disclosure. Part 20 of FDA's regulations sets forth FDA's general regulations concerning public availability of FDA records.

Like with drugs and devices, the intent to market a tobacco product is often considered confidential commercial information, as premature disclosure could result in a competitive advantage to competitors. Therefore, FDA is proposing § 1114.47(b), which would address the confidentiality of a PMTA prior to the issuance of a marketing order. Under the proposed

regulation and consistent with part 20, FDA would not publicly disclose the existence of a PMTA unless the applicant has publicly disclosed or acknowledged that it has submitted the application to FDA (as such disclosure is defined in § 20.81), the applicant has authorized FDA in writing to publicly disclose or acknowledge the submission of the PMTA, or FDA has referred the application to TPSAC. Proposed § 1114.47(b)(2) provides that FDA would not disclose the fact or contents of an FDA communication with an applicant or regarding an application or information contained in the application unless the applicant has publicly disclosed, acknowledged, or authorized FDA in writing to publicly disclose or acknowledge the existence of the FDA communication or information contained in the application. However, if the applicant has disclosed that it received a communication from FDA regarding the application, FDA may disclose the record of the communication after redacting confidential commercial or trade secret information. Proposed § 1114.47(b)(3) provides that if FDA refers the application to TPSAC, the PMTA will be available for public disclosure under part 20 as described in § 14.75 (which concerns the public disclosure of advisory committee records), except information that has been shown to fall within the exemption established for trade secrets and confidential commercial or financial information in § 20.61, or personal privacy in § 20.63.

Proposed § 1114.47(c) describes the information that FDA will make available after issuing a marketing order consistent with the requirements of § 20.61. Under proposed § 1114.47(c), FDA would make available data previously disclosed to the public, protocols for a test or study, information and data in the application that demonstrate the new tobacco product is appropriate for the protection of the public health, any correspondence between FDA and the applicant, the environmental assessment or request for categorical exclusion, and information and data contained in postmarket reports that are not exempted from disclosure under § 20.61 for trade secrets and confidential commercial information, or in § 20.63 for personal privacy.

Even after receipt of a no marketing order, the intent to market may still constitute confidential commercial information, as the applicant may still have the goal to market the new tobacco product that is the subject of the PMTA. Under proposed § 1114.47(d), FDA may also make certain information available after it issues a no marketing order unless the information is otherwise exempt from disclosure under part 20. The information that FDA may disclose would include product category, subcategory, package size, and the basis for the no marketing order.

C. Electronic Submission (Proposed § 1114.49)

Consistent with FDA's authority to issue regulations for the efficient enforcement of the FD&C Act, proposed § 1114.49 would require an applicant to submit a PMTA and all supporting and related documents to FDA in electronic format that FDA can process, review, and archive unless an applicant requests, and FDA grants, a waiver from this requirement. Reasons that an applicant might request a waiver would include that the applicant has no access to email or a computer. Under proposed § 1114.49(c), an applicant that has a waiver would submit a paper submission to the address that FDA provides in the letter granting the waiver. FDA is proposing § 1114.49 based on FDA's general experience with electronic submissions, which FDA has found help facilitate premarket reviews because electronic submissions typically enable FDA to receive, access, search, and review a submission more quickly than a submission submitted on paper through postal mail. FDA intends to provide technical specifications on its website for submitting information in an electronic format that FDA can review, process, and archive (*e.g.,* method of transmission, media, file formats, preparation, organization of files, accompanying metadata) (*https://www.fda.gov/tobacco-products*). FDA intends to update this information as needed (*e.g.,* to accommodate changes in technology).

XI. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). A description of these provisions is given in the *Description* section of this document with an estimate of the annual reporting and recordkeeping. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Premarket Tobacco Product Applications and Recordkeeping Requirements, OMB Control Number 0910–0768.

Description: This proposed rule would interpret and codify requirements related to the content and format of PMTAs, the procedure by which FDA would review PMTAs, and the maintenance of records regarding the legal marketing of certain tobacco products without PMTAs. The proposed rule also addresses issues such as the procedures of retention of records related to the PMTA, confidentiality of application information, electronic submission of the PMTA and amendments, and postmarket reporting requirements.

Description of Respondents: This proposed rule applies to tobacco product manufacturers. Manufacturer is defined here as any person, including any repacker or relabeler, who: (1) Manufactures, fabricates, assembles, processes, or labels a tobacco product; or (2) imports a finished tobacco product for sale or distribution in the United States.

FDA is proposing requirements for the content, format, submission, and review of PMTAs, as well as other requirements related to PMTAs, including recordkeeping requirements, and postmarket reporting. FDA is also proposing recordkeeping requirements regarding the legal marketing of grandfathered tobacco products and products that are exempt from the requirements of demonstrating substantial equivalence.

Section 910(a)(2) of the FD&C Act generally requires that a new tobacco product be the subject of a PMTA marketing order unless FDA has issued an order finding it to be substantially equivalent to a predicate product or it is exempt from the requirements of demonstrating substantial equivalence. A manufacturer may choose to submit a PMTA under section 910(b) of the FD&C Act in an attempt to satisfy the requirements of premarket review. Section 910(b)(1) describes the required contents of a PMTA, which in addition

to specific items, allows FDA to require applicants to submit other information relevant to the subject matter of the application.

Under proposed § 1114.5 an applicant may submit a PMTA to demonstrate that a new tobacco product meets the requirements to receive a marketing order. A new tobacco product may not be introduced or delivered for introduction into interstate commerce under this part until FDA has issued a marketing order for the product. Proposed § 1114.7 describes the required content and format of the PMTA. The PMTA must contain sufficient information for FDA to determine whether any of the grounds for denial specified in section 910(c)(2) of the FD&C Act apply. The application must contain the following sections: General information, descriptive information, product samples as required by FDA, a statement of compliance with 21 CFR part 25, a summary, product formulation, manufacturing, health risk investigations, and a certification statement.

Proposed § 1114.9 provides that FDA may request, and an applicant may submit, an amendment to a pending PMTA. FDA generally expects that when an applicant submits a PMTA, the submission will include all information required by section 910(b)(1) of the FD&C Act and proposed part 1114 to enable FDA to determine whether it should authorize the marketing of a new tobacco product. However, FDA recognizes that additional information may be needed to complete the review of a PMTA and, therefore, is proposing § 1114.9 to allow the submission of amendments to a pending application.

Proposed § 1114.13 describes the steps that an applicant would be required to take when it changes ownership of a PMTA. This proposed section is intended to facilitate transfers of ownership and help ensure that FDA has current information regarding the ownership of a PMTA. An applicant may transfer ownership of its PMTA at any time, including when FDA has yet to act on it.

Proposed § 1114.15 discusses supplemental PMTAs, which are an alternative format for submitting a PMTA. Specifically, supplemental PMTAs are a standardized cross-referencing format that FDA would implement under its authority of section 701(a) of the FD&C Act to efficiently enforce section 910 for submissions that are based on a PMTA that FDA has previously reviewed. Applicants that have received a marketing order would be able to submit a supplemental PMTA to seek marketing authorization for a new tobacco product that results from a modification or modifications to the original tobacco product that received the marketing order. FDA is proposing to restrict the use of supplemental PMTAs to only changes that require the submission of limited information or revisions to ensure that FDA is able to efficiently review the application. An applicant would also be able to submit a supplemental PMTA for modifications made to comply with a product standard issued under section 907 of the FD&C Act where FDA specifies that the submission of supplemental PMTAs would be appropriate.

Proposed § 1114.17 describes resubmissions, which are an alternative format for submitting an application that meets the requirements of § 1114.7(b) or § 1114.15 to seek a marketing order for a tobacco product by responding to the deficiencies outlined in a no marketing order. An applicant may submit a resubmission for the same tobacco product that received a no marketing order or for a different new tobacco product that results from changes necessary to address the deficiencies outlined in a no marketing order. This application format allows an applicant to address the deficiencies described in a no marketing order without having to undertake the effort of submitting a standard PMTA. The resubmission format is not available for PMTAs that FDA refused to accept, refused to file, cancelled, or administratively closed, or that the applicant withdrew because FDA has not previously completed reviews of such applications upon which it can rely, and such applications may need significant changes to be successfully resubmitted.

Proposed § 1114.41 would require applicants that receive a marketing order to submit postmarket reports. FDA requires such reports as necessary to determine or facilitate a determination of whether there may be grounds to withdraw or temporarily suspend a marketing order. Proposed § 1114.41 describes the reports that FDA would require through this regulation; however, FDA may require additional reporting in an individual applicant's marketing order. Applicants would be required under proposed § 1114.41 to submit two types of reports after receiving a marketing order: Periodic reports and adverse experience reports.

Applicants would need to submit periodic reports within 60 calendar days of the reporting date specified in the marketing order. FDA anticipates that the reports would be required on an annual basis, but FDA may require in a specific order that reports be made more or less frequently depending upon a number of factors. Applicants would also be required to report all serious and unexpected adverse experiences associated with the tobacco product that have been reported to the applicant or of which the applicant is aware under proposed § 1114.41(a)(2). The serious and unexpected adverse experience reports must be submitted to CTP's Office of Science through the HHS Safety Reporting Portal within 15 calendar days after receiving or becoming aware of a serious and unexpected adverse experience.

Proposed § 1114.45 would require applicants receiving a marketing order to maintain all records necessary to facilitate a determination of whether there are or may be grounds to withdraw or temporarily suspend the marketing order, including records related to both the application and postmarket reports, and ensure that such records remain readily available to the Agency upon request. Under proposed § 1114.45(a)(1), an applicant must retain all documents submitted to FDA as part of an application and postmarket reports. An applicant must also retain any additional documentation supporting the application and postmarket reports that was not submitted to FDA.

Proposed § 1100.200 states that subpart C of part 1100 would establish requirements for the maintenance of records by tobacco product manufacturers who introduce a grandfathered tobacco product, or deliver it for introduction, into interstate commerce

Proposed § 1107.3 describes that each applicant who submits an abbreviated report under section 905(j)(1)(A)(ii) of the FD&C Act and receives a letter acknowledging the receipt of an abbreviated report from FDA must maintain all records to support a determination that their exemption request meets the requirements of section 905(j)(3)(A)(i) of the FD&C Act that the modification to a product additive described in the exemption request was a minor modification made to a tobacco product that can be sold under the FD&C Act.

Proposed § 1114.49 would require an applicant to submit a PMTA and all supporting and related documents to FDA in electronic format. Under proposed § 1114.49(c), an applicant that has a waiver would submit a paper submission to the address that FDA provides in the letter granting the waiver. FDA is proposing § 1114.49 based on FDA's general experience with electronic submissions, which FDA has found help facilitate premarket reviews

because electronic submissions typically enable FDA to receive, access, search, and review a submission more quickly than a submission submitted on paper through postal mail.

FDA estimates the burden of this collection of information as follows:

TABLE 21—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
PMTA Submission (ENDS)	200	3.75	750	1,713	1,284,750 [2]

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] This total will not be added to the total burden for this rule as its currently approved under a separate OMB control number.

TABLE 22—ESTIMATED ANNUAL REPORTING BURDEN [1]

"21 CFR part"; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
1114.5 Submission of Standard Bundled PMTAs [2]	1	1	1	1,713	1,713
Premarket Tobacco Product Application (PMTA) Submission (FDA Form 4057)	24	1	24	.50	12
Premarket Tobacco Product Application Amendment And General Correspondence Submission (FDA Form 4057a)	24	14	336	.083	28
1114.41 Reporting Requirements (periodic reports)	3	1	3	50	150
1114.9 Amendments	24	4	96	188	18,048
1114.13 Change in Ownership	1	1	1	1	1
1114.15 Supplemental applications	2	1	2	428	856
1114.17 Resubmissions	3	1	3	565	1,695
1114.41(a)(2) Adverse Experience Reports	3	6	18	.60	11
1114.49(b) and (c) Waiver from Electronic Submission	1	1	1	.25	.25
Total					22,514

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] FDA anticipates that applicants will submit bundled PMTAs, which are single submissions containing PMTAs for a number of similar or related products. We estimate that a bundle will contain on average between 6 and 11 distinct products.

FDA has based these estimates on the full analysis of economic impacts and experience with current PMTA submissions. Table 21 describes the current estimates for OMB control number 0910–0768 which covers the burden for ENDS products PMTA submissions. These estimates were originally published in the Deeming Rule and recently in the **Federal Register** of April 22, 2019 (84 FR 16673). FDA estimates that it will take each respondent approximately 1,500 hours to prepare a PMTA seeking an order from FDA allowing the marketing of a new tobacco product. FDA also estimates that it would on average take an additional 213 hours to prepare an environmental assessment in accordance with the requirements of § 25.40, for a total of 1,713 hours per PMTA application.

Table 22 describes the estimated annual reporting burden per the requirements that the proposed rule would create beyond what is covered in the existing information collection. For this analysis, FDA assumes that firms will submit all applications as PMTA bundles. We also considered updated data on market consolidation that has occurred since the Deeming Rule was published. For originally regulated products we expect to receive one full PMTA submission for a total of 1,713 hours.

FDA developed Form FDA 4057 for use when submitting PMTA single and bundled submissions. FDA estimates that 24 respondents will submit PMTA bundles using this form at .50 (30 minutes) per response. The number 24 is accounting for the bundles of ENDS products and the 1 bundle we expect to receive yearly for originally regulated products. (200 + 1 = 201/8.5 products on average in a bundle) for a total of 12 hours.

FDA developed FDA Form 4057a for use when firms are submitting amendments and other general correspondence. Our estimate is 0.83 (5 minutes) per response to fill out this form. We estimate there will be at least one amendment per application for a total of 28 hours. With most applications being submitted toward the end of our 3-year range, we expect fewer amendments during this period. However, FDA expects correspondence from earlier applications to be submitted during this period.

FDA estimates under proposed § 1114.41 that three respondents will submit a periodic report. This number is based on the average number of periodic report submissions expected between 2020–2022. The preliminary regulatory impact analysis (PRIA) estimates that periodic reports will take between 20 and 80 hours per submission. For this estimate, we use the average of 50 per response for a total of 150 hours.

Under proposed § 1114.9 firms would prepare amendments to PMTA bundles in response to deficiency letters. These amendments contain additional information that we need to complete substantive review. In the PRIA we state in our limited history reviewing PMTAs, we on average issue four deficiency letters. Based on this, we would anticipate four responses back per bundle. Therefore, we estimate that 24 respondents will submit 96 amendments (24 × 4). Assuming 1,500 hours as the time to prepare and submit a full PMTA and amendments may on average take 10 percent to 15 percent of that time (150–225). We averaged this time out (12.5 percent of a full submission preparation time) and arrived at 188 hours per response. FDA

estimates the total burden hours for preparing amendments is 18,048 hours.

Proposed § 1114.13 would allow an applicant to transfer ownership of a PMTA to a new owner. FDA believes this will be infrequent, so we have assigned 1 token hour acknowledging the requirement.

Proposed § 1114.15 is an alternative format of submitting a PMTA that meets the requirements of proposed § 1114.7 that would reduce the burden associated with the submission and review of an application. Our estimated number of 2 respondents is based on the number estimated for postmarket reports which is 3 bundles (which is approximately 26 products). Not all applicants will resubmit modifications to previously authorized products, so we estimate 2 bundles (which is approximately 17 products). FDA estimates further that a supplemental PMTA will take 25 percent of the time it takes to do an original submission (including EA hours) for 428 hours per response. We estimate a total of 856 burden hours for this activity.

Under proposed § 1114.17 an applicant may submit a resubmission for the same tobacco product that received a no marketing order or for a different new tobacco product that results from changes necessary to address the deficiencies outlined in a no marketing order. Based on the PRIA, we are estimating that out of all bundles received in 2020, 2021, and 2022, that an average of 3 bundles are authorized. If we receive 24 bundles yearly, and based on historical data, 58 percent fail at acceptance (down to 8 bundles remaining), 17 percent fail at filing (down to 7 bundles remaining), and 25 percent receive marketing orders (5 left). We estimate that 50 percent will try to resubmit in a year. Thus, this number of respondents is three (rounded up). FDA estimates that a resubmission will take 33 percent of the time it takes to complete an original submission (including EA hours) at 565 hours per response for a total of 1,695 hours.

Under proposed § 1114.41(a)(2), firms would also submit adverse experience reports for tobacco products with marketing orders. We assume the same number of firms submitting periodic reports will submit adverse experience reports. Currently firms may voluntarily submit adverse experience reports using Form FDA 3800 under OMB control number 0910–0645. We have based our estimates on this information collection which estimates that it takes 1 hour (for mandatory reporting) to complete this form for tobacco products for a total of 18 hours. Proposed § 1114.49 would require an applicant to submit a PMTA and all supporting and related documents to FDA in electronic format that FDA can process, review, and archive unless an applicant requests, and FDA grants, a waiver from this requirement. FDA does not believe we will receive many waivers, so we have assigned one respondent to acknowledge the option to submit a waiver. Consistent with our other application estimates for waivers, we believe it would take .25 (15 minutes) per waiver for a total of .25.

TABLE 23—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

"21 CFR part" and "activity"	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total Hours
1114.45 PMTA Records	24	1	24	2	48
1100.204 Grandfathered products records	1	1	1	2	2
1107.3 Exemptions from Substantial Equivalence records	1	1	1	2	2
Total					52

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 23 describes the annual recordkeeping burden per the requirements in this rule. FDA estimates that 26 recordkeepers will maintain records at 2 hours per record. Additionally, the proposed rule, if finalized, would require that firms establish and maintain records related to SE Exemption Requests and Grandfathered products. We expect the burden hours of this proposed rule to be negligible for SE Exemption Requests. Firms would have already established the required records when submitting the SE Exemption Request. Similarly, we expect the hours of this proposed rule to be negligible for any Grandfathered products that have already submitted Standalone Grandfathered Submissions, because firms would have established the required records when submitting the Standalone Grandfathered Submissions. We believe this time is usual and customary for these firms. We estimate that it would take 2 hours per record to establish the required records for a total of 4 hours. Therefore, the total recordkeeping burden hours is estimated to be 52 hours.

The total burden for these new collections of information in this rulemaking is 22,514 reporting hours and 52 recordkeeping hours for a total of 22,566.

To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB (see **ADDRESSES**). All comments should be identified with the title of the information collection.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407(d)), the Agency has submitted the information collection provisions of this proposed rule to OMB for review. These requirements will not be effective until FDA obtains OMB approval. FDA will publish a notice concerning OMB approval of these requirements in the **Federal Register**.

XII. Executive Order 13132: Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive Order requires Agencies to "construe . . . a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute."

Section 916(a)(2) of the FD&C Act (21 U.S.C. 387p) is an express preemption provision. Section 916(a)(2) provides that "no State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of this chapter

relating to . . . premarket review.'' Thus, if this proposed rule is made final, the final rule would create requirements that fall within the scope of section 916(a)(2) of the FD&C Act.

XIII. Consultation and Coordination With Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We have tentatively determined that the rule does not contain policies that would have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. The Agency solicits comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

XIV. Analysis of Environmental Impact

The Agency has determined under § 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. No extraordinary circumstances exist to indicate that the specific proposed action may significantly affect the quality of the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

XV. Preliminary Economic Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 13771 requires that the costs associated with significant new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' This proposed rule is a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed rule, if finalized, would generate net benefits or negligible costs for most affected small entities, we propose to certify that the proposed rule would not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $154 million, using the most current (2018) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

The proposed rule, if finalized, would add a requirement that tobacco manufacturers of grandfathered tobacco products and products that are exempt from the requirements of demonstrating substantial equivalence maintain records to demonstrate that they can legally market their products. For products that receive a PMTA marketing order, the proposed rule, if finalized, would require certain postmarket reporting, including recordkeeping, periodic reporting and adverse experience reporting. The proposed rule also sets forth requirements for the content and format of PMTA and the procedures we follow to review the PMTA.

If finalized, the proposed rule would create cost savings for firms and for us by reducing the number of follow-on submissions for PMTAs. The proposed rule would also create cost savings for us by reducing the cost of review, reducing the number of deficiency letters we would issue during substantive scientific review, and eliminating the need to process unnecessary data. In Table 24, we present the total benefits of the proposed rule. We estimate that average annualized benefits over 20 years would equal $5.54 million at a 7 percent discount rate and $5.44 million at a 3 percent discount rate.

If finalized, the proposed rule would create costs for firms and for us by increasing the number of complete PMTA submissions for deemed and originally regulated tobacco products. Moreover, because this is the first regulation to account for the costs of the PMTA requirements for originally regulated products, we also include the costs to submit and review PMTAs for these tobacco products; we already included the costs to submit and review PMTAs for deemed tobacco products in the final regulatory impact analysis for the Deeming Rule. Firms would incur costs to maintain and submit postmarket reports, and we would incur costs to review postmarket reports. Finally, firms would incur costs to read and understand the rule and costs to maintain records for some grandfathered products. In Table 24, we present the total costs of the proposed rule. We estimate that average annualized costs over 20 years would equal $7.05 million at a 7 percent discount rate and $6.76 million at a 3 percent discount rate.

TABLE 24—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF THE PROPOSED RULE

	Category	Primary estimate	Low estimate	High estimate	Units			Notes
					Year dollars	Discount rate (percent)	Period covered (years)	
Benefits	Annualized Monetized ($m/year).	$5.54	$2.57	$9.23	2017	7	20	All quantified benefits are cost savings.
		5.44	2.54	9.03	2017	3	20	
	Annualized Quantified					7		
						3		
	Qualitative							
Costs	Annualized Monetized ($m/year).	7.05	3.18	11.65	2017	7	20	
		6.76	3.12	11.05	2017	3	20	
	Annualized Quantified					7		
						3		
	Qualitative							

TABLE 24—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF THE PROPOSED RULE—Continued

	Category	Primary estimate	Low estimate	High estimate	Units			Notes
					Year dollars	Discount rate (percent)	Period covered (years)	
Transfers	Federal Annualized Monetized ($m/year).	From:			To:			
	Other Annualized Monetized ($m/year).	From: Products without marketing orders.			To: Products with marketing orders.			
Effects	State, Local, or Tribal Government: None Small Business: None Wages: None Growth: None							

In line with Executive Order 13771, in Table 15 we estimate present and annualized values of costs and cost savings over an infinite time horizon.

TABLE 15—E.O. 13771 SUMMARY TABLE

[In $ millions 2016 dollars, over an infinite time horizon] [a]

	Primary estimate (7%)	Lower bound (7%)	Upper bound (7%)	Primary estimate (3%)	Lower bound (3%)	Upper bound (3%)
Present Value of Costs	$104.04	$47.84	$170.31	$214.04	$101.20	$349.33
Present Value of Cost Savings	83.18	38.76	138.98	177.26	82.15	296.89
Present Value of Net Costs	20.86	(0.23)	44.29	36.78	(14.19)	91.71
Annualized Costs	3.03	1.39	4.96	6.23	2.95	10.17
Annualized Cost Savings	2.42	1.13	4.05	5.16	2.39	8.65
Annualized Net Costs	0.61	(0.01)	1.29	1.07	(0.41)	2.67

[a] Only the primary estimates (mean) sum in simulation results.

We have developed a comprehensive Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full analysis of economic impacts is available in the docket for this proposed rule (Ref. 118) and at *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations.*

XVI. Proposed Effectivre Date

FDA proposes that any final rule that issues based on this proposal become effective 30 days after the final rule publishes in the **Federal Register**.

XVII. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff (see **ADDRESSES**). FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Brunnemann, K.D. et al., ''Formation and Analysis of Tobacco-Specific N-Nitrosamines,'' *Critical Reviews in Toxicology,* 26:2, 121–137, 2008, available at: *https://www.tandfonline.com/doi/abs/10.3109/10408449609017926.*
2. Wayne, G. F. and G. N. Connolly, ''Application, Function, and Effects of Menthol in Cigarettes: A Survey of Tobacco Industry Documents,'' *Nicotine & Tobacco Research,* 6(1):S43–S54, 2004, available at: *https://academic.oup.com/ntr/article/6/Suppl_1/S43/1124538.*
3. Brunnemann, K.D., J.C. Scott, and D. Hoffman. ''N-Nitrosomorpholine and Other Volatile N-Nitrosamines in Snuff Tobacco.'' *Carcinogensis* 3(6):693–696, 1982, available at: *https://academic.oup.com/carcin/article/3/6/693/2476604.*
4. *Institute of Food Technologists, ''Evaluation and Definition of Potentially Hazardous Foods—Chapter 3: Factors That Influence Microbial Growth,'' A Report of the Institute of Food Technologists for the FDA of the HHS, 2001, available at: *https://www.fda.gov/files/food/published/Evaluation-and-Definition-of-Potentially-Hazardous-Foods.pdf.*
5. Gale, N., G. Errington, and K. McAdam, ''Effects of Product Format on Nicotine and TSNA Extraction from Snus Pouches,'' Presentation at the 67th Tobacco Science Research Conference, Williamsburg, VA, September 15–18, 2013, available at: *https://www.researchgate.net/publication/299854728_Effects_of_Product_Format_on_Nicotine_and_TSNA_Extraction_from_Snus_Pouches.*
6. *Form FDA 4057.
7. Lovato, C., A. Watts, and L.F. Stead, ''Impact of tobacco advertising and promotion on increasing adolescent smoking behaviours,'' Cochrane Database of Systematic Review, 10, 2011, available at: *https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD003439/full.*
8. *National Cancer Institute, ''The Role of Media in Promoting and Reducing Tobacco Use,'' *Tobacco Control Monograph* No. 19, NIH Pub No. 07–6242, 2008, available at: *https://cancercontrol.cancer.gov/brp/tcrb/monographs/19/m19_complete.pdf.*
9. Pepper, J.K., S.L. Emery, K.M. Ribsi, et al., ''Effects of advertisement on smokers' interest in trying e-cigarettes: the role of product comparison and visual cues,'' *Tobacco Control,* 23:ii21–ii36, 2014, available at: *https://tobaccocontrol.bmj.com/content/23/suppl_3/iii31.*
10. Dave, D. and Saffer, H., ''Demand for smokeless tobacco: Role of adverstising,'' *Journal of Health Economics,* 32:682–697, 2013, available at: *https://www.sciencedirect.com/science/article/pii/S0167629613000374.*

11. *FDA Form 4057a.
12. *HHS, ''Preventing Tobacco Use Among Youth and Young Adults,'' A Report of the Surgeon General, 2012, available at: *https://www.hhs.gov/surgeongeneral/reports-and-publications/tobacco/index.html.*
13. Weiss, J., S. Cen, D. Shuster, et al., ''Longitudinal effects of pro-tobacco and anti-tobacco messages on adolescent smoking susceptibility,'' *Nicotine and Tobacco Research,* 8(3):455–465, 2006, available at: *https://academic.oup.com/ntr/article/8/3/455/1100269.*
14. Beiner, L., and Albers, A., ''Young Adults: Vulnerable New Targets of Tobacco Marketing,'' *American Journal of Public Health,* 92(2):326–330, 2004, available at: *https://www.ncbi.nlm.nih.gov/pubmed/14759950.*
15. Pucci, L.G., et al., ''Exposure to Brand-Specific Cigarette Advertising in Magazines and Its Impact on Youth Smoking,'' *Preventive Medicine,* 29:313–320, 1999, available at: *https://www.sciencedirect.com/science/article/pii/S0091743599905546?via%3Dihub.*
16. *Beiner, L. and Siegel, M., ''The Role of Tobacco Advertising and Promotion in Smoking Initiation,'' Chapter 13 in *The Role of Media in Promoting and Reducing Tobacco Use,* Tobacco Control Monograph No. 14, National Institutes of Health, National Cancer Institute, NIH Pub No. 02–5086 (2001), available at *https://cancercontrol.cancer.gov/brp/tcrb/monographs/14/m14.pdf.*
17. Wakefield, M., et al., ''Role of the media influencing trajectories of youth smoking,'' *Society for the Study of Addiction,* 98(1):79–103, 2009, available at: *https://onlinelibrary.wiley.com/doi/pdf/10.1046/j.1360-0443.98.s1.6.x.*
18. Feighery, E., et al., ''Seeing, wanting, owning: the relationship between receptivity of tobacco marketing and smoking suceptibility in your people,'' *Tobacco Control,* 7:123–128, 1998, available at: *https://tobaccocontrol.bmj.com/content/7/2/123.*
19. Pierce, J.P, et al., ''Receptivity to Tobacco Advertising and Susceptibility to Tobacco Products,'' *Pediatrics,* 139(6), 2017, available at: *https://pediatrics.aappublications.org/content/139/6/e20163353.*
20. DiFranza, J.R., ''Tobacco Promotion and the Initiation of Tobacco Use: Assessing the Evidence for Causality,'' *Pediatrics,* 117(6), 2006, available at: *https://pediatrics.aappublications.org/content/pediatrics/117/6/e1237.full.pdf.*
21. Agaku, I.T. and Ayo, O., ''The Effect of Exposure to Pro-Tobacco Advertising on Experimentation With Emerging Tobacco Products Among U.S Adolescents,'' *Health Education & Behavior,* 41(3):275–280, 2013, available at: *https://www.ncbi.nlm.nih.gov/pubmed/24347143.*
22. Fischer, P., et al., ''Brand Logo Recognition by Children Aged 3 to 6 Years,'' *JAMA,* 266(22):3145–3148, 1991, available at: *https://jamanetwork.com/journals/jama/fullarticle/393811.*
23. DiFranza, J.R, et al., ''RJR Nabisco's Cartoon Camel Prmotes Camel Cigarettes to Children,'' *JAMA,* 266(22), 1991, available at: *https://jamanetwork.com/journals/jama/fullarticle/393814.*
24. Arnett, J.J., ''Adolescents' responses to cigarette advertisements: links between exposure, liking, and appeal of smoking,'' *Tobacco Control,* 7:129–133, 1998, available at: *https://tobaccocontrol.bmj.com/content/7/2/129.*
25. *HHS, ''E-Cigarette Use Among Youth and Young Adults,'' A Report of the Surgeon General; 2016, available at: *https://e-cigarettes.surgeongeneral.gov/documents/2016_sgr_full_report_non-508.pdf.*
26. *Centers for Disease Control and Prevention, ''Tobacco Use Among Middle and High School Students—United States,'' 2011–2015, Morbidity and Mortality Weekly Report, 65(14):361–367, 2016, available at: *https://www.cdc.gov/mmwr/volumes/65/wr/mm6514a1.htm.*
27. Mantey D.S., Cooper, M.R., Clendennen S.L., et al., ''E-Cigarette marketing exposure is associated with e-cigarette use among U.S. youth,'' *Journal of Adolescent Health,* 58:686–90, 2016, available at: *https://www.ncbi.nlm.nih.gov/pubmed/27080732.*
28. *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, No. 83 .IARC Working Group on the Evaluation of Carcinogenic Risk to Humans. Lyon (FR): International Agency for Research on Cancer; 2004, available at: *https://monographs.iarc.fr/wp-content/uploads/2018/06/mono83.pdf.*
29. Hammond, D., et al., ''Cigarette Yields and Human Exposure: A Comparison of Alternative Testing Regimens,'' *Cancer Epidemiology, Biomarkers & Prevention* 15(8):1495–1501, 2006, available at: *https://cebp.aacrjournals.org/content/15/8/1495.article-info.*
30. Rees, V.W., et al., ''Physical Design Analysis and Mainstream Smoke Constituent Yields of the New Potential Reduced Exposure Product, Marlboro UltraSmooth,'' *Nicotine & Tobacco Research* 9(11):1197–1206, 2007, available at: *https://academic.oup.com/ntr/article/9/11/1197/1063505.*
31. Davis, D. and Neilsen, M., ''Tobacco: Production, Chemistry and Technology,'' Wiley-Blackwell, 1999, available at: *https://www.wiley.com/en-us/Tobacco+%3A+Production%2C+Chemistry+and+Technology-p-9780632047918.*
32. *HHS, ''The Health Consequences of Smoking-The Changing Cigarette,'' A Report of the Surgeon General; 1981, available at: *https://profiles.nlm.nih.gov/ps/access/nnbbsn.pdf.*
33. Agaku, I.T., et al., ''Cigarette Rod Length and Its Impact on Serum Cotinine and Urinary Total NNAL Levels, NHANES 2007–2010,'' *Nicotine & Tobacco Research* 16(1):100–107, 2014
34. Eaker, D.W., ''Dynamic Behavior and Filtration of Mainstream Smoke in the Tobacco Column and Filter,'' R.J. Reynolds Tobacco Co., 103–187, 1990, available at *https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/#id=rtpx0204.*
35. Connolly, G.N., et al., ''Trends in Nicotine Yield in Smoke and Its Relationship with Design Characteristics Among Popular U.S. Cigarette Brands, 1997–2005,'' *Tobacco Control* 16 (5):1–8, 2007, available at: *https://academic.oup.com/ntr/article/16/1/100/1044569.*
36. Minnesota Tobacco Litigation, ''Cigarette Pressure Drop,'' American Tobacco, available at: *https://www.industrydocuments.ucsf.edu/tobacco/docs/#id=kjjw0179.*
37. Spears, A.W., ''Effect of Manufacturing Variables on Cigarette Smoking Composition,'' Lorillard Records, n.d. 65–78, available at *https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/#id=fncx0121.*
38. *Geiss, O., and D. Kotzias., ''Tobacco, Cigarettes and Cigarette Smoke: An Overview,'' European Comission Directorate-General, 2007, available at: *https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/tobacco-cigarettes-and-cigarette-smoke-overview.*
39. Hoffmann, D., and I. Hoffmann., ''The Changing Cigarette: Chemical Studies and Bioassays,'' National Cancer Institute, *Smoking and Tobacco Control Monograph No. 13,* Chapter 5, 159–192, 2001 available at: *https://cancercontrol.cancer.gov/brp/tcrb/monographs/13/m13_5.pdf.*
40. DeBardeleben, M.Z., W.E. Claflin, and W.F. Gannon, ''Role of Cigarette Physical Characteristics on Smoke Composition,'' *Recent Advances in Tobacco Science,* 4:85–110, 1978, available at: *https://www.researchgate.net/publication/308096263_Role_of_cigarette_physical_characteristics_on_smoke_composition.*
41. Owens, W.F., ''Effect of Cigarette Paper on Smoke Yield and Composition,'' *Recent Advances in Tobacco Science,* 4:3–24, 1978, available at: *https://www.industrydocuments.ucsf.edu/tobacco/docs/#id=nqdl0023.*
42. British American Tobacco, ''Lower Ignition Propensity,'' n.d.
43. Baker, R.R., and R.A. Crellin, ''The Diffusion of Carbon Monoxide out of Cigarettes,'' *Beitrage zur Tabakforschung* 9(3):131–140, 1977, available at: *https://content.sciendo.com/view/journals/cttr/9/3/article-p131.xml.*
44. Browne, C.L., ''The Design of Cigarettes,'' Hoeschst Celanese Corporation, 3, 1990, available at: *https://www.industrydocuments.ucsf.edu/tobacco/docs/#id=qllj0086.*
45. World Health Organization, ''The Scientific Basis of Tobacco Product Regulation—Report of a WHO Study Group,'' WHO Technical Report Series 945, 2007, available at: *https://www.who.int/tobacco/global_interaction/tobreg/publications/tsr_955/en/.*
46. Taylor, M.J., ''The Role of Filter Technology in Reduced Yield Cigarettes,'' Text of Presentation for

Kunming World Tobacco Symposium. Filtrona Technology Centre, 2004.
47. Podraza, K., ''Basic Principles of Cigarette Design and Function,'' Presentation to LSRO 10/29–30/01, Philip Morris USA, 2001.
48. O'Connor, R.J., et al., ''How Do Different Cigarette Design Features Influence the Standard Tar Yields of Popular Cigarette Brands Sold in Different Countries?'' *Tobacco Control,* 17:i1-i5, 2008, available at: *https://tobaccocontrol.bmj.com/content/17/Suppl_1/i1.*
49. Dash, S., et al., ''Kinetic Modeling on Drug Release From Controlled Drug Delivery Systems,'' *Acta Poloniae Pharmaceutica—Drug Research* 67(3): 217–223, 2010, available at: *https://ptfarm.pl/pub/File/Acta_Poloniae/2010/3/217.pdf.*
50. Stepanov, I., et al., ''Increased Pouch Sizes and Resulting Changes in the Amounts of Nicotine and Tobacco-Specific N-Nitrosamines in Single Pouches of Camel Snus and Marlboro Snus,'' *Nicotine & Tobacco Research* 14(10):1241–1245, 2012, available at: *https://academic.oup.com/ntr/article/14/10/1241/1077814.*
51. Zhang, H., J. Zhang, and J.B. Streisand., ''Oral Mucosal Drug Delivery—Clinical Pharmacokinetics and Therapeutic Applications,'' *Clinical Pharmacokinetics* 41(9):661–680, 2002, available at: *https://www.ncbi.nlm.nih.gov/pubmed/12126458.*
52. Lewis, S., et al., ''Design, Evaluation and Pharmacokinetic Study of Mucoadhesive Buccal Tablets of Nicotine for Smoking Cessation,'' *Indian Journal of Pharmaceutical Sciences* 68:829–840, 2006, available at: *http://www.ijpsonline.com/articles/design-evaluation-and-pharmacokinetic-study-of-mucoadhesive-buccal-tablets-of-nicotine-for-smoking-cessation.html.*
53. Jambhekar, S.S., and P.J. Breen, ''Drug Dissolution: Significance of Physicochemical Properties and Physiological Conditions,'' *Drug Discovery Today* 18(23/24):1173–1184, 2013, available at: *https://www.ncbi.nlm.nih.gov/pubmed/24042023.*
54. *HHS, ''The Health Consequences of Smoking—Nicotine Addiction,'' A Report of the Surgeon General, 1988, available at: *https://profiles.nlm.nih.gov/NN/B/B/Z/D/.*
55. *Rice, R.L., and M. Scherbak, ''A Method for Measuring the Burn Characteristics of Cigars,'' *Beitrage zur Tabakforschung* 8(5):326–329, 1976, available at: *https://content.sciendo.com/view/journals/cttr/8/5/article-p326.xml.*
56. Rickert, W.S., et al., ''Characterization of Tobacco Products: A Comparative Study of the Tar, Nicotine, and Carbon Monozide Yields of Cigars, Manufactured Cigarettes, and Cigarettes Made From Fine-Cut Tobacco,'' *Preventative Medicine,* 14:226–233, 1985, available at: *https://www.ncbi.nlm.nih.gov/pubmed/4048085.*
57. Hoffmann, D., and E.L. Wynder, ''Smoke of Cigarettes and Little Cigars: An Analytical Comparison,'' *Science* 178(4066):1197–1199, 1972.
58. Schmeltz, I., et al. ''On the Chemistry of Cigar Smoke: Comparisons Between Experimental Little and Large Cigars,'' *Beitrage zur Tabakforschung* 9(6):367–377, 1976, available at: *https://science.sciencemag.org/content/sci/178/4066/1197.full.pdf.*
59. Boyd, D.F., C.D. Briggs, and P.W. Darby, ''Dependence of the Gas Phase Composition of Smoke on the Combustion Temperature of Tobacco Products,'' *Tobacco Science,* 16:160–166, 1972, available at: *https://www.industrydocuments.ucsf.edu/docs/#id=xmpn0207.*
60. Abdelall, F.F., et al. ''Pressure Drop Caused by Abrupt Flow Area Changes in Small Channels,'' *Experimental Thermal and Fluid Science,* 29:425–434, 2005, available at: *https://www.sciencedirect.com/science/article/pii/S0894177704000597.*
61. Saleh, R., and A. Shihadeh, ''Elevated Toxicant Yields With Narghile Waterpipes Smoked Using a Plastic Hose,'' *Food and Chemical Toxicology* 46:1461–1466, 2008, available at: *https://www.sciencedirect.com/science/article/pii/S0278691507005649?via%3Dihub.*
62. Shihadeh, A., ''Investigation of Mainstream Smoke Aerosol of the Argileh Water Pipe,'' *Food and Chemical Toxicology,* 41:143–152, 2003, available at: *https://www.sciencedirect.com/science/article/pii/S027869150200220X?via%3Dihub.*
63. Brinkman, M.C., et al., ''Design and Validation of a Research-Grade Waterpipe Equipped with Puff Topography Analyzer,'' *Nicotine & Tobacco Research* 18(5):785–793, 2016, available at: *https://academic.oup.com/ntr/article/18/5/785/2511010.*
64. Monzer, B., et al. ''Charcoal Emissions as a Source of CO and Carcinogenic PAH in Mainstream Narghile Waterpipe Smoke,'' *Food and Chemical Toxicology,* 26:2991–2995, 2008, available at: *https://www.sciencedirect.com/science/article/pii/S0278691508002780?via%3Dihub.*
65. Zhao, T., et al., ''Effects of Design Parameters and Puff Topography on Heating Coil Temperature and Mainstream Aerosols in Electronic Cigarettes,'' *Atmoshpheric Environment* 134:61–69, 2016, available at: *https://www.sciencedirect.com/science/article/pii/S1352231016301972.*
66. Brown, C.J., and J.M. Cheng, ''Electronic Cigarettes: Product Characterisation and Design Considerations,'' *Tobacco Control,* 23:ii4-ii10, 2013, available at: *https://tobaccocontrol.bmj.com/content/23/suppl_2/ii4.*
67. Kosmider, L., et al., ''Carbonyl Compounds in Electronic Cigarette Vapors: Effects of Nicotine Solvent and Battery Output Voltage,'' *Nicotine & Tobacco Research* 16(10):1319–1326, 2014, available at: *https://academic.oup.com/ntr/article/16/10/1319/2509282.*
68. *Geiss, O., I. Bianchi, and J. Barrero-Moreno, ''Correlation of Volatile Carbonyl Yields Emitted by E-Cigarettes With the Temperature of the Heating Coil and the Perceived Sensorial Quality of the Generated Vapours,'' *International Journal of Hygiene and Environmental Health,* 219:268–277, 2016, available at: *https://www.sciencedirect.com/science/article/pii/S1438463916000158?via%3Dihub.*
69. Talih, S., et al., ''Direct Dripping: A High-Temperature, High-Formaldehyde Emission Electronic Cigarette Use Method,'' *Nicotine & Tobacco Research* 18(4):453–459, 2016, available at: *https://academic.oup.com/ntr/article/18/4/453/2583999.*
70. Talih, S., et al., ''Effects of User Puff Topography, Device Voltage, and Liquid Nicotine Concentration on Electronic Cigarette Nicotine Yield: Measurements and Model Predictions,'' *Nicotine & Tobacco Research* 17(2):150–157, 2015, available at: *https://academic.oup.com/ntr/article/17/2/150/2857963.*
71. *Williams, M., et al., ''Strategies to Reduce Tin and Other Metals in Electronic Cigarette Aerosol,'' *PLoS ONE* 10(9):1–15, 2015, available at: *https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0138933.*
72. *Williams, M., et al., ''Metal and Silicate Particles Including Nanoparticles Are Present in Electronic Cigarette Cartomizer Fluid and Aerosol,'' *PLoS ONE* 8(3):1–11, 2013, available at: *https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0057987.*
73. *Gillman, I.G., et al., ''Effect of Variable Power Levels on the Yield of Total Aerosol Mass and Formation of Aldehydes in E-Cigarette Aerosols,'' *Regulatory Toxicology and Pharmacology* 75:58–65, 2016, available at: *https://www.sciencedirect.com/science/article/pii/S0273230015301549.*
74. *Farsalinos, K.E., et al., ''Evaluation of Electronic Cigarette Use (Vaping) Topography and Estimation of Liquid Consumption: Implications for Research Protocol Standards Definition and for Public Health Authorities' Regulation,'' Intern*ational Journal of Environmental Research and Public Health,* 10:2500–2514, 2013, available at: *https://www.mdpi.com/1660-4601/10/6/2500.*
75. *Behar, R.Z., M. Hua, and P. Talbot, ''Puffing Topography and Nicotine Intake of Electronic Cigarette Users,'' *PLoS ONE,* 1–18, 2015, available at: *https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0117222.*
76. Rudy, S.F. and E.L. Durmowicz, ''Electronic Nicotine Delivery Systems: Overheating, Fires and Explosions,'' *Tobacco Control,* 26:10–18, 2017, available at: *https://tobaccocontrol.bmj.com/content/26/1/10.*
77. Farsalinos, K.E., et al., ''Protocol Proposal for, and Evaluation of, Consistency in Nicotine Delivery From the Liquid to the Aerosol of Electronic Cigarettes Atomizers: Regulatory Implications,'' *Addiction,* 111:1069–1076, 2016,

available at: *https://onlinelibrary.wiley.com/doi/full/10.1111/add.13299.*

78. Sleiman, M., et al., ''Emissions From Electronic Cigarettes: Key Parameters Affecting the Release of Harmful Chemicals,'' *Environmental Science & Technology,* 50:9644–9651, 2016, available at: *https://pubs.acs.org/doi/10.1021/acs.est.6b01741#.*
79. *Williams, M., et al., ''Comparison of the Performance of Cartomizer Style Electronic Cigarettes From Major Tobacco and Independent Manufacturers,'' *PLoS ONE,* 11(2):1–14, 2016, available at: *https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0149251.*
80. Zhang, Y., W. Sumner, and D. Chen, ''In Vitro Particle Size Distributions in Electronic and Conventional Cigarette Aerosols Suggest Comparable Deposition Patterns,'' *Nicotine & Tobacco Research* 15(2):501–508, 2013, available at: *https://academic.oup.com/ntr/article/15/2/501/1061205.*
81. Xing, Y., et al., ''The Impact of $PM_{2.5}$ on the Human Respiratory System,'' *Journal of Thoracic Disease* 8(1):E69–E74, 2016, available at: *https://www.ncbi.nlm.nih.gov/pubmed/26904255.*
82. Qasim, H., et al., ''Impact of Electronic Cigarettes on the Cardiovascular System,'' *Journal of the American Heart Association,* 1–14, 2017, available at: *https://www.ahajournals.org/doi/10.1161/JAHA.117.006353.*
83. Dai, J., et al., ''A Simple Method for the Parallel Quantification of Nicotine and Major Solvent Components in Electronic Cigarette Liquids and Vaped Aerosols,'' *Microchemical Journal* 133:237–245, 2017, available at: *https://www.sciencedirect.com/science/article/pii/S0026265X17300115.*
84. Richter, P. et. al., ''Surveillance of moist snuff: total nicotine, moisture, pH, un-ionized nicotine, and tobacco-specifi nitrosamines,'' *Nicotine and Tobacco Research,* 10(11):1645–1652, 2008, available at: *https://academic.oup.com/ntr/article/10/11/1645/1515595.*
85. Nokhodchi, A., et al., ''The Role of Oral Controlled Release Matrix Tablets in Drug Delivery Systems,'' *BioImpacts,* 2(4):175–187, 2012, available at: *https://www.ncbi.nlm.nih.gov/pubmed/23678458.*
86. Ashley, D., et al., ''Approaches, Challenges, and Experience in Assessing Free Nicotine,'' *Nicotine Psychopharmacology,* 437–456, 2009, available at: *https://link.springer.com/chapter/10.1007/978-3-540-69248-5_15.*
87. Henningfield, J., London, E., and Pogun, S., Eds., ''Nicotine Psychopharmacology,'' *Handbook of Experimental Pharmacology,* Volume 192, 2009, available at: *https://link.springer.com/chapter/10.1007%2F978-3-540-69248-5_18#citeas.*
88. Teichert, A., P. Brossard, and M.L. Felber, et al., ''Evaluation of Nicotine Pharmacokinetics and Subjective Effects following Use of a Novel Nicotine Delivery System,'' *Nicotine Tob Res,* 20(4):458–465, 2018, available at: *https://academic.oup.com/ntr/article/20/4/458/3800072.*
89. Talih, S., R. Salman, and R. El-Hage et al., ''Characteristics and toxicant emissions of JUUL electronic cigarettes,'' *Tob Control,* 0:1–3, 2019, available at *https://tobaccocontrol.bmj.com/content/early/2019/02/21/tobaccocontrol-2018-054616.*
90. Goniewicz, M.L., R. Boykan, and C.R. Messina, ''High exposure to nicotine among adolescents who use Juul and other vape pod systems ('pods'),'' *Tob Control,* 0(0):1–2, 2018, available at: *https://tobaccocontrol.bmj.com/content/early/2018/08/30/tobaccocontrol-2018-054565.*
91. Smith, T.E., ''A Literature Review of Aging and Fermentation of Tobacco,'' *Brown & Williamson Records,* 1964, available at *https://www.industrydocuments library.ucsf.edu/tobacco/docs/fpgv0147.*
92. Cornell, A., W.F. Cartwright, and T.A. Bertinuson, ''Influence of Microorganisms (Fermantation) on the Chemistry of Tobacco, 1979,'' Food and Agriculture Organization of the United Nations, 5:v.27–62, 2012, available at: *http://agris.fao.org/agris-search/search.do?recordID=US19830880784.*
93. Schulthess, D., ''Project Clover Marlboro—Roll Your Own Report on the Microbial Analysis,'' *Philip Morris Records,* 1984, available at: *https://www.industrydocuments.ucsf.edu/docs/#id=zzwl0112.*
94. Geiss, V.L., ''Control and Use of Microbes in Tobacco Product Manufacturing,'' *Recent Advances in Tobacco Science,* 15:182–212, 1989, available at: *https://www.industrydocuments.ucsf.edu/docs/#id=krfd0003.*
95. Andersen, R.A., et al., ''pH Changes in Smokeless Tobaccos Undergoing Nitrosation During Prolonged Storage: Effects of Moisture, Temperature, and Duration,'' *Journal of Agriculture and Food Chemistry.* 41:968–972, 1993, available at: *https://pubs.acs.org/doi/abs/10.1021/jf00030a026.*
96. Mutasa, E.S., K.J. Seal, and N. Magan, ''The Water Content/Water Activity Relationship of Cured Tobacco and Water Relations of Associated Spoilage Fungi,'' *International Biodeterioration,* 26:381–896, 1990, available at: *https://www.sciencedirect.com/science/article/pii/026530369090003P.*
97. St. Charles, F.K., ''Reduction of the Water Activity of Wet Snuff,'' Brown and Williamson Tobacco Corporation, 1989, available at: *https://www.industrydocuments.ucsf.edu/docs/#id=ymjx0138.*
98. DiGiacomo, M., Paolino, M., et al., ''Microbial Community Structure and Dynamics of Dark Fire-Cured Tobacco Fermentation,'' *Applied and Environmental Microbiology,* 73(3):825–837, 2007, available at: *https://aem.asm.org/content/73/3/825.*
99. Andersen, R.A., H.R. Burton, P.D. Fleming, et al., ''Effect of Storage Conditions on Nitrosated, Acylated, and Oxidized Pyridine Alkaloid Derivatives in Smokeless Tobacco Products,'' *Cancer Research,* 49:5895–5900, 1989, available at: *https://cancerres.aacrjournals.org/content/49/21/5895.*
100. Rutqvist, L.E., et al., ''Swedish snus and the GothiaTek standard,'' *Harm Reduction Journal,* 8(11):1–9, 2011, available at: *https://harmreductionjournal.biomedcentral.com/articles/10.1186/1477-7517-8-11.*
101. Fisher. M.T., et al., ''Sources of and technical approaches for the abatement of tobacco specific nitrosamine formation in moist smokeless tobacco products,'' *Food and Chemical Toxicology,* 50:942–948, 2012, available at: *https://www.sciencedirect.com/science/article/pii/S0278691511006260?via%3Dihub.*
102. Law, A., et al., ''Tobacco, Microbes, and Carcinogens: Correlation Between Tobacco Cure Conditions, Tobacoo-Specific Nitrosamine Content, and Cured Leaf Microbial Community,'' *Environmental Microbiology,* 72:120–129, 2016, available at: *https://link.springer.com/article/10.1007%2Fs00248-016-0754-4.*
103. Shi, H., et al., ''Changes in TSNA Contents during Tobacco Storage and the Effect of Temperature and Nitrate Level on TSNA Formation,'' *Journal for Agricultural and Food Chemistry,* 61:11588–11594, 2013, available at: *https://pubs.acs.org/doi/10.1021/jf404813m.*
104. Sapkota, A. and Chorpyk, J., ''Temporal Variations in Cigarette Tobacco Bacterial Community Composition and Tobacco-Specific Nitrosamine Content Are Influenced by Brand and Storage Conditions,'' *Frontiers in Microbiology,* 8(358):1–14, 2017, available at: *https://www.frontiersin.org/articles/10.3389/fmicb.2017.00358/full.*
105. Goniewicz, M.L., T. Kuma, M. Gawron, et al., ''Nicotine Levels in Electronic Cigarettes,'' *Nicotine & Tobacco Research,* 15(1):158–166, 2013, available at: *https://academic.oup.com/ntr/article/15/1/158/1105400.*
106. *Farsalinos, K.E., et al., ''Nicotine Levels and Presence of Selected Tobacco-Derived Toxins in Tobacco Flavoured Electronic Cigarette Refill Liquids,'' *International Journal of Environmental Research and Public Health,* 12:3439–3452, 2015, available at: *https://www.mdpi.com/1660-4601/12/4/3439.*
107. Davis, B., et al., ''Nicotine Concentrations in Electronic Cigarette Refill and Do-It-Yourself Fluids,'' *Nicotine & Tobacco Research,* 17(2):134–141, 2015, available at: *https://academic.oup.com/ntr/article/17/2/134/1258864.*
108. Brownson, E.G., C.M. Thompson, S. Goldsberry, et al., ''Explosion Injuries from E-Cigarettes,'' *N. Engl. J. Med.,* 375:1400–1402, 2016, available at: *https://www.nejm.org/doi/full/10.1056/NEJMc1608478.*
109. Le Houezec, J., ''Role of nicotine pharmacokinetics in nicotine addiction

and nicotine replacement therapy: a review,'' *The International Journal of Tuberculosis and Lung Disease,* 7(9):811–819, 2003, available at: *https://www.ingentaconnect.com/content/iuatld/ijtld/2003/00000007/00000009/art00002%3bjsessionid=1dhaw06j75tmx.x-ic-live-02.*

110. Oldendorf, W.H., ''Some Relationships Between Addiction and Drug Delivery to the Brain,'' 120:13–25, 1992, available at: *https://www.ncbi.nlm.nih.gov/pubmed/1501682.*
111. Gorelick, D.A., ''The Rate Hypothesis and Agonist Substitution Approaches to Cocaine Abuse Treatment,'' *Advances in Pharmacology,* 42:995–997, 1997, available at: *https://www.sciencedirect.com/science/article/abs/pii/S105435890860914X.*
112. *HHS, ''The Health Consequences of Smoking—50 Years of Progress,'' A Report of the Surgeon General, 2014, available at: *https://www.hhs.gov/surgeongeneral/reports-and-publications/tobacco/index.html.*
113. Kasza, K.A., et al., ''Tobacco-Product by Adults and Youths in the United States in 2013 and 2014,'' *New England Journal of Medicine,* 376(4):342–353, 2017, available at: *https://www.nejm.org/doi/full/10.1056/nejmsa1607538.*
114. *Jamal, A., et al., ''Tobacco Use Among Middle and High School Students—United States, 2011–2016,'' *Morbidity and Mortality Weekly Report,* 66.23, 2017, available at: *https://www.cdc.gov/mmwr/volumes/66/wr/mm6623a1.htm.*
115. Shahab, L., et al., ''Nicotine, Carcinogen, and Toxin Exposure in Long-Term E-Cigarette and Nicotine Replacement Therapy Users: A Cross-Sectional Study,'' *Annals of Internal Medicine* 166(6):390–400, 2017, available at: *https://annals.org/aim/fullarticle/2599869/nicotine-carcinogen-toxin-exposure-long-term-e-cigarette-nicotine-replacement.*
116. O'Connell, G., D.W. Graff, and C.D. D'Ruiz, ''Reductions in Biomarkers of Exposure (BoE) to Harmful or Potentially Harmful Constituents (HPHCs) Following Partial or Complete Substitution of Cigarettes with Electronic Cigarettes in Adult Smokers,'' *Toxicology Mechanisms and Methods,* 26(6):453–464, 2016, available at: *https://www.ncbi.nlm.nih.gov/pubmed/27401591.*
117. Song, A.V., et al., ''Perceptions of Smoking-Related Risks and Benefits as Predictors of Adolescent Smoking Initiation,'' *American Journal of Public Health Research and Practice* 99(3):487–492, 2009, available at: *https://ajph.aphapublications.org/doi/abs/10.2105/AJPH.2008.137679.*
118. *Preliminary Regulatory Impact Analysis; Initial Regulatory Flexibility Analysis; Unfunded Mandates Reform Act Analysis, Premarket Tobacco Product Applications and Recordkeeping Requirements; Proposed Rule.

List of Subjects

21 CFR Part 1100

Administrative practice and procedure, Smoke, Smoking, Tobacco, Tobacco products.

21 CFR Part 1107

Administrative practice and procedure, Smoke, Smoking, Tobacco, Tobacco products.

21 CFR Part 1114

Administrative practice and procedure, Smoke, Smoking, Tobacco, Tobacco products.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that chapter I of title 21 of the Code of Federal Regulations be amended as follows:

PART 1100—GENERAL

■ 1. The authority citation for part 1100 is revised to read as follows:

Authority: 21 U.S.C. 371, 374, 387a(b), 387e, and 387i; Pub. L. 111–31.

■ 2. Revise the part heading to read as set forth above.

§§ 1100.1, 1100.2, 1100.3, and 1100.5 [Desingated as Subpart A]

■ 3. Designate §§ 1100.1, 1100.2, 1100.3, and 1100.5 as subpart A under the following heading:

Subpart A—Tobacco Products Subject to FDA Authority

Subpart B [Reserved]

■ 4. Add reserved subpart B.

■ 5. Add subpart C, consisting of §§ 1100.200, 1100.202, and 1100.204, to read as follows:

Subpart C—Maintenance of Records Demonstrating That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007

Sec.
1100.200 Purpose and scope.
1100.202 Definitions.
1100.204 Recordkeeping requirements.

Subpart C— Maintenance of Records Demonstrating That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007

§ 1100.200 Purpose and scope.

This subpart sets out requirements under the Federal Food, Drug, and Cosmetic Act for the maintenance of records by tobacco product manufacturers that introduce a grandfathered tobacco product, or deliver it for introduction, into interstate commerce.

§ 1100.202 Definitions.

For the purposes of this part:

Commercially marketed means the offering of a tobacco product for sale to consumers in all or parts of the United States. Factors FDA may consider include advertising or any other manner used to communicate, that the tobacco product is available for purchase. Tobacco products that are exclusively in a test market are not commercially marketed.

Grandfathered tobacco product means a tobacco product that was commercially marketed in the United States as of February 15, 2007, and does not include a tobacco product exclusively in test markets as of that date. A grandfathered tobacco product is not subject to the premarket requirements of section 910 of the Federal Food, Drug, and Cosmetic Act.

Tobacco product means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). The term ''tobacco product'' does not mean an article that under the Federal Food, Drug, and Cosmetic Act is a drug (section 201(g)(1)), a device (section 201(h)), or a combination product (section 503(g)).

Tobacco product manufacturer means any person, including any repacker or relabeler, who—

(1) Manufactures, fabricates, assembles, processes, or labels a tobacco product; or

(2) Imports a finished tobacco product for sale or distribution in the United States.

§ 1100.204 Recordkeeping requirements.

(a) Any tobacco product manufacturer that introduces a grandfathered tobacco product, or delivers it for introduction, into interstate commerce must maintain records that demonstrate that the tobacco product was commercially marketed in the United States as of February 15, 2007, as described in this subpart. These records may include items such as:

(1) Dated copies of advertisements;
(2) Dated catalog pages;
(3) Dated promotional material;
(4) Dated trade publications;
(5) Dated bills of lading;
(6) Dated freight bills;
(7) Dated waybills;

(8) Dated invoices;
(9) Dated purchase orders;
(10) Dated customer receipts;
(11) Dated manufacturing documents;
(12) Dated distributor or retailer inventory lists; or
(13) Any other dated document that demonstrates that the tobacco product was commercially marketed (not exclusively in test markets) in the United States as of February 15, 2007.

(b) All records must be legible, in the English language, and available for inspection and copying by officers or employees duly designated by the Secretary. Documents that have been translated from another language into English (*e.g.,* advertisements written in a language other than English) must be accompanied by the original language version of the document, a signed statement by an authorized representative of the manufacturer certifying that the English language translation is complete and accurate, and a brief statement of the qualifications of the person that made the translation.

(c) All records required by this subpart must be retained for a period of not less than 4 years after the date either FDA makes a determination that the product is a grandfathered tobacco product, or the tobacco product manufacturer permanently ceases the introduction or delivery for introduction into interstate commerce of the tobacco product, whichever occurs sooner.

PART 1107—EXEMPTION REQUESTS AND SUBSTANTIAL EQUIVALENCE REPORTS

■ 6. The authority citation for part 1107 is revised to read as follows:

Authority: 21 U.S.C. 371, 374, 387e(j), 387i, 387j.

■ 7. Revise the part heading as set forth above.

■ 8. Add § 1107.3 to subpart A to read as follows:

§ 1107.3 Recordkeeping.

(a) *Definition.* The term ''grandfathered tobacco product'' means a tobacco product that was commercially marketed in the United States on February 15, 2007. The term does not include a tobacco product exclusively in test markets as of that date. A grandfathered tobacco product is not subject to the premarket requirements of section 910 of the Federal Food, Drug, and Cosmetic Act.

(b) *Record maintenance.* (1) Each applicant who submits an abbreviated report under section 905(j)(1)(A)(ii) of the Federal Food, Drug, and Cosmetic Act and receives a letter acknowledging the receipt of an abbreviated report from FDA must maintain all records (including those created by third parties on the applicant's behalf) that support the submission. Such records may include, but are not limited to:

(i) A copy of the abbreviated report and, if applicable, the exemption request and all amendments thereto.

(ii) A copy of the acknowledgement letter issued in response to an abbreviated report and, if applicable, the exemption order issued by FDA.

(iii) Documents related to formulation of product, design specifications, packaging, and related items.

(iv) Documents showing design specifications are consistently met.

(v) Product labeling.

(vi) Documents related to product packing and storage conditions.

(vii) Analytical test method records, including:

(A) Performance criteria.

(B) Validation or verification documentation; and

(C) Reports/results from these test methods.

(viii) Source data and related summaries.

(2) An applicant that submits an abbreviated report for a modification to a grandfathered tobacco product must also maintain records demonstrating that the grandfathered tobacco product was commercially marketed in the United States as of February 15, 2007, such as the records described in § 1100.204 of this chapter.

(3) An applicant that submits an abbreviated report for a modification to a tobacco product that received an exemption (and for which the applicant has submitted an abbreviated report under section 905(j)(1)(A)(ii)) of the Federal Food, Drug, and Cosmetic Act, or a substantial equivalence (SE) or premarket tobacco product application marketing order must maintain a copy of the exemption order or marketing order.

(4) An applicant that submits an abbreviated report for a modification to a tobacco product marketed consistent with section 910(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act, but for which an SE order has not been granted, must maintain all communications to and from FDA relating to the pending SE Report (*e.g.,* acknowledgement letter, deficiency letters), including the SE Report.

(c) *Record quality.* All records must be legible, in the English language, and available for inspection and copying by officers or employees duly designated by the Secretary. Documents that have been translated from another language into English (*e.g.,* advertisements written in a language other than English) must be accompanied by the original language version of the document, a signed statement by an authorized representative of the manufacturer certifying that the English language translation is complete and accurate, and a brief statement of the qualifications of the person that made the translation.

(d) *Record retention.* All records required by this subpart must be retained for a period of 4 years from the date that an acknowledgement letter is issued by FDA.

■ 9. Add part 1114 to subchapter K to read as follows:

PART 1114—PREMARKET TOBACCO PRODUCT APPLICATIONS

Subpart A—General Provisions

Sec.
1114.1 Scope.
1114.3 Definitions.

Subpart B—Premarket Tobacco Product Applications

1114.5 Application submission.
1114.7 Required content and format.
1114.9 Amendments.
1114.11 Withdrawal by applicant.
1114.13 Change in ownership of an application.
1114.15 Supplemental applications.
1114.17 Resubmissions.

Subpart C—FDA Review

1114.25 Communication between FDA and applicants.
1114.27 Review procedure.
1114.29 FDA action on an application.
1114.31 Issuance of a marketing order.
1114.33 Issuance of a no marketing order.
1114.35 Withdrawal of a marketing order.
1114.37 Temporary suspension of a marketing order.

Subpart D—Postmarket Requirements

1114.39 Postmarket changes.
1114.41 Reporting requirements.

Subpart E—Miscellaneous

1114.45 Record retention.
1114.47 Confidentiality.
1114.49 Electronic submission.

Authority: 21 U.S.C. 371, 374, 387a, 387i, and 387j.

Subpart A—General Provisions

§ 1114.1 Scope.

(a) This part sets forth the procedures and requirements for submitting a premarket tobacco product application (PMTA), the general procedures FDA will follow when evaluating a PMTA, and postmarket reporting requirements.

(b) This part does not apply to modified risk tobacco product applications, except that single applications under section 911(l)(4) of

the Federal Food, Drug, and Cosmetic Act seeking both a marketing order under section 910(c) of the Federal Food, Drug, and Cosmetic Act and an order under section 911(g) of the Federal Food, Drug, and Cosmetic Act must satisfy the requirements of this part in addition to the requirements of section 911 of the Federal Food, Drug, and Cosmetic Act.

(c) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

§ 1114.3 Definitions.

For purposes of this part:

Accessory means any product that is intended or reasonably expected to be used with or for the human consumption of a tobacco product; does not contain tobacco and is not made or derived from tobacco; and meets either of the following:

(1) Is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product; or

(2) Is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a tobacco product, but:

(i) Solely controls moisture and/or temperature of a stored tobacco product; or

(ii) Solely provides an external heat source to initiate but not maintain combustion of a tobacco product.

Additive means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), except that such term does not include tobacco, or a pesticide chemical residue in or on raw tobacco or a pesticide chemical.

Adverse experience means any unfavorable physical or psychological effect in a person that is temporally associated with the use of or exposure to a tobacco product, whether or not the person uses the tobacco product, and whether or not the effect is considered to be related to the use of or exposure to the tobacco product.

Applicant means any person that submits a premarket tobacco product application to receive a marketing order for a new tobacco product.

Brand means a variety of tobacco product distinguished by the tobacco used, tar content, nicotine content, flavoring used, size, filtration, packaging, logo, registered trademark, brand name(s), identifiable pattern of colors, or any combination of such attributes.

Characteristics means the materials, ingredients, design, composition, heating source, or other features of a tobacco product.

Component or *part* means

(1) Any software or assembly of materials intended or reasonably expected:

(i) To alter or affect the tobacco product's performance, composition, constituents, or characteristics; or

(ii) To be used with or for the human consumption of a tobacco product.

(2) Component or part excludes anything that is an accessory of a tobacco product.

Composition means the materials in a tobacco product, including ingredients, additives, and biological organisms. The term includes the manner in which the materials, for example, ingredients, additives, and biological organisms, are arranged and integrated to produce a tobacco product.

Constituent means any chemical or chemical compound in a tobacco product or in tobacco smoke or emission that is or potentially is inhaled, ingested, or absorbed into the body.

Container closure system means any packaging materials that are a component or part of the tobacco product.

Design means the form and structure concerning, and the manner in which components or parts, ingredients, software, and materials are integrated to produce a tobacco product.

Finished tobacco product means a tobacco product, including all components and parts, sealed in final packaging (*e.g.,* filters or filter tubes sold to consumers separately or as part of kits).

Harmful or potentially harmful constituent or *HPHC* means any chemical or chemical compound in a tobacco product or tobacco smoke or emission that:

(1) Is or potentially is inhaled, ingested, or absorbed into the body, including as an aerosol or any other emission; and

(2) Causes or has the potential to cause direct or indirect harm to users or nonusers of tobacco products.

Heating source means the source of energy used to burn or heat the tobacco product.

Ingredient means tobacco, substances, compounds, or additives contained within or added to the tobacco, paper, filter, or any other component or part of a tobacco product, including substances and compounds reasonably expected to be formed through a chemical reaction during tobacco product manufacturing.

Label means a display of written, printed, or graphic matter upon the immediate container of any article.

Labeling means all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article.

Line data means an analyzable dataset of observations for each individual study participant, laboratory animal, or test replicate.

Marketing order means the order described in section 910(c)(1)(A)(i) of the Federal Food, Drug, and Cosmetic Act stating that the new tobacco product may be introduced or delivered for introduction into interstate commerce.

Material means an assembly of ingredients. Materials are assembled to form the tobacco product or components or parts of a tobacco product.

New tobacco product means:

(1) Any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or

(2) Any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.

No marketing order means the order described in section 910(c)(1)(A)(ii) of the Federal Food, Drug, and Cosmetic Act stating that the product may not be introduced or delivered for introduction into interstate commerce.

Other features means any distinguishing qualities of a tobacco product similar to those specifically enumerated in section 910(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act. Such other features include harmful and potentially harmful constituents and any other product characteristics that relate to the chemical, biological, and physical properties of the tobacco product.

Package or *packaging* means a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane), in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers.

Premarket tobacco product application or *PMTA* means the application described in section 910(b) of the Federal Food, Drug, and Cosmetic Act. This term includes the initial

premarket tobacco product application and all subsequent amendments.

Serious adverse experience means an adverse experience that results in any of the following outcomes:

(1) Death;

(2) A life-threatening condition or illness;

(3) Inpatient hospitalization or prolongation of existing hospitalization;

(4) A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;

(5) A congenital anomaly/birth defect; or

(6) Any other adverse experience that, based upon appropriate medical judgment, may jeopardize the health of a person and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

Tobacco product means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). The term ''tobacco product'' does not mean an article that under the Federal Food, Drug, and Cosmetic Act is a drug (section 201(g)(1)), a device (section 201(h)), or a combination product (section 503(g)).

Tobacco product manufacturer means any person, including a repacker or relabeler, who:

(1) Manufactures, fabricates, assembles, processes, or labels a tobacco product, or

(2) Imports a finished tobacco product for sale or distribution in the United States.

Unexpected adverse experience means an adverse experience occurring in one or more persons in which the nature, severity, or frequency of the experience is not consistent with:

(1) The known or foreseeable risks of adverse experiences associated with the use or exposure to the tobacco product as described in the PMTA and other relevant sources of information, such as the product labeling and postmarket reports;

(2) The expected natural progression of any underlying disease, disorder, or condition of the persons(s) experiencing the adverse experience and the person's predisposing risk factor profile for the adverse experience; or

(3) The results of nonclinical investigations.

Subpart B—Premarket Tobacco Product Applications

§ 1114.5 Application submission.

An applicant may submit a PMTA to demonstrate that a new tobacco product meets the requirements to receive a marketing order. A new tobacco product may not be introduced or delivered for introduction into interstate commerce under this part until FDA has issued a marketing order for the product.

§ 1114.7 Required content and format.

(a) *General.* The PMTA must contain sufficient information for FDA to determine whether any of the grounds for denial specified in section 910(c)(2) of the Federal Food, Drug, and Cosmetic Act apply. The application must contain the following sections:

(1) General information (as described in paragraph (c) of this section);

(2) Descriptive information (as described in paragraph (d) of this section);

(3) Product samples (as described in paragraph (e) of this section);

(4) Labeling (as described in paragraph (f) of this section);

(5) Statement of compliance with part 25 of this chapter (as described in paragraph (g) of this section);

(6) Summary (as described in paragraph (h) of this section);

(7) Product formulation (as described in paragraph (i) of this section);

(8) Manufacturing (as described in paragraph (j) of this section);

(9) Health risk investigations (as described in paragraph (k) of this section); and

(10) The effect on the population as a whole (as described in paragraph (l) of this section);

(11) Certification statement (as described in paragraph (m) of this section).

(b) *Format.* (1) The application must be submitted using the form(s) that FDA provides, contain a comprehensive index (*i.e.,* a listing of files and data associated with those files) and table of contents, be well-organized and legible, and be written in English. Documents that have been translated from another language into English (*e.g.,* original study documents written in a language other than English) must be accompanied by: The original language version of the document, signed a statement by an authorized representative of the manufacturer certifying that the English language translation is complete and accurate, and a brief statement of the qualifications of the person that made the translation. As described in § 1114.49, the applicant must submit the application and all information supporting the application in an electronic format that FDA can process, read, review, and archive, unless FDA has granted a waiver.

(2) An applicant may include content in a submission by cross-reference to a tobacco product master file or a pending modified risk tobacco product application for the same tobacco product. Applicants using a master file must provide documentation of their right of reference for the master file and clearly identify the specific content being incorporated into the PMTA submission. Except as provided for in §§ 1114.15 and 1114.17, FDA will not consider content included by cross-reference to other sources of information outside of the submission.

(c) *General information.* The applicant must, by using the form FDA provides, specify the following general information:

(1) Applicant name, address, and contact information;

(2) Authorized representative or U.S. agent (for a foreign applicant), including the name, address, and contact information;

(3) The following information to uniquely identify the product:

(i) Manufacturer;

(ii) Product name(s), including brand and subbrand (or other commercial name(s) used in commercial distribution); and

(iii) The product category, product subcategory, and product properties as provided in the following table. If the product does not have a listed product property, such as ventilation or characterizing flavor, the application must state ''none'' for that property.

TABLE 1 TO § 1114.7(c)(3)(iii)

Tobacco product category:	Tobacco product subcategory:	Product properties:
(A) Cigarettes	*(1)* Combusted, Filtered	—Package type (*e.g.,* hard pack, soft pack, clam shell). —Product quantity (*e.g.,* 20 cigarettes). —Length (*e.g.,* 89 millimeters (mm), 100 mm). —Diameter (*e.g.,* 6 mm, 8.1 mm).

TABLE 1 TO § 1114.7(c)(3)(iii)—Continued

Tobacco product category:	Tobacco product subcategory:	Product properties:
		—Ventilation (*e.g.,* 0%, 10%, 25%). —Characterizing flavor(s) (*e.g.,* none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(2) Combusted, Nonfiltered	—Package type (*e.g.,* hard pack, soft pack, clam shell). —Product quantity (*e.g.,* 20 cigarettes). —Length (*e.g.,* 89 mm, 100 mm). —Diameter (*e.g.,* 6 mm, 8.1 mm). —Characterizing flavor(s) (*e.g.,* none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(3) Combusted, Bidi, and Other	—Package type (*e.g.,* hard pack, soft pack, clam shell). —Product quantity (*e.g.,* 20 cigarettes). —Length (*e.g.,* 89 mm, 100 mm). —Diameter (*e.g.,* 6 mm, 8.1 mm). —Ventilation (*e.g.,* 0%, 10%, 25%) (if applicable). —Characterizing flavor(s) (*e.g.,* none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(4) Noncombusted (*e.g.,* heated tobacco).	—Package type (*e.g.,* hard pack, soft pack, clam shell). —Product quantity (*e.g.,* 20 cigarettes, 25 cigarettes). —Length (*e.g.,* 89 mm, 100 mm). —Diameter (*e.g.,* 6 mm, 8.1 mm). —Ventilation (*e.g.,* 0%, 10%, 25%). —Characterizing flavor(s) (*e.g.,* none, menthol). —Source of energy (*e.g.,* charcoal, electrical heater). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(5) Cigarette, Co-Package	—For a new co-packaged tobacco product composed of multiple cigarette tobacco products, include, as applicable, all properties for each individual tobacco product, as identified above.
(B) Roll-Your-Own Tobacco Products.	*(1)* Roll-Your-Own Tobacco Filler	—Package type (*e.g.,* bag, pouch). —Product quantity (*e.g.,* 20 g, 40 grams (g)). —Characterizing flavor(s) (*e.g.,* none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(2) Rolling Paper	—Package type (*e.g.,* bag, box, booklet). —Product quantity (*e.g.,* 200 papers). —Length (*e.g.,* 79 mm, 100 mm, 110 mm). —Width (*e.g.,* 45 mm, 60 mm, 78 mm). —Characterizing flavor(s) (*e.g.,* none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(3) Cigarette Tube, Filtered	—Package type (*e.g.,* bag, box). —Product quantity (*e.g.,* 100 tubes, 200 tubes). —Length (*e.g.,* 89 mm, 100 mm). —Diameter (*e.g.,* 6 mm, 8.1 mm). —Ventilation (*e.g.,* 0%, 10%, 25%). —Characterizing flavor(s) (*e.g.,* none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(4) Cigarette Tube, Nonfiltered	—Package type (*e.g.,* bag, box). —Product quantity (*e.g.,* 100 tubes, 200 tubes). —Length (*e.g.,* 89 mm, 100 mm). —Diameter (*e.g.,* 6 mm, 8.1 mm). —Characterizing flavor(s) (*e.g.,* none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(5) Filter	—Package type (*e.g.,* bag, box). —Product quantity (*e.g.,* 100 filters, 200 filters). —Length (*e.g.,* 8 mm, 12 mm). —Diameter (*e.g.,* 6 mm, 8.1 mm). —Ventilation (*e.g.,* 0%, 10%, 25%). —Characterizing flavor(s) (*e.g.,* none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(6) Paper Tip	—Package type (*e.g.,* bag, box). —Product quantity (*e.g.,* 200 tips, 275 tips). —Length (*e.g.,* 12 mm, 15 mm). —Width (*e.g.,* 27 mm). —Characterizing flavor(s) (*e.g.,* none, menthol).

TABLE 1 TO § 1114.7(c)(3)(iii)—Continued

Tobacco product category:	Tobacco product subcategory:	Product properties:
		—Additional properties needed to uniquely identify the tobacco product (if applicable).
	(7) Roll-Your-Own, Co-Package	—For a new tobacco product composed of multiple roll-your-own tobacco products, include all applicable properties for each tobacco product (*e.g.,* roll-your own tobacco, rolling paper, filtered cigarette tube, nonfiltered cigarette tube, filter, paper tip) as identified above. —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(8) Other	—Package type (*e.g.,* bag, box). —Product quantity. —Characterizing flavor(s) (*e.g.,* none, menthol). —Additional properties needed to uniquely identify the tobacco product.
(C) Smokeless Tobacco Products	*(1)* Moist Snuff, Loose	—Package type (*e.g.,* plastic can with metal lid, plastic can with plastic lid). —Product quantity (*e.g.,* 20 g, 30 g). —Tobacco cut size (*e.g.,* 5 mm, 7 mm). —Characterizing flavor(s) (*e.g.,* none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(2) Moist Snuff, Portioned	—Package type (*e.g.,* plastic can with metal lid, plastic can with plastic lid). —Product quantity (*e.g.,* 22.5 g, 20 g). —Portion count (*e.g.,* 15 pouches, 20 pieces). —Portion mass (*e.g.,* 1.5 g/pouch, 2 g/piece). —Portion length (*e.g.,* 15 mm, 20 mm). —Portion width (*e.g.,* 10 mm, 15 mm). —Portion thickness (*e.g.,* 5 mm, 7 mm). —Tobacco cut size (*e.g.,* 5 mm, 7 mm). —Characterizing flavor(s) (*e.g.,* none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(3) Snus, Loose	—Package type (*e.g.,* plastic can with metal lid, plastic can with plastic lid). —Product quantity (*e.g.,* 20 g, 2 ounces). —Tobacco cut size (*e.g.,* 5 mm, 7 mm). —Characterizing flavor(s) (*e.g.,* none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(4) Snus, Portioned	—Package type (*e.g.,* plastic can with metal lid, plastic can with plastic lid). —Product quantity (*e.g.,* 22.5 g, 20 g). —Portion count (*e.g.,* 15 pouches, 20 pieces). —Portion mass (*e.g.,* 1.5 g/pouch, 2 g/piece). —Portion length (*e.g.,* 15 mm, 20 mm). —Portion width (*e.g.,* 10 mm, 15 mm). —Portion thickness (*e.g.,* 5 mm, 7 mm). —Tobacco cut size (*e.g.,* 5 mm, 7 mm). —Characterizing flavor(s) (*e.g.,* none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(5) Dry Snuff, Loose	—Package type (*e.g.,* plastic can with metal lid, plastic can with plastic lid). —Product quantity (*e.g.,* 20 g, 2 ounces). —Tobacco cut size (*e.g.,* 0.05 mm, 0.07 mm). —Characterizing flavor(s) (*e.g.,* none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(6) Dry Snuff, Portioned	—Package type (*e.g.,* plastic can with metal lid, plastic can with plastic lid). —Product quantity (*e.g.,* 22.5 g, 20 g). —Portion count (*e.g.,* 15 pouches, 20 pieces). —Portion mass (*e.g.,* 1.5 g/pouch, 2 g/piece). —Portion length (*e.g.,* 10 mm, 15 mm). —Portion width (*e.g.,* 5 mm, 8 mm). —Portion thickness (*e.g.,* 3 mm, 4 mm). —Tobacco cut size (*e.g.,* 5 mm, 7 mm). —Characterizing flavor(s) (*e.g.,* none, menthol, cherry, wintergreen).
	(7) Dissolvable	—Package type (*e.g.,* plastic can with metal lid, plastic can with plastic lid). —Product quantity (*e.g.,* 22.5 g, 20 g).

TABLE 1 TO § 1114.7(c)(3)(iii)—Continued

Tobacco product category:	Tobacco product subcategory:	Product properties:
		—Product form (*e.g.,* strip, tablet, stick). —Portion count (*e.g.,* 15 sticks, 20 tablets). —Portion mass (*e.g.,* 1.5 g/strip, 1.0 g/piece). —Portion length (*e.g.,* 10 mm, 15 mm). —Portion width (*e.g.,* 5 mm, 8 mm). —Portion thickness (*e.g.,* 3 mm, 4 mm). —Tobacco cut size (*e.g.,* 0.05 mm, 0.07 mm). —Characterizing flavor(s) (*e.g.,* none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(8) Chewing Tobacco, Loose	—Package type (*e.g.,* bag, pouch). —Product quantity (*e.g.,* 20 g, 40 g). —Tobacco cut size (*e.g.,* 0.05 mm, 0.07 mm). —Characterizing flavor(s) (*e.g.,* none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(9) Chewing Tobacco, Portioned ..	—Package type (*e.g.,* plastic can with metal lid, plastic can with plastic lid). —Product quantity (*e.g.,* 20 g). —Product form (*e.g.,* plug, twist, portioned chewing tobacco). —Portion count (*e.g.,* 1 plug, 3 twists, 10 bits). —Portion mass (*e.g.,* 2 g/bit). —Portion length (*e.g.,* 8 mm, 10 mm). —Portion width (*e.g.,* 6 mm, 8 mm). —Portion thickness (*e.g.,* 5 mm, 7 mm). —Characterizing flavor(s) (*e.g.,* none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(10) Smokeless Co-Package	—For a new tobacco product composed of multiple smokeless tobacco products, include all applicable properties for each individual tobacco product as identified above. —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(11) Other	—Package type (*e.g.,* bag, box). —Product quantity. —Characterizing flavor(s) (*e.g.,* none, menthol). —Additional properties needed to uniquely identify the tobacco product.
(D) ENDS (Electronic Nicotine Delivery System).	*(1)* E-Liquid, Open	—Package type (*e.g.,* bottle, box). —Product quantity (*e.g.,* 1 bottle, 5 bottles). —Characterizing flavor(s) (*e.g.,* none, tobacco, menthol, cherry, wintergreen). —E-liquid volume (*e.g.,* 10 milliliter (ml)). —Nicotine concentration (*e.g.,* 0, 0.2 mg/ml). —Propylene glycol/vegetable glycerin (PG/VG) ratio (*e.g.,* N/A, 0/100, 50/50). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(2) E-Liquid, Closed	—Package type (*e.g.,* cartridge). —Product quantity (*e.g.,* 1 cartridge, 5 cartridges). —Characterizing flavor(s) (*e.g.,* none, tobacco, menthol, cherry, wintergreen). —E-liquid volume (*e.g.,* 10 ml). —Nicotine concentration (*e.g.,* 0, 0.2 mg/ml). —PG/VG ratio (*e.g.,* N/A, 0/100, 50/50). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(3) E-Cigarette, Closed	—Package type (*e.g.,* box, none, plastic clamshell). —Product quantity (*e.g.,* 1 e-cigarette, 5 e-cigarettes). —Characterizing flavor(s) (*e.g.,* none, tobacco, menthol, cherry, wintergreen). —Length (*e.g.,* 100 mm, 120 mm). —Diameter (*e.g.,* 6 mm, 8 mm). —E-liquid volume (*e.g.,* 2 ml, 5 ml). —Nicotine concentration (*e.g.,* 0, 0.2 mg/ml). —PG/VG ratio (*e.g.,* N/A, 0/100, 50/50). —Wattage (*e.g.,* 100 W, 200 W). —Battery capacity (*e.g.,* 100 mAh, 200 mAh). —Additional properties needed to uniquely identify the tobacco product.
	(4) E-Cigarette, Open	—Package type (*e.g.,* box, none, plastic clamshell). —Product quantity (*e.g.,* 1 e-cigarette, 5 e-cigarettes).

TABLE 1 TO § 1114.7(c)(3)(iii)—Continued

Tobacco product category:	Tobacco product subcategory:	Product properties:
		—Characterizing flavor(s) (*e.g.,* none, tobacco, menthol, cherry, wintergreen). —Length (*e.g.,* 100 mm, 120 mm). —Diameter (*e.g.,* 8 mm, 14 mm). —E-liquid volume (*e.g.,* 2 ml, 5 ml). —Wattage (*e.g.,* 100 W, 200 W). —Battery capacity (*e.g.,* 100 mAh, 200 mAh). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(5) ENDS Component	—Package type (*e.g.,* box, none, plastic clamshell). —Product quantity (*e.g.,* 1 e-cigarette, 5 e-cigarettes). —Characterizing flavor(s) (*e.g.,* none, tobacco, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(6) ENDS Co-Package	—For a new tobacco product composed of multiple ENDS tobacco products, include all applicable properties for each individual tobacco product as identified above. —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(7) ENDS Other	—Package type (*e.g.,* bag, box). —Product quantity. —Characterizing flavor(s) (*e.g.,* none, tobacco, menthol). —Additional properties needed to uniquely identify the tobacco product.
(E) Cigars	*(1)* Cigar, Filtered Sheet-Wrapped	—Package type (*e.g.,* hard pack, soft pack, clam shell). —Product quantity (*e.g.,* 20 filtered cigars, 25 filtered cigars). —Characterizing flavor (*e.g.,* none, menthol). —Length (*e.g.,* 89 mm, 100 mm). —Diameter (*e.g.,* 6 mm, 8.1 mm). —Ventilation (*e.g.,* none, 10%, 25%). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(2) Cigar, Unfiltered Sheet-Wrapped.	—Package type (*e.g.,* box, film sleeve). —Product quantity (*e.g.,* 1 cigar, 5 cigarillos). —Characterizing flavor (*e.g.,* none, menthol). —Length (*e.g.,* 100 mm, 140 mm). —Diameter (*e.g.,* 8 mm, 10 mm). —Tip (*e.g.,* none, wood tips, plastic tips). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(3) Cigar, Leaf-Wrapped	—Package type (*e.g.,* box, film, sleeve, none). —Product quantity (*e.g.,* 1 cigar, 5 cigars). —Characterizing flavor (*e.g.,* none, whiskey). —Length (*e.g.,* 150 mm, 200 mm). —Diameter (*e.g.,* 8 mm, 10 mm). —Wrapper material (*e.g.,* burley tobacco leaf, Connecticut shade grown tobacco leaf). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(4) Cigar Component	—Package type (*e.g.,* box, booklet). —Product quantity (*e.g.,* 10 wrappers, 20 leaves). —Characterizing flavor (*e.g.,* none, menthol, cherry). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(5) Cigar Tobacco Filler	—Package type (*e.g.,* bag, pouch). —Product quantity (*e.g.,* 20 g, 16 ounces). —Characterizing flavor (*e.g.,* none, menthol, cherry). —Tobacco cut size (*e.g.,* 15 cuts per inch). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(6) Cigar Co-Package	—For a new tobacco product composed of multiple cigar tobacco products, include all applicable properties for each individual tobacco product as identified above. —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(7) Other	—Package type (*e.g.,* bag, box). —Product quantity. —Characterizing flavor(s) (*e.g.,* none, menthol). —Additional properties needed to uniquely identify the tobacco product.
(F) Pipe Tobacco Products	*(1)* Pipe	—Package type (*e.g.,* box, none).

TABLE 1 TO § 1114.7(c)(3)(iii)—Continued

Tobacco product category:	Tobacco product subcategory:	Product properties:
		—Product quantity (*e.g.,* 1 pipe). —Length (*e.g.,* 200 mm, 300 mm). —Diameter (*e.g.,* 25 mm). —Characterizing flavor(s) (*e.g.,* none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(2) Pipe Tobacco Filler	—Package type (*e.g.,* bag, pouch). —Product quantity (*e.g.,* 20 g, 16 ounces). —Characterizing flavor(s) (*e.g.,* none, menthol, cavendish, cherry). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(3) Pipe Component	—Package type (*e.g.,* bowl, shank, stem, screen, filter). —Product quantity (*e.g.,* 1 bowl, 1 stem, 100 filters). —Characterizing flavor(s) (*e.g.,* none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(4) Pipe Co-Package	—For a new tobacco product composed of multiple pipe tobacco products, include all applicable properties for each individual tobacco product as identified above. —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(5) Other	—Package type (*e.g.,* bag, box). —Product quantity. —Characterizing flavor(s) (*e.g.,* none, menthol). —Additional properties needed to uniquely identify the tobacco product.
(G) Waterpipe Tobacco Products	*(1)* Waterpipe	—Package type (*e.g.,* box, none). —Product quantity (*e.g.,* 1 waterpipe). —Length (*e.g.,* 200 mm, 500 mm). —Width (*e.g.,* 100 mm, 300 mm). —Number of hoses (*e.g.,* 1, 2, 4). —Characterizing flavor(s) (*e.g.,* none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(2) Waterpipe Tobacco Filler	—Package type (*e.g.,* bag, pouch). —Product quantity (*e.g.,* 20 g, 16 ounces). —Characterizing flavor(s) (*e.g.,* none, tobacco, menthol, apple). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(3) Waterpipe Heat Source	—Package type (*e.g.,* box, film sleeve, bag, none). —Product quantity (*e.g.,* 150 g, 680 g). —Characterizing flavor(s) (*e.g.,* none, menthol, apple). —Portion count (*e.g.,* 20 fingers, 10 discs, 1 base). —Portion mass (*e.g.,* 15 g/finger). —Portion length (*e.g.,* 40 mm, 100 mm). —Portion width (*e.g.,* 10 mm, 40 mm). —Portion thickness (*e.g.,* 10 mm, 40 mm). —Source of energy (*e.g.,* charcoal, battery, electrical). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(4) Waterpipe Component	—Package type (*e.g.,* bag, box, none). —Product quantity (*e.g.,* 1 base, 1 bowl, 1 hose, 10 mouthpieces). —Characterizing flavor(s) (*e.g.,* none, menthol, apple). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(5) Waterpipe Co-Package	—For a new tobacco product composed of multiple waterpipe tobacco products, include all applicable properties for each individual tobacco product as identified above. —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(6) Waterpipe Other	—Package type (*e.g.,* bag, box). —Product quantity. —Characterizing flavor(s) (*e.g.,* none, tobacco, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
Other	Other	—Package type (*e.g.,* bag, box). —Product quantity. —Characterizing flavor(s) (*e.g.,* none, tobacco, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).

(4) The type of PMTA (*i.e.,* PMTA, supplemental PMTA, or resubmission);

(5) Whether the applicant requests that FDA refer the PMTA to the Tobacco Products Scientific Advisory Committee (TPSAC);

(6) Identifying information regarding any prior submissions regarding the tobacco product (*e.g.,* submissions related to investigational tobacco products, substantial equivalence reports, PMTAs), including submission tracking numbers (STNs) where applicable;

(7) Dates and purpose of any prior meetings with FDA regarding the new tobacco product;

(8) Address and the Facility Establishment Identifier (FEI) number(s), if available, of the establishment(s) involved in the manufacture of the new tobacco product;

(9) A brief statement regarding how the PMTA satisfies the content requirements of section 910(b)(1) of the Federal Food, Drug, and Cosmetic Act;

(10) A brief description of how marketing of the new tobacco product would be appropriate for the protection of the public health; and

(11) A list identifying all enclosures, labels, and labeling being submitted with the application.

(d) *Descriptive information.* The application must contain descriptive information in this section that outlines the major aspects of the new tobacco product, including the following items:

(1) A concise description of the new tobacco product;

(2) A statement identifying all tobacco product standards issued under section 907 of the Federal Food, Drug, and Cosmetic Act that are applicable to the new tobacco product and a brief description of how the new tobacco product fully meets any identified tobacco product standard, or if the new tobacco product deviates from a product standard, if applicable, the application must include adequate information to identify and justify those deviations;

(3) The name(s) of the product as designated on the product's label;

(4) A description of problems that were identified in prototypes that are the subject of studies in the application and previous or similar versions of the new tobacco product that were marketed, if any. If there are previous or similar versions that are the subject of studies in the application or were marketed, the application must contain a bibliography of all reports regarding the previous or similar version of the product, whether adverse or supportive; and

(5) Any restrictions on the sale, distribution, advertising, or promotion of the new tobacco product that the applicant proposes to be included as part of a marketing order under section 910(c)(1)(B) of the Federal Food, Drug, and Cosmetic Act to help support a showing that the marketing of the product is appropriate for the protection of the public health. If there are no proposed restrictions, the application must contain a statement to that effect.

(e) *Samples of new tobacco products.* After FDA accepts a PMTA for review, it may require the submission of samples of the new tobacco product, including its components and parts. If required, the applicant must submit samples of the finished tobacco product or its components or parts in accordance with instructions provided by FDA. FDA may also require the submission of additional samples to further aid in its review.

(f) *Labeling and marketing plans*—(1) *Labeling.* The application must contain specimens of all proposed labeling for the new tobacco product, including labels, inserts, onserts, instructions, and other accompanying information. The specimens of labeling must include all panels, reflect the actual size and color proposed to be used for the tobacco product, and include any warning label statements and other information required by regulation or statute, as applicable.

(2) *Marketing plans.* A PMTA must contain a description of the applicant's plans for labeling, advertising, marketing, promotion, and other consumer-directed activities regarding the new tobacco product developed by the time of filing. Such marketing plans must contain descriptions of actions that would be taken by the applicant, on behalf of the applicant, or at the applicant's direction for at least the first year the product would be marketed after receiving an order. If an applicant does not intend to use any advertising, marketing, promotion, or other communication activities directed at consumers, or has not developed marketing plans by the time of submission, the PMTA must contain a statement to that effect. As part of the description of the marketing plan, the PMTA must specify items such as the intended target audience(s), media and distribution channels, particular tactics, total dollar amount(s) of media buys and marketing and promotional activities (where applicable), and timing for the activities, including, but not limited to, information describing:

(i) The use of competent and reliable data sources, tools, technologies, and methodologies to establish, maintain, and monitor highly targeted marketing plans and media buys;

(ii) The target adult audiences by age-range(s) (including young adult audiences ages 18 to 24), and other demographic or psychographic characteristics;

(iii) The insights into the target audience the applicant is using to inform its marketing plans, including its strategic approach, key messages and themes, creative direction, and potential marketing tactics or channels.

(iv) Any means by which youth-access or youth-exposure to the products' labeling, advertising, marketing, and promotion would be limited;

(v) The use of owned, earned, shared, or paid media to advertise or promote the products;

(vi) The use of partners, sponsors, influencers, bloggers, or brand ambassadors to advertise or promote the products;

(vii) The use of consumer engagements, including events at which the products will be demonstrated or sampled; and

(viii) The use of earned media, public-relations, or other communications outreach to promote the products.

(g) *Statement of compliance with 21 CFR part 25.* (1) The application must contain an environmental assessment prepared in accordance with § 25.40 of this chapter, or a valid claim of categorical exclusion, if applicable. If the applicant believes that the action qualifies for an available categorical exclusion, the applicant must state under § 25.15(a) and (d) of this chapter that the action requested qualifies for a categorical exclusion, citing the particular exclusion that is claimed, and that to the applicant's knowledge, no extraordinary circumstances exist under § 25.21 of this chapter.

(2) Where the new tobacco product results from modifications to a legally marketed predecessor product, the environmental assessment must state whether the new tobacco product is intended to replace the predecessor tobacco product once the new tobacco product receives market authorization and is commercially marketed, be a line extension of the predecessor tobacco product, be marketed along with the predecessor product by the same manufacturer, or be marketed along with the predecessor tobacco product by a different manufacturer.

(h) *Summary.* The application must include a summary of all information contained in the application, including the following items, and identify areas in which there is a lack of information, where applicable:

(1) A summary of the product formulation section of the application;

(2) A summary of the manufacturing section of the application;

(3) A summary of the health risk investigations section of the application, including all information regarding:

(i) The health risks of the tobacco product to both users and nonusers of the product and whether the tobacco product may present less health risk than other tobacco products;

(ii) The impact the product and its marketing will have on the likelihood of changes in tobacco use behavior, including cessation, of tobacco product users;

(iii) The impact the product and its marketing will have on the likelihood of tobacco use initiation by tobacco products nonusers;

(iv) How users and nonusers perceive the risk of the tobacco product based upon its labeling, packaging, and marketing;

(v) Whether users are able to understand the labeling and instructions for use, and use the product in accordance with those instructions; and

(vi) The impact of human factors on the health risks to product users and nonusers (as described in paragraph (k)(1)(v) of this section);

(4) A concluding discussion describing how the data and information contained in the PMTA both constitute valid scientific evidence and establish that permitting marketing of the new tobacco product is appropriate for the protection of the public health, as determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product.

(i) *Product formulation.* The application must contain a full statement of the components or parts, materials, ingredients, additives, constituents, properties, and the principle or principles of operation, of the tobacco product, including the following information:

(1) *Components or parts, materials, ingredients, additives, and constituents.* The applicant must provide a full statement of:

(i) *Components or parts.* The quantity, function, and purpose of, and, where applicable, target specification(s) of, each component or part in the product. Where the tobacco product contains software components, the applicant must provide:

(A) A description of the software or technology (*e.g.,* Bluetooth);

(B) The purpose of the software or technology, such as monitoring where tobacco products are located, activated, or used;

(C) A description of the data collected by the software and how it will be used.

(ii) *Materials.* For each material in the product, include:

(A) The material name and common name(s), if applicable;

(B) The component or part of the tobacco product where the material is located;

(C) The subcomponent or subpart where the material is located, if applicable;

(D) The function of the material;

(E) The quantities (including ranges or means and acceptance limits) of the material(s) in the new tobacco product;

(F) The specification(s) (including quality/grades and suppliers) used for the new tobacco product; and

(G) Any other material properties to fully characterize the new tobacco product.

(iii) *Ingredients other than tobacco.* For ingredients other than tobacco in each component or part of the product, include:

(A) The International Union of Pure and Applied Chemistry (IUPAC) chemical name and common name, if applicable;

(B) The Chemical Abstracts Service (CAS) number or FDA Unique Ingredient Identifier (UNII);

(C) The function of the ingredient;

(D) The quantity with the unit of measure (including ranges or means and acceptance limits) of the material(s) of the ingredients in the tobacco product reported as mass per gram of tobacco for nonportioned tobacco products and as mass per portion for portioned tobacco products;

(E) The specification(s) (including purity or grade and supplier); and

(F) For complex purchased ingredients, each single chemical substance reported separately.

(iv) *Tobacco ingredients.* For tobacco ingredients in each component or part, include the following information or, if applicable, a statement that the product does not contain tobacco ingredients:

(A) The type(s), including grade(s) and variety/varieties;

(B) The quantity with the unit of measure (including ranges or means, acceptance limits) of tobacco in the tobacco product reported as mass per gram of tobacco for nonportioned tobacco products and as mass per portion for portioned tobacco products (with any specification variation, if applicable);

(C) The specification of tobacco used for the new tobacco product (with any specification variation, if applicable); and

(D) A description of any genetic engineering of the tobacco that impacts product characteristics.

(v) *Constituents.* Constituents, including HPHCs and other constituents, contained within, or emitted from (including its smoke or aerosol), the product, including any reaction product from leaching or aging, by providing:

(A) The constituent names in alphabetical order;

(B) The common name(s);

(C) The Chemical Abstract Services number;

(D) The mean quantity and variance with unit of measure;

(E) The number of samples and measurement replicates for each sample;

(F) The analytical methods used and associated reference(s);

(G) The name and location of the testing laboratory or laboratories and documentation showing that the laboratory or laboratories is (or are) accredited by a nationally or internationally recognized external accreditation organization;

(H) Length of time between dates of manufacture and date(s) of testing;

(I) Storage conditions of the tobacco product before it was tested; and

(J) Test data including test protocols, any deviation(s) from the test protocols, quantitative acceptance (pass/fail) criteria, and line data for all testing performed. Test data for combusted or inhaled products must reflect testing conducted using both intense and nonintense smoking regimens.

(vi) *Container closure system.* A description of the container closure system, including:

(A) Information describing how the container closure system protects and preserves the product from damage during transport, environmental contaminants, and potential leaching and migration of packaging constituents into the new tobacco product; and

(B) Information describing design features developed to prevent the risk of accidental exposure, if any.

(vii) *Statement of tobacco blending, reconstitution, or manipulation.* Information regarding tobacco blending, reconstitution, or manipulation, where applicable.

(2) *Other properties.* The applicant must provide a full description of the additional properties of the tobacco product that includes:

(i) *Product dimensions and construction.* The product dimensions and the overall construction of the product using a diagram or schematic drawing that clearly depicts the finished tobacco product and its components with dimensions, operating parameters, and materials.

(ii) *Design parameters and test data.* (A) All final design parameters of the

product, specifying nominal values or the explicit range of values as well as the design tolerance (where appropriate), including, but not limited to, the parameters specified in tables 1 to 20 of this paragraph as applicable; and

(B) A quantitative description of the performance criteria, including test protocols, line data, and a summary of the results, for each applicable intermediate and final design parameter and manufacturing step, that includes, but is not limited to the test data specified in tables 1 to 20 of this paragraph for the product category as applicable:

TABLE 1 TO § 1114.7(i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR CIGARETTES

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Cigarette mass (mg). • Cigarette length (mm). • Cigarette diameter (mm). • Cigarette draw resistance (mm H_2O). • Tobacco rod length (mm). • Tobacco filler mass (mg). • Tobacco rod density (g/cm^3). • Tobacco cut size (mm). • Tobacco moisture (%). • Cigarette paper length (mm). • Cigarette paper width (mm). • Cigarette paper base paper basis weight (g/m^2). • Cigarette paper base paper porosity (CU). • Cigarette paper band porosity (CU). • Cigarette paper band diffusivity (cm^2/s). • Cigarette paper band width (mm). • Cigarette paper band space (mm). • Filter length (mm). • Filter diameter (mm). • Filter mass (mg) • Filter density (g/cm^3). • Filter tow crimping index. • Filter pressure drop (mm H_2O). • Filter efficiency (%). • Filter total denier (g/9000m). • Filter denier per filament (dpf) • Plug wrap length (mm). • Plug wrap width (mm). • Plug wrap basis weight (g/m^2). • Plug wrap porosity (CU). • Tipping paper length (mm). • Tipping paper width (mm). • Tipping paper basis weight (g/m^2). • Tipping paper perforation (CU). • Filter ventilation (%). • Filter ventilation position of holes. • Filter ventilation number of holes. • Filter ventilation number of rows.	• Cigarette mass (mg). • Cigarette length (mm). • Cigarette diameter(mm). • Cigarette draw resistance (mm H_2O). • Puff count. • Tobacco rod length (mm). • Tobacco filler mass (mg). • Tobacco rod density (g/cm^3). • Tobacco cut size (mm). • Tobacco moisture (%). • Cigarette paper length (mm). • Cigarette paper width (mm). • Cigarette paper base paper basis weight (g/m^2). • Cigarette paper base paper porosity (CU). • Cigarette paper band porosity (CU). • Cigarette paper band diffusivity (cm^2/s). • Cigarette paper band width (mm). • Cigarette paper band space (mm). • Filter length (mm). • Filter diameter (mm). • Filter mass (mg). • Filter density (g/cm^3). • Filter tow crimping index. • Filter pressure drop (mm H_2O). • Filter efficiency (%). • Filter total denier (g/9000m). • Filter denier per filament (dpf). • Plug wrap length (mm). • Plug wrap width (mm). • Plug wrap basis weight (g/m^2). • Plug wrap porosity (CU). • Tipping paper length (mm). • Tipping paper width (mm). • Tipping paper basis weight (g/m^2). • Tipping paper perforation (CU). • Filter ventilation (%).

TABLE 2 TO § 1114.7(i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR PORTIONED AND NONPORTIONED SMOKELESS TOBACCO PRODUCTS

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
Portioned Smokeless Tobacco Products	
• Tobacco cut size (mm). • Tobacco moisture (%). • Portion length (mm). • Portion width (mm). • Portion mass (mg). • Portion thickness (mm). • Pouch material basis weight (g/m^2). • Pouch material air permeability (L/m^2/s). • Pouch material nicotine dissolution rate (%/min). • Pouch material nicotine dissolution extent (mg). • Pouch material thickness (μm).	• Tobacco cut size (mm). • Tobacco moisture (%). • Portion length (mm). • Portion width (mm). • Portion mass (mg). • Portion thickness (mm). • Pouch material basis weight (g/m^2). • Pouch material air permeability (L/m^2/s). • Pouch material nicotine dissolution rate (%/min). • Pouch material nicotine dissolution extent (mg). • Pouch material thickness (μm).
Nonportioned Smokeless Tobacco Products	
• Tobacco cut size (mm).	• Tobacco cut size (mm).

TABLE 2 TO § 1114.7(i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR PORTIONED AND NONPORTIONED SMOKELESS TOBACCO PRODUCTS—Continued

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Tobacco moisture (%).	• Tobacco moisture (%).

TABLE 3 TO § 1114.7(i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR RYO TOBACCO ROLLING PAPERS

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Roll-your-own (RYO) paper length (mm). • RYO paper width (mm). • RYO paper mass (mg). • RYO paper base paper basis weight (g/m^2). • RYO paper base paper porosity (CU). • RYO paper band porosity (CU). • RYO paper band diffusivity (cm^2/s). • RYO paper band width (mm). • RYO paper band space (mm).	• RYO paper length (mm). • RYO paper width (mm). • RYO paper mass (mg). • RYO paper base paper basis weight (g/m^2). • RYO paper base paper porosity (CU). • RYO paper band porosity (CU). • RYO paper band diffusivity (cm^2/s). • RYO paper band width (mm). • RYO paper band space (mm).

TABLE 4 TO § 1114.7(i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR RYO TOBACCO TUBES

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Tube mass (mg). • Tube length (mm). • Tube diameter (mm). • Tube paper length (mm). • Tube paper width (mm). • Tube paper base paper basis weight (g/m^2). • Tube paper base paper porosity (CU). • Tube paper band porosity (CU). • Tube paper band diffusivity (cm^2/s). • Tube paper band width (mm). • Tube paper band space (mm).	• Tube mass (mg). • Tube length (mm). • Tube diameter (mm). • Tube paper length (mm). • Tube paper width (mm). • Tube paper base paper basis weight (g/m^2). • Tube paper base paper porosity (CU). • Tube paper band porosity (CU). • Tube paper band diffusivity (cm^2/s). • Tube paper band width (mm). • Tube paper band space (mm).

TABLE 5 TO § 1114.7(i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR RYO TOBACCO FILTERED TUBES

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Tube mass (mg). • Tube length (mm). • Tube diameter (mm). • Tube paper length (mm). • Nonfilter tube length (mm). • Tube paper width (mm). • Tube paper base paper basis weight (g/m^2). • Tube paper base paper porosity (CU). • Tube paper band porosity (CU). • Tube paper band diffusivity (cm^2/s). • Tube paper band width (mm). • Tube paper band space (mm). • Filter length (mm). • Filter diameter (mm). • Filter mass (mg). • Filter density (g/cm^3). • Filter tow crimping index. • Filter pressure drop (mm H_2O). • Filter efficiency (%). • Filter total denier (g/9000m). • Filter denier per filament (dpf). • Plug wrap length (mm). • Plug wrap width (mm). • Plug wrap basis weight (g/m^2). • Plug wrap porosity (CU). • Tipping paper length (mm). • Tipping paper width (mm). • Tipping paper basis weight (g/m^2).	• Tube mass (mg). • Tube length (mm). • Tube diameter (mm). • Tube paper length (mm). • Nonfilter tube length (mm). • Tube paper width (mm). • Tube paper base paper basis weight (g/m^2). • Tube paper base paper porosity (CU). • Tube paper band porosity (CU). • Tube paper band diffusivity (cm^2/s). • Tube paper band width (mm). • Tube paper band space (mm). • Filter length (mm). • Filter diameter (mm). • Filter mass (mg). • Filter density (g/cm^3). • Filter tow crimping index. • Filter pressure drop (mm H_2O). • Filter efficiency (%). • Filter total denier (g/9000m). • Filter denier per filament (dpf). • Plug wrap length (mm). • Plug wrap width (mm). • Plug wrap basis weight (g/m^2). • Plug wrap porosity (CU). • Tipping paper length (mm). • Tipping paper width (mm). • Tipping paper basis weight (g/m^2).

TABLE 5 TO § 1114.7(i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR RYO TOBACCO FILTERED TUBES—Continued

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Tipping paper perforation (CU). • Filter ventilation (%). • Filter ventilation position of holes. • Filter ventilation number of holes. • Filter ventilation number of rows.	• Tipping paper perforation (CU). • Filter ventilation (%).

TABLE 6 TO § 1114.7(i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR RYO TOBACCO

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Tobacco filler mass (mg). • Tobacco cut size (mm). • Tobacco moisture (%).	• Tobacco filler mass (mg). • Tobacco cut size (mm). • Tobacco moisture (%).

TABLE 7 TO § 1114.7(i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR RYO TOBACCO PAPER TIPS

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• RYO paper tip length (mm). • RYO paper tip width (mm). • RYO paper tip mass (mg). • RYO paper base paper basis weight (g/m^2). • RYO paper perforation (CU). • RYO paper tip ventilation (%).	• RYO paper tip length (mm). • RYO paper tip width (mm). • RYO paper tip mass (mg). • RYO paper base paper basis weight (g/m^2). • RYO paper perforation (CU). • RYO paper tip ventilation (%).

TABLE 8 TO § 1114.7(i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR FILTERED SHEET-WRAPPED CIGARS

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Cigar length (mm). • Cigar diameter (mm). • Tobacco filler mass (mg). • Tobacco rod density (g/cm^3). • Tobacco cut size (mm). • Tobacco moisture (%). • Cigar wrapper porosity (CU). • Cigar binder porosity (CU). • Filter length (mm). • Filter diameter (mm). • Filter pressure drop (mm H_2O). • Filter efficiency (%). • Tipping paper length (mm). • Filter ventilation (%).	• Cigar length (mm). • Cigar diameter (mm). • Tobacco filler mass (mg). • Tobacco rod density (g/cm^3). • Tobacco cut size (mm). • Tobacco moisture (%). • Cigar wrapper porosity (CU). • Cigar binder porosity (CU). • Filter length (mm). • Filter diameter (mm). • Filter pressure drop (mm H_2O). • Filter efficiency (%). • Tipping paper length (mm). • Filter ventilation (%).

TABLE 9 TO § 1114.7(i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR UNFILTERED SHEET-WRAPPED CIGARS

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Cigar mass (mg). • Cigar length (mm). • Cigar minimum diameter (mm). • Cigar maximum diameter (mm). • Tobacco filler mass (mg). • Cigar wrapper porosity (CU). • Cigar tip length (mm) (if applicable). • Cigar tip inner diameter (mm) (if applicable). • Cigar tip width (mm) (if applicable).	• Cigar mass (mg). • Cigar length (mm). • Cigar minimum diameter (mm). • Cigar maximum diameter (mm). • Tobacco filler mass (mg). • Cigar wrapper porosity (CU). • Cigar tip length (mm) (if applicable). • Cigar tip inner diameter (mm) (if applicable). • Cigar tip width (mm) (if applicable).

TABLE 10 TO § 1114.7(i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR LEAF-WRAPPED CIGARS

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Cigar mass (mg). • Cigar length (mm). • Cigar minimum diameter (mm). • Cigar maximum diameter (mm). • Tobacco moisture (%).	• Cigar mass (mg). • Cigar length (mm). • Cigar minimum diameter (mm). • Cigar maximum diameter (mm). • Tobacco moisture (%).

TABLE 11 TO § 1114.7(i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR CIGAR TOBACCO

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Tobacco cut size (mm). • Tobacco moisture (%).	• Tobacco cut size (mm). • Tobacco moisture (%).

TABLE 12 TO § 1114.7(i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR CIGAR WRAPPERS

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Cigar wrapper length (mm). • Cigar wrapper minimum width (mm). • Cigar wrapper maximum width (mm).	• Cigar wrapper length (mm). • Cigar wrapper minimum width (mm). • Cigar wrapper maximum width (mm).

TABLE 13 TO § 1114.7(i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR WATERPIPES

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Number of hoses. • Bowl volume (ml).	• Bowl volume (ml).

TABLE 14 TO § 1114.7(i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR WATERPIPE TOBACCO

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Tobacco cut size (mm). • Tobacco moisture (%).	• Tobacco cut size (mm). • Tobacco moisture (%).

TABLE 15 TO § 1114.7(i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR WATERPIPE HEATING SOURCES

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Heating source type. • Charcoal temperature (°C) (if applicable). • Coil temperature range (°C) (if applicable). • Power delivery unit (PDU) temperature cut-off (°C) (if applicable).	• Charcoal temperature (°C) (if applicable). • Coil temperature range (°C) (if applicable). • PDU temperature cut-off (°C) (if applicable).

TABLE 16 TO § 1114.7(i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR WATERPIPE FOIL

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Foil length (mm). • Foil width (mm).	• Foil length (mm). • Foil width (mm).

TABLE 17 TO § 1114.7(i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR PIPES

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Bore minimum diameter (mm). • Bore maximum diameter (mm). • Bit length (mm).	• Bore minimum diameter (mm). • Bore maximum diameter (mm). • Bit length (mm).

TABLE 17 TO § 1114.7(i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR PIPES—Continued

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Bit diameter (mm). • Stem length (mm). • Stem diameter (mm).	• Bit diameter (mm). • Stem length (mm). • Stem diameter (mm).

TABLE 18 TO § 1114.7(i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR PIPE TOBACCO

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Tobacco cut size (mm). • Tobacco moisture (%).	• Tobacco cut size (mm). • Tobacco moisture (%).

TABLE 19 TO § 1114.7(i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR ENDS

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Airflow rate (cc/min). • Coil resistance (ohms). • Overall atomizer resistance (ohms). • Wick ignition temperature (°C). • Battery mAh rating (mAh). • PDU wattage operating range (W). • Coil temperature cut-off (°C). • Coil temperature range (°C).	• Airflow rate (cc/min). • Coil resistance (ohms). • Overall atomizer resistance (ohms). • Wick ignition temperature (°C). • Battery mAh rating (mAh). • PDU wattage operating range (W). • Coil temperature cut-off (°C). • Coil temperature range (°C).

TABLE 20 TO § 1114.7(i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR E-LIQUIDS

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• E-liquid volume (ml).	• E-liquid volume (ml).

(iii) *Function.* How the product is intended to function.

(iv) Product *pH and nicotine formulation.* The pH of the product and the formulation of nicotine in the product, if applicable, including the form (*e.g.,* unprotonated nicotine, nicotine salts) and quantity.

(v) *Fermentation process.* For those products that contain fermented tobacco, information on the fermentation process, including the following:

(A) Composition of the inoculum (starter culture) with genus and species name(s) and concentration(s) (if applicable);

(B) Any step(s) taken to reduce endogenous microbes (*e.g.,* cleaning of product contact surfaces);

(C) Specifications and test data for pH, temperature, moisture content, and water activity;

(D) Frequency of aeration or turning (if applicable);

(E) Duration of fermentation;

(F) Added ingredients; and

(G) Method used to stabilize or stop (if applicable), fermentation, including data to demonstrate that the process is effective at reducing microbial content of the product and to suppress microbial activity of residual microorganisms to preclude further in-package fermentation.

(vi) *Storage and stability information.* The application must contain product storage and stability information that establishes the microbial and chemical stability of the product throughout the shelf life, including:

(A) A description of the shelf life and how it is indicated on the tobacco product, if applicable; and

(B) Testing on the tobacco product in the same container closure system that will be used if granted a marketing order that was performed at the beginning (zero time), middle, and end of the expected storage time for the chemical and microbial endpoints for the following items: Microbial content data, including total aerobic microbial count and total yeast and mold count along with identification of detected microbiological organisms by genus and species names, if applicable; pH; moisture content; water activity; tobacco-specific nitrosamines (TSNAs) (reported as separate amounts for the total TSNAs, NNN (N′-nitrosonornicotine), NNK (4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone)); nitrate and nitrite levels; preservatives and microbial metabolic inhibitors (if any); and method of heat treatment, pasteurization, or other method used to reduce microbial loads.

(vii) *Product and packaging design risks and misuse hazards.* A review and assessment of reasonably foreseeable risks associated with the design of the tobacco product and its package that may occur during normal use of the tobacco product or during any foreseeable misuse of the product, including user error, which may cause illness, injury, or death not normally associated with the use of the tobacco product. The review and assessment must identify the measures taken to reduce or eliminate each risk associated with the design of the tobacco product and package.

(3) *Principles of operation.* The applicant must provide a full statement of the principle or principles of operation of the tobacco product, including full narrative descriptions of:

(i) The way in which a typical consumer will use the new tobacco

product, including a description of how a consumer operates the product and, where applicable, can change the product design and add or subtract ingredients;

(ii) The length of time it takes for a user to consume a single unit of the product; and

(iii) Whether the product incorporates a heating source, and if so, a description of the heating source.

(4) *Product testing and analysis information.* Each analysis required in this paragraph must be performed on test samples that reflect the finished tobacco product composition and design, and must be conducted using a sufficient sample size and number of replicates to substantiate the results of the type of testing conducted. Additionally, the applicant must provide the following information:

(i) The name and location of the testing laboratory or laboratories and documentation showing that the laboratory or laboratories is (or are) accredited by a nationally or internationally recognized external accreditation organization;

(ii) The length of time between dates of manufacture and date(s) of testing;

(iii) The storage conditions of the tobacco product before it was tested;

(iv) The number of samples and measurement replicates for each sample;

(v) A description of method procedure, method validation information and rationale for selecting each test method, including relevant voluntary testing standards, test protocols, quantitative acceptance criteria, line data, and a summary of the results;

(vi) Reports of product formulation testing that include test protocols, quantitative acceptance criteria, line data, and a summary of the results, for each applicable parameter; and

(vii) Complete descriptions of any smoking or aerosol-generating regimens used for analytical testing that are not standardized or widely accepted by the scientific community, if applicable.

(j) *Manufacturing.* The application must contain a full description of the methods used in, and the facilities and controls used for, the design (including design validation and design verification, to assess whether the tobacco product, as manufactured, performs in accordance with design specifications), manufacture, packing, and storage of the tobacco product in sufficient detail to demonstrate whether the product meets manufacturing specifications, can be manufactured in a manner consistent with the information submitted in the application, and conforms to the requirements of any regulations issued under section 906(e) of the Federal Food, Drug, and Cosmetic Act, including:

(1) A list of all manufacturing, packaging, storage, and control facilities for the product, including the facilities name, address, and FEI number, if applicable, and a contact name and telephone number for a representative from each facility;

(2) A narrative description, accompanied by a list and summary, of all standard operating procedures (SOPs) and examples of relevant forms and records for the following categories of information for all manufacturing, design controls, packing, and storage for the tobacco product:

(i) Manufacturing and production process activities at each establishment, including a description of each establishment, all production steps, and process controls, process specifications with relevant acceptance criteria, and monitoring and acceptance activities;

(ii) Managerial oversight and employee training related to the manufacture, processing, packing, and installation of the tobacco product, as applicable;

(iii) Monitoring procedures and manufacturing controls for product design, product characteristics, and changes in products, specifications, methods, processes, or procedures, including a hazard analysis that details the correlation of the product design attributes with public health risk, as well as any mitigation strategies implemented;

(iv) Activities related to identifying and monitoring suppliers and the products supplied (including, for example, purchase controls and product acceptance activities);

(v) Handling of complaints, nonconforming products and processes, and corrective and preventative actions;

(vi) Testing procedures carried out before the product is released to market, including:

(A) A list and summary of any standards used for all testing methods;

(B) Validation and verification activities for all test methods used to ensure that the tobacco product meets specifications;

(C) Documentation of accreditation information for all testing laboratories;

(D) Complete description of smoking or aerosol-generating regimes used for analytical testing, if any; and

(E) Tobacco product specifications (including any physical, chemical, and biological specifications) and acceptance criteria for those specifications;

(F) Reports of release testing performed on finished products to demonstrate conformity with established specifications, including test protocols, line data, and a summary of the results for each applicable testing.

(k) *Health risk investigations*—(1) *Study types.* The application must contain full reports of all information, including the substantive information required by § 1114.27(b)(1)(ii) for application filing, both favorable and unfavorable, published or known to, or which should reasonably be known to, the applicant concerning investigations, including nonclinical and human subject studies, which have been made to show:

(i) *Health risks of the product.* The potential health risks of the tobacco product to users and nonusers, including potential exposures, and whether the product may present different risks than other tobacco products, including:

(A) The health effects of the constituents, including HPHCs, at the quantitative levels delivered to both users and nonusers under the range of conditions under which the product might be used;

(B) The toxicological profile of the new tobacco product related to the route of administration, including the genotoxicity, carcinogenicity, reproductive toxicity, immunotoxicity, acute toxicity, and repeat dose (chronic) toxicity of the new tobacco product, including those relative to other tobacco products. The toxicological profile also includes information on the toxicity of the ingredients, additives, and HPHCs, relative to the route of administration and the range of potential levels of exposure resulting from the use of, or exposure to, the new tobacco product, including studies which discuss the toxicological effects of any leachables and extractables that can appear from the container closure system and the ingredient mixture, such as additive or synergistic effects;

(C) The pharmacological profile of the new tobacco product, including the pharmacokinetics, pharamacodynamics, metabolism, and elimination profile, of any of the ingredients, additives, and HPHCs for the range of potential levels of exposure resulting from the use of, or exposure to, the new tobacco product relative to other tobacco products. The applicant must specify whether the studies were conducted in vitro, in vivo, ex vivo, or in silico; and

(D) The health risks of the tobacco product compared to other tobacco products on the market, never using tobacco products, quitting tobacco product use, and using the tobacco product in conjunction with other tobacco products.

(ii) *Impacts on tobacco use behavior of tobacco product users.* How the product and its label, labeling, and advertising will affect the tobacco use behavior of tobacco product users, including:

(A) The abuse liability of the tobacco product;

(B) How users actually use the product, including use topography, product use frequency, use trends over time, and how such use affects the health risks of the product to individual users;

(C) The likelihood that users will use the product in conjunction with other tobacco products;

(D) The likelihood that current tobacco product users will start using the product;

(E) The likelihood that current tobacco users who adopt the product will switch to or switch back to other tobacco products that may present increased risks to individual health; and

(F) The likelihood that current tobacco users who may have otherwise quit using tobacco products will instead start or continue to use the product.

(iii) *Impacts on tobacco use initiation by nonusers, including youth and young adults.* The impact of the tobacco product, its label, labeling, and advertising on tobacco use initiation by nonusers, including:

(A) The likelihood that consumers who have never used tobacco products, particularly youth and young adults, will initiate use of the tobacco product;

(B) The likelihood that nonusers of tobacco products who adopt the tobacco product will switch to other tobacco products that may present higher levels of individual health risk; and

(C) The likelihood that former users of tobacco products will re-initiate use with the tobacco product.

(iv) *Perceptions and use intentions.* The impact of the product and its label, labeling, and advertising on individuals:

(A) Perception of the product;

(B) Use intentions; and

(C) Ability to understand the labeling and instructions for use and use the product in accordance with those instructions.

(v) *Human factors.* The impact of human factors on product risk, including discussion of use conditions, use environments, use related hazards, estimated use error risk, potential unintended uses, risk controls to ensure that harms and unintended consequences are minimized, and adverse experiences related to such uses.

(2) *Literature search.* The applicant must conduct a literature search for each type of information described in paragraph (k)(1) of this section, and the application must contain a description of the literature search performed, including the databases searched and the date searched, search terms, reasons for inclusion or exclusion of documents, and the strategy for study quality assessment. The application must also contain a bibliography of all published studies and articles referenced in the application. If a literature search was performed and resulted in no information found, the application must contain a statement to that effect.

(3) *Study reports.* The full report of each study included in the application must describe the specific product studied and include the following items, where applicable and to the extent reasonably available. For applicable items not contained in the full report of an investigation, the applicant must contain a description of the actions taken to obtain the information and why the document is not reasonably available.

(i) Full copies of any published articles and other reference materials;

(ii) Documentation of all actions taken to ensure the reliability of the study. For nonclinical laboratory studies, the application must contain, for each study, documentation of all actions taken to ensure the reliability of the study, *e.g.,* documentation of whether the study was conducted in accordance with good laboratory practices, such as those specified in part 58 of this chapter. For studies involving human subjects, to the extent reasonably available or obtainable, the application must contain a certification that clinical investigators do not have, or documentation fully disclosing, any financial conflicts of interest, such as the financial arrangements specified in the Financial Disclosure by Clinical Investigators regulation in part 54 of this chapter;

(iii) Copies of all versions of protocols and amendments that were used in the study;

(iv) Copies of all versions of investigator instructions, if any were produced in addition to the protocol;

(v) The statistical analysis plan, including a detailed description of the statistical analyses used (including all variables, confounders, and subgroup analyses), the scientific rationale for the choice of sample sizes, and any amendments to the plan;

(vi) Line data, including data definition files that include the names of the variables, codes, and formats in each dataset, and copies of programs and any necessary macro-programs used to create derived datasets, and the results included in the study reports;

(vii) A list of sites and clinical investigators that conducted the study, including contact information and physical address(es);

(viii) The location of all source data. If the site where the study was conducted has not maintained all of the source data, indicate where the data are located;

(ix) The format of the records and data (*e.g.,* electronic or hard copy);

(x) A list of all sites that had early termination and the reason for early termination, along with any audit certificates and inspection results, if applicable;

(xi) A list of contractors who participated in the study, the role of each contractor, and the initiation and termination dates of the participation of each contractor;

(xii) A signed full report of all findings;

(xiii) For human subject studies:

(A) All versions of study materials (*e.g.,* consent forms, questionnaires, stimuli) used;

(B) All versions of case report forms used; and

(C) Individual case report forms related to participant deaths, other serious and unexpected adverse experiences, withdrawals, and participant discontinuation where the study participant was exposed to the tobacco product that is the subject of the PMTA or similar products; and

(xiv) For tobacco product perception and use intention studies that use advertising as stimuli, a statement describing whether the advertising used is representative of advertising that the applicant intends to use in marketing the product. If the advertising is not representative of the advertising an applicant intends to use in marketing the product, the applicant must describe whether the study results are still relevant to the likely impact of the advertising on tobacco product perceptions and use intentions.

(l) *The effect on the population as a whole.* The application must contain an analysis and discussion of how the data and information contained in the application establish that permitting the tobacco product to be marketed would be appropriate for the protection of public health determined with respect to the population as a whole, including users and nonusers of the tobacco product. The analysis and discussion must integrate all of the information regarding the product and its likely effects on health, and tobacco use behavior, including tobacco use cessation and initiation, to provide an overall assessment of the likely effect that the marketing of the tobacco

product may have on overall tobacco-related morbidity and mortality.

(m) *Certification statement.* The application must contain the following certification, with the appropriate information inserted (as indicated by parenthetical italicized text), signed by an authorized representative of the applicant:

''I (*name of responsible official*) on behalf of the applicant, (*applicant name*), hereby certify that the applicant will maintain all records to substantiate the accuracy of this application for the period of time required in 21 CFR 1114.45 and ensure that such records remain readily available to FDA upon request. I certify that this information and the accompanying submission are true and correct, that no material fact has been omitted, and that I am authorized to submit this on the applicant's behalf. I understand that under section 1001 of title 18 of the United States Code anyone who knowingly and willfully makes a materially false, fictitious, or fraudulent statement or representation in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States is subject to criminal penalties.''

§ 1114.9 Amendments.

(a) *General.* FDA may request, or an applicant may submit on its own initiative, an amendment to a PMTA containing information that is necessary for FDA complete the review of a pending PMTA. An amendment must include the appropriate form and specify the STN assigned to the original submission and, if submitted other than at FDA's request, the reason for submitting the amendment. An amendment must also include the certification statement set forth in § 1114.7(m), with the appropriate information inserted, and signed by an authorized representative of the applicant.

(b) *Review of an amendment.* Submission of an amendment may affect the timing of review of an amended submission as follows:

(1) If the amendment is a major amendment (*e.g.,* an amendment that contains significant new data from a previously unreported study, detailed new analyses of previously submitted data), FDA may restart the 180-day review period after receipt of the amendment.

(2) If FDA requests a minor amendment (*i.e.,* an amendment that is not a major amendment) and receives a written response submitting the requested amendment, FDA may pause the review period for the number of days elapsed between the date of the request and the date that FDA receives the written response.

(c) *Failure to respond to amendment request.* If FDA requests an amendment and the applicant does not respond within 180 days of FDA's request, FDA may consider the applicant to have submitted a request to voluntarily withdraw the pending PMTA under § 1114.11 and issue an acknowledgment letter notifying the applicant of the withdrawal.

(d) *No amendment to closed or withdrawn application.* An applicant may not amend an application after FDA has closed the application through an action under § 1114.29 or it has been withdrawn under § 1114.11.

§ 1114.11 Withdrawal by applicant.

(a) An applicant may at any time make a written request using the appropriate form to withdraw a PMTA that FDA has not acted on as described in § 1114.29. The withdrawal request must state:

(1) Whether the withdrawal is due to a health concern related to the tobacco product and, if so, a description of those concerns, including the extent, duration, and frequency of the health effects, and what gave rise to the concerns, such as reports of adverse experiences;

(2) The application STN; and

(3) The name(s) of the new tobacco product that is the subject of the application.

(b) An application will be considered withdrawn when FDA issues an acknowledgement letter stating that the application has been withdrawn.

(c) The application is an Agency record, even if withdrawn. FDA will retain the withdrawn application under Federal Agency records schedules. The availability of the withdrawn application will be subject to FDA's public information regulation in § 20.45 of this chapter.

§ 1114.13 Change in ownership of an application.

An applicant may transfer of ownership of a PMTA. At or before the time of transfer, the new owner and the former owner must submit information to FDA using the appropriate form as follows:

(a) The new and former owner must sign and submit a notice to FDA stating that all of the former applicant's rights and responsibilities relating to the PMTA have been transferred to the new owner. This notice must identify the name and address of the new owner and the PMTA transferred by tobacco product name(s) and STN.

(b) The new owner must sign and submit a notice to FDA containing the following:

(1) The new owner's commitment to agreements, promises, and conditions made by the former owner and contained in the application and marketing order, if applicable;

(2) The date that the change in ownership is effective;

(3) Either a statement that the new owner has a complete copy of the application, including all amendments, the marketing order (if applicable), and any records that are required to be kept under § 1114.45, or a request for a copy of the application, including all amendments, and the modified risk order (if applicable) from FDA's files in accordance with part 20 of this chapter. In accordance with the Freedom of Information Act, FDA will provide a copy of the application to the new owner under the fee schedule in FDA's public information regulations in § 20.45 of this chapter; and

(4) A certification that no modifications have been made to the tobacco product since the application, including amendments (if any), was submitted to FDA.

§ 1114.15 Supplemental applications.

(a) *Supplemental PMTA submission.* Applicants that have received a marketing order for a tobacco product may, as an alternative format of submitting an application that meets the content requirements of § 1114.7, submit a supplemental PMTA to seek marketing authorization for modifications to such product, which result in a new tobacco product under 910(a)(1) of the Federal Food, Drug, and Cosmetic Act. Supplemental PMTAs must include new information concerning modifications that create the new tobacco product but allow the applicant to satisfy the remaining application requirements by cross-referencing applicable content from the previously submitted PMTA for the original tobacco product. Applicants may submit supplemental PMTAs only for modifications that require the submission of limited new information. An applicant may not submit a supplemental PMTA where:

(1) Modifications to the product that result in the new tobacco product require the submission of new information or revisions to the PMTA for the original product to the extent that reviewing a supplemental application for the new tobacco product would be confusing, cumbersome, or otherwise inefficient and submitting a standard PMTA under § 1114.7 would better facilitate review.

(2) The marketing order for the original tobacco product has been withdrawn; or

(3) The marketing order for the original tobacco product has been temporarily suspended or is subject to temporary suspension or withdrawal proceedings by FDA, except where authorized in writing by FDA following a presubmission meeting.

(b) *Required format.* The supplemental PMTA must comply with format requirements of § 1114.7(b), except that an applicant must include content in a supplemental PMTA by cross-referencing a PMTA, or, where applicable, a supplemental PMTA, for an original tobacco product that is owned by that applicant and may include content by cross-referencing a tobacco product master file and postmarket reports for the original tobacco product. FDA will not consider content included by cross-reference to other sources of information outside of the submission.

(c) *Required content.* The supplemental PMTA must provide sufficient information for FDA to determine whether any of the grounds for denial listed in section 910(c)(2) of the Federal Food, Drug, and Cosmetic Act apply to the application.

(1) The application must contain the full text of all the information described in the following sections:

(i) General information that identifies the submission as a supplemental PMTA (as described in § 1114.7(c));

(ii) New product information (as described in paragraph (d) of this section);

(iii) Statement of compliance with part 25 of this chapter (as described in § 1114.7(g));

(iv) Labeling (as described in § 1114.7(f)) if the labeling is not identical to the labeling submitted in the PMTA or postmarket reports for the original product;

(v) Postmarket information (as described in paragraph (e) of this section); and

(vi) Certification statement (as described in paragraph (f) of this section);

(2) The application must include the following sections by cross-reference to the PMTA for the original tobacco product and contain any additional information that is necessary to supplement or update the cross-referenced information:

(i) Descriptive information (as described in § 1114.7(d));

(ii) Product samples (as described in § 1114.7(e));

(iii) Labeling (as described in § 1114.7(f)) if the labeling is identical to the labeling that was submitted in the PMTA or postmarket reports for the original tobacco product;

(iv) Summary of all research findings (as described in § 1114.7(h));

(v) Product formulation (as described in § 1114.7(i));

(vi) Manufacturing (as described in § 1114.7(j)); and

(vii) Health risk investigations (as described in § 1114.7(k)).

(d) *New product information.* The application must contain a section that includes:

(1) Full descriptions of each modification to the product and comparisons to the original product version described in the previously authorized PMTA;

(2) A statement as to whether the new tobacco product, if it receives a marketing order, will replace the original tobacco product, will be a line extension of the original tobacco product, or will be introduced as an additional product by the same manufacturer;

(3) All data and information relating to each modification to the product that would be required in an application under § 1114.7; and

(4) A concluding summary of how the new tobacco product meets the requirements to receive a marketing order, including how the data and information contained in both the supplemental PMTA and cross-referenced from the previously authorized PMTA constitute valid scientific evidence and establishes that the PMTA meets the requirements of section 910(c) of the Federal Food, Drug, and Cosmetic Act to receive a marketing order, including that permitting the new tobacco product to be marketed would be appropriate for the protection of the public health determined with respect to the risks and benefits on the population as a whole, including users and nonusers of the tobacco product.

(e) *Postmarket reports.* (1) If an applicant has submitted postmarket reports for the original tobacco product, the applicant must include all such reports in the application by cross-reference.

(2) If an applicant is required to, but has not yet submitted a postmarket report, the applicant must submit a report as part of its application of all information required under § 1114.41 covering the period of time from when it received a marketing order to when it submits the supplemental PMTA.

(f) *Certification statement.* The application must contain the following certification, with the appropriate information inserted as indicated by parenthetical italicized text, signed by an authorized representative of the applicant:

''I, (*name of responsible official*), on behalf of (*name of applicant*), certify that (*new tobacco product name*) has a different (*describe each modification to the product*) than (*name of original tobacco product*) described in (*STN of the PMTA for the original product*) but is otherwise identical to (*name(s) of original tobacco product*). I certify that (*name of applicant*) understands this means there is no other modification to the materials, ingredients, design, composition, heating source, or any other feature of the original tobacco product. I also certify that (*name of applicant*) will maintain all records that substantiate the accuracy of this application and ensure that such records remain readily available to FDA upon request for the period of time required in 21 CFR 1114.45. I certify that this information and the accompanying submission are true and correct, and that I am authorized to submit this on the applicant's behalf. I understand that under section 1001 of title 18 of the United States Code, anyone who knowingly and willfully makes a materially false, fictitious, or fraudulent statement or representation in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States is subject to criminal penalties.''

§ 1114.17 Resubmissions.

(a) *General.* An applicant may, as an alternative format of submitting an application that meets the content requirements of § 1114.7 or § 1114.15 (if applicable), submit a resubmission to address deficiencies set forth in a no marketing order. The resubmission must contain new information necessary to address application deficiencies and cross-reference applicable content from the PMTA that received the no marketing order. An applicant may utilize the resubmission format for the same tobacco product for which FDA issued a no marketing order or a new tobacco product that results from modifications to the product necessary to address the deficiencies described in a no marketing order. An applicant may not submit a resubmission when:

(1) It incorporates new information or revisions to the PMTA for the original product to the extent that reviewing a resubmission for the new tobacco product would be confusing, cumbersome, or otherwise inefficient and submitting a standard PMTA under § 1114.7 would better facilitate review; or

(2) The no marketing order states that the applicant may not submit a resubmission.

(b) *Required format.* The resubmission must comply with format requirements of § 1114.7(b), except that an applicant must include content in the resubmission by cross-referencing the PMTA, or, where applicable, supplemental PMTA, that received the

no marketing order. FDA will not consider content included by cross-reference to other sources of information outside of the submission.

(c) *Required content.* The resubmission must provide sufficient information for FDA to determine whether any of the grounds for denial listed in section 910(c)(2) of the Federal Food, Drug, and Cosmetic Act apply to the application.

(1) The application must include the full text of the information described in the following paragraphs:

(i) General information that identifies the submission as a resubmission (as described in paragraph § 1114.7(c));

(ii) Response to deficiencies (as described in paragraph (d) of this section); and

(iii) Certification statement (as described in paragraph (e) of this section).

(2) The application must include the following sections from the PMTA that received a no marketing order by cross-reference and contain all additional information that is necessary to supplement or update the cross-referenced information:

(i) Descriptive information (as described in § 1114.7(d));

(ii) Product samples (as described in § 1114.7(e));

(iii) Labeling (as described in § 1114.7(f));

(iv) Statement of compliance with part 25 of this chapter (as described in § 1114.7(g));

(v) Summary of all research findings (as described in § 1114.7(h));

(vi) Product formulation (as described in § 1114.7(i));

(vii) Manufacturing (as described in § 1114.7(j)); and

(viii) Health risk investigations (as described in § 1114.7(k)).

(d) *Response to deficiencies.* (1) The application must include a section that lists and provides a separate response to each deficiency described by FDA in the original no marketing order, including all data and information necessary to complete each response, and also addresses any applicant-identified deficiencies.

(2) Where an applicant modifies the product in a way that would result in a new tobacco product under section 910(a)(1) of the Federal Food, Drug, and Cosmetic Act in order to address the deficiencies, the application must also include:

(i) A full description of each modification to the product and comparisons of that change to the original version described in the previously submitted PMTA; and

(ii) All data and information relating to each modification to the product that would be required in an application under § 1114.7.

(e) *Certification statement.* The application must contain the following certification that corresponds to the application, with the appropriate information inserted as indicated by parenthetical italicized text, signed by an authorized representative of the applicant.

(1) *Same tobacco product certification.* An application for the same tobacco product must contain the following certification:

''I, (*name of responsible official),* on behalf of (*name of applicant*), certify that this submission for (*new tobacco product name(s)*) responds to all deficiencies outlined in the no marketing order issued in response to (*STN of the previously submitted PMTA*) and the new tobacco product described herein is identical to the product described in the previously submitted PMTA. I certify that (*name of applicant*) understands this means there is no modification to the materials, ingredients, design, composition, heating source, or any other feature. I also certify that (*name of applicant*) will maintain all records that substantiate the accuracy of this statement, and ensure that such records remain readily available to FDA upon request for the period of time required in 21 CFR 1114.45. I certify that this information and the accompanying submission are true and correct, and that I am authorized to submit this on the company's behalf. I understand that under section 1001 of title 18 of the United States Code, anyone who knowingly and willfully makes a materially false, fictitious, or fraudulent statement or representation in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States is subject to criminal penalties.''

(2) *Different tobacco product certification.* An application for a different tobacco product than the original tobacco product that results from changes necessary to address the deficiencies must contain the following certification:

''I, (*name of responsible official*), on behalf of (*name of applicant*), certify that this submission for (*new tobacco product name(s)*) responds to all deficiencies outlined in the no marketing order issued in response to (*STN of the previously submitted PMTA*) and the new tobacco product described herein has a different (*describe each modification to the product*) than (*name(s) of original tobacco product*) described in (*STN of the previously submitted PMTA*) but is otherwise identical to (*name(s) of original tobacco product*) described in (*STN of the previously submitted PMTA*). I certify that (*name of applicant*) understands this means there is no modification to the materials, ingredients, design features, heating source, or any other feature of the original tobacco product, except for the (*describe each modification to the tobacco product*). I also certify that (*name of applicant*) will maintain all records that substantiate the accuracy of this statement, and ensure that such records remain readily available to FDA upon request for the period of time required in 21 CFR 1114.45. I certify that this information and the accompanying submission are true and correct, and that I am authorized to submit this on the company's behalf. I understand that under section 1001 of title 18 of the United States Code, anyone who knowingly and willfully makes a materially false, fictitious, or fraudulent statement or representation in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States is subject to criminal penalties.''

Subpart C—FDA Review

§ 1114.25 Communication between FDA and applicants.

During the course of reviewing an application, FDA may communicate with an applicant about relevant matters, including scientific, medical, and procedural issues that arise during the review process and inspections. These communications may take the form of telephone conversations, letters, electronic communications, or meetings, and will be documented in the administrative file in accordance with § 10.65 of this chapter.

§ 1114.27 Review procedure.

(a) *Acceptance review.* (1) After an applicant submits a PMTA, FDA will perform an initial review of the PMTA to determine whether it may be accepted for further review. FDA may refuse to accept an application that:

(i) Does not comply with the applicable format requirements in § 1114.7(b), § 1114.15, or § 1114.17 (as applicable);

(ii) Is not administratively complete because it does not appear to contain the information required by § 1114.7 (excluding product samples), § 1114.15, or § 1114.17, as applicable;

(iii) Does not pertain to a tobacco product subject to chapter IX of the Federal Food, Drug, and Cosmetic Act (as required by § 1105.10 of this chapter); or

(iv) FDA can otherwise refuse to accept under § 1105.10.

(2) If FDA accepts an application for further review, FDA will issue an acknowledgement letter to the applicant that specifies the PMTA STN. If FDA determines that it will require product samples as part of the PMTA, it will send instructions on how and where to submit product samples, as described in § 1114.7(e) of this chapter.

(3) If FDA refuses to accept an application, FDA will issue a letter to the applicant identifying the deficiencies, where practicable, that

prevented FDA from accepting the application.

(b) *Filing review.* (1) After accepting a PMTA, FDA will make a threshold determination of whether the application contains sufficient information to permit a substantive review. FDA may refuse to file a PMTA if any of the following applies:

(i) The PMTA does not include sufficient information required by section 910(b)(1)(A) through (b)(1)(F) of the Federal Food, Drug, and Cosmetic Act and by § 1114.7, § 1114.15, or § 1114.17, as applicable, to permit a substantive review of the application;

(ii) The application does not contain any information, including information from published literature or bridged from an investigation of another tobacco product, regarding:

(A) The health risks of the new tobacco product (as described in § 1114.7(k)(1)(i)(A) through (C));

(B) The health risks of the new tobacco product compared to the health risks generally presented by both products in the same product category and products in at least one different category that are used by the consumers an applicant expects will use its new tobacco product (as set forth in a portion of § 1114.7(k)(1)(i)(D)).

(C) The abuse liability of the new tobacco product (as set forth in § 1114.7(k)(1)(ii)(A));

(D) How consumers would be expected to actually use the product, including use frequency, use trends over time, and how such use affects the health risks of the product to individual users (as set forth in § 1114.7(k)(1)(ii)(B));

(E) The impact that marketing the new tobacco product would have on the likelihood that current tobacco product users would start using the new tobacco product, use the product in conjunction with other tobacco products, and, after using the product, switch to or switch back to other tobacco products that may present increased risks to individual health (as set forth in § 1114.7(k)(1)(ii)(C) through (F));

(F) The impact that the marketing of the new tobacco product would have on tobacco product use behavior of current nonusers of tobacco products (as described in § 1114.7(k)(1)(iii)); or

(G) The impact of the product and its label, labeling, and advertising on individuals' perception of the product and their use intentions (as described in § 1114.7(k)(1)(iv));

(iii) The PMTA contains a false statement of material fact;

(iv) The PMTA is a supplemental PMTA that does not comply with § 1114.15; or

(v) The PMTA is a resubmission that does not comply with § 1114.17.

(2) If FDA refuses to file an application, FDA will issue a letter to the applicant identifying the deficiencies, where practicable, that prevented FDA from filing the application.

(3) If FDA files an application, FDA will issue a filing letter to the applicant.

(c) *Application review.* (1) Except as described in this paragraph and § 1114.9(b), within 180 days of receipt of an application described in section 910(b)(1) of the Federal Food, Drug, and Cosmetic Act, FDA will complete its review of the PMTA and act on the application.

(2) FDA will begin substantive review of the application after it is filed under paragraph (b) of this section. FDA may communicate with the applicant as set forth under § 1114.25 to seek additional or clarifying information.

(3) FDA may refer the PMTA or portions of the PMTA, upon its own initiative or applicant request, to TPSAC for reference and for the submission of a report and recommendation respecting the application, together with all underlying data and the reasons or basis for the recommendation.

(4) FDA may conduct inspections of the applicant's manufacturing sites, and sites and entities involved with clinical and nonclinical research (including third parties and contract research organizations) to support FDA's review of the PMTA. Where an applicant prevents FDA from scheduling and conducting inspections that are necessary for FDA to complete its review of the PMTA in a timely manner, FDA may pause the 180-day review period for the number of days necessary to complete the inspection.

(5) FDA may defer review of a PMTA for a new product that, if introduced or delivered for introduction into interstate commerce, would be adulterated or misbranded due to the manufacturer or importer's failure to comply with user fee payment and reporting requirements under part 1150.

§ 1114.29 FDA action on an application.

After receipt of an application, FDA will:

(a) Refuse to accept the application as described in § 1114.27(a);

(b) Issue a letter administratively closing the application;

(c) Issue a letter canceling the application if FDA finds that it mistakenly accepted the application or that the application was submitted in error;

(d) Refuse to file the application as described in § 1114.27(b);

(e) Issue a marketing order as described in § 1114.31; or

(f) Issue a no marketing order as described in § 1114.33.

§ 1114.31 Issuance of a marketing order.

(a) FDA will issue a marketing order if it finds that none of the grounds for denial listed in section 910(c)(2) of the Federal Food, Drug, and Cosmetic Act apply. A marketing order becomes effective on the date it is issued.

(b) FDA may include, as part of the marketing order:

(1) Restrictions on the sale and distribution of the product, including restrictions on the access to, and the advertising and promotion of, the tobacco product, to the extent that it would be authorized to impose such restrictions under a regulation issued under section 906(d) of the Federal Food, Drug, and Cosmetic Act;

(2) Any restrictions on the sales, distribution, advertising, and promotion of the new tobacco product that the applicant proposed to be included as part of a marketing order under section 910(c)(1)(B) of the Federal Food, Drug, and Cosmetic Act to help FDA make the finding that permitting the product to be marketed would be appropriate for the protection of the public health; and

(3) Requirements to establish and maintain records, and submit postmarket reports under section 910(f) of the Federal Food, Drug and Cosmetic Act in addition to those described in § 1114.41, including but not limited to information such as labeling, advertising, marketing, promotional materials, or marketing plans not previously submitted to FDA.

§ 1114.33 Issuance of a no marketing order.

(a) *Issuance.* FDA will issue a no marketing order if:

(1) FDA finds that any of the grounds for denial listed in section 910(c)(2) of the Federal Food, Drug, and Cosmetic Act apply;

(2) The applicant does not permit an authorized FDA employee, at a reasonable time and in a reasonable manner, an opportunity to:

(i) Inspect the facilities and controls described in the application; or

(ii) Have access to, copy, and verify all records pertinent to the application,

which results in FDA finding that one or more of the grounds for denial specified in section 910(c)(2) of the Federal Food, Drug and Cosmetic Act apply.

(b) *Description of deficiencies.* The no marketing order will, where practicable, identify measures to remove the application from deniable form.

§ 1114.35 Withdrawal of a marketing order.

(a) *Grounds for withdrawal.* FDA may withdraw a marketing order for a new tobacco product issued under this part if FDA determines that:

(1) Any of the grounds for withdrawal under section 910(d)(1) of the Federal Food, Drug, and Cosmetic Act apply; or

(2) Any postmarket requirement imposed by the marketing order or by this part has not been met, which results in FDA finding that one or more of the grounds for withdrawal specified in section 910(d)(1) of the Federal Food, Drug and Cosmetic Act apply.

(b) *Advice and other information.* (1) FDA may seek advice on scientific matters from any appropriate FDA advisory committee in deciding whether to withdraw a marketing order.

(2) FDA may use information other than that submitted by the applicant in deciding whether to withdraw a marketing order.

(c) *Informal hearing.* Prior to withdrawing a marketing order, FDA will offer the holder of the marketing order an opportunity for an informal hearing under part 16 of this chapter.

(d) *Order issuance.* If the applicant does not request a hearing or, if after the part 16 hearing is held, the Agency decides to proceed with the withdrawal, FDA will issue to the holder of the marketing order an order withdrawing the marketing order for the new tobacco product.

(e) *Public notice.* FDA will give the public notice of an order withdrawing a marketing order for a tobacco product and will announce the basis of the withdrawal.

§ 1114.37 Temporary suspension of a marketing order.

(a) FDA will temporarily suspend a marketing order if FDA determines that there is a reasonable probability that the continued distribution of such tobacco product would cause serious, adverse health consequences or death, that is greater than ordinarily caused by tobacco products on the market.

(b) Before temporarily suspending a marketing order of a tobacco product, FDA will offer the holder of the marketing order an opportunity for an informal hearing under part 16 of this chapter.

(c) If, after offering the holder of the marketing order an opportunity for a part 16 hearing, the Agency decides to proceed with the temporary suspension, FDA will issue an order temporarily suspending the marketing order for a tobacco product.

(d) After issuing an order temporarily suspending the marketing order, FDA will proceed expeditiously to initiate proceedings to withdraw the marketing order for the tobacco product.

Subpart D—Postmarket Requirements

§ 1114.39 Postmarket changes.

A marketing order authorizes the marketing of a new tobacco product in accordance with the terms of the order. Prior to the introduction or delivery for introduction into interstate commerce of a new tobacco product that results from modification(s) to the product, an applicant must submit a new PMTA under § 1114.7 or a supplemental PMTA under § 1114.15 and obtain a marketing order for the new tobacco product, unless the new tobacco product can be legally marketed through another premarket pathway.

§ 1114.41 Reporting requirements.

(a) *Required reports.* Except as specified in § 1114.43, each applicant that receives a marketing order must submit to FDA all information required by the terms of the marketing order and by this section as described below. Each postmarket report must be well-organized, legible, and written in English. Documents that have been translated from another language into English (*e.g.,* original study documents written in a language other than English) must be accompanied by the original language version of the document, a signed statement by an authorized representative of the manufacturer certifying that the English language translation is complete and accurate, and a brief statement of the qualifications of the person that made the translation.

(1) *Periodic reports.* Each applicant must submit a periodic report to the Center for Tobacco Products (CTP) within 60 calendar days of the reporting dates specified in the applicant's marketing order for the life of the order and as may be required for the submission of a supplemental PMTA under § 1114.15. The report must include the following:

(i) A cover letter that contains the PMTA STN, tobacco product name(s) (including the original name described in the PMTA if different), company name, date of report, and reporting period;

(ii) A description of all changes made to the manufacturing, facilities, or controls during the reporting period, including:

(A) A comparison of each change to what was described in the PMTA;

(B) The rationale for making each change and, if any, a listing of any associated changes; and

(C) The basis for concluding that each change does not result in a new tobacco product that is outside the scope of the marketing order and will not result in a finding that the marketing order must be withdrawn or temporarily suspended under section 910(d) of the Federal Food, Drug, and Cosmetic Act;

(iii) An inventory of ongoing and completed studies about the tobacco product conducted by, or on behalf of, the applicant, that have not been previously reported;

(iv) Full reports of information published or known to, or which should be reasonably known to, the applicant concerning scientific investigations and literature about the tobacco product that have not been previously reported, as well as significant findings from publications not previously reported;

(v) A summary and analysis of all serious and unexpected adverse experiences associated with the tobacco product that have been reported to the applicant or that the applicant is aware of, accompanied by a statement of any changes to the overall risk associated with the tobacco product, and a summary of any changes in the health risks, including the nature and frequency of the adverse experience, and potential risk factors;

(vi) A summary of sales and distribution of the tobacco product for the reporting period, to the extent that the applicant collects or receives such data, including:

(A) Total U.S. sales reported in dollars, units, and volume with breakdowns by U.S. census region, major retail markets, and channels in which the product is sold;

(B) The Universal Product Code that corresponds to the product(s) identified in the PMTA; and

(C) Demographic characteristics of product(s) purchasers, such as age, gender, and tobacco use status;

(vii) Specimens of all labeling and descriptions of all labeling changes that have not been previously submitted under section 905(i) of the Federal Food, Drug, and Cosmetic Act, including the date the labeling was first disseminated and the date when dissemination was completely terminated;

(viii) Full color copies of all advertising for the tobacco product that has not been previously submitted, and the original date the materials were first disseminated and the date when their dissemination was completely terminated;

(ix) A description of the implementation of all advertising and marketing plans, by channel and by product, and the dollar amount(s) and flighting of such plans, by channel and

by product, including a description of any:

(A) Use of competent and reliable data sources, methodologies, and technologies to establish, maintain, and monitor highly targeted advertising and marketing plans and media buys;

(B) Targeting of specific adult audiences by age-range(s), including young adults, ages 18 to 24, and other demographic or psychographic characteristics that reflect the intended target audience, including a list of all data sources used to target advertising and marketing plans and media buys;

(C) Actions taken to restrict youth-access and limit youth-exposure to the products' labeling, advertising, marketing, or promotion;

(D) Use of owned, earned, shared, or paid social media to create labeling for, advertise, market, or promote the products;

(E) Use of partners, influencers, bloggers, or brand ambassadors to create labeling for, advertise, market, or promote the products;

(F) Consumer engagements conducted by the applicant, on its behalf, or at its direction, including events at which the products were demonstrated; and

(G) Use of earned media or public-relations outreach to create labeling for, advertise, market, or promote the products;

(x) An analysis of the actual delivery of advertising impressions, by channel, by product (if applicable), and by audience demographics, including a breakout by age-group, that have not been previously submitted, verified against post-launch delivery-verification reports submitted to the applicant from an accredited source;

(xi) Additional information required to be reported under the terms of a marketing order (if applicable); and

(xii) An overall assessment of how the tobacco product continues to be appropriate for the protection of the public health.

(2) *Serious and unexpected adverse experience reporting.* The applicant must report all serious and unexpected adverse experiences associated with the tobacco product that have been reported to the applicant or that the applicant is aware of to CTP's Office of Science through the Health and Human Services' Safety Reporting Portal or in another manner designated by FDA (if applicable) within 15 calendar days after the report is received by the applicant.

(b) *FDA review of postmarket reports.* (1) As part of its review of a postmarket report, FDA may require the applicant to submit additional information to enable it to determine whether a change results in a new tobacco product, or to facilitate a determination of whether there are or may be grounds to withdraw or temporarily suspend the marketing order.

(2) FDA may notify an applicant that FDA has determined that a change described in a periodic report made under this section results in a new tobacco product outside the scope of the marketing order, requiring the submission of a new PMTA under § 1114.7 or a supplemental PMTA under § 1114.15 and issuance of a marketing order if the applicant seeks to market the new tobacco product, unless the new tobacco product can be legally marketed through a different premarket pathway.

Subpart E—Miscellaneous

§ 1114.45 Record retention.

(a) *Record retention by the applicant.* (1) Each applicant that receives a marketing order must maintain all records necessary to facilitate a determination of whether there are or may be grounds to withdraw or temporarily suspend the marketing order, including records related to both the application and postmarket reports, and ensure that such records remain readily available to the Agency upon request. These records include, but are not limited to:

(i) All documents submitted to FDA as part of an application, periodic postmarket reports, and adverse experience reports;

(ii) All documentation demonstrating whether each:

(A) Nonclinical laboratory study was conducted in accordance with good laboratory practices that support the reliability of the results, such as the records described in part 58 of this chapter; and

(B) Clinical investigator has any financial conflicts of interest that may be a source of bias, such as the documentation described in part 54 of this chapter;

(iii) All other documents generated during the course of a study necessary to substantiate the study results, including:

(A) Communications related to the investigation between the investigator and the sponsor, the monitor, or FDA; and

(B) All source data for human subject and nonclinical investigations included in the application and postmarket reports, including records of each study subject's case history and exposure to tobacco products used in the investigation, including case report forms, progress notes, hospital records, clinical charts, X-rays, lab reports, and subject diaries; and

(iv) A list of each complaint, and a summary and analysis of all complaints, associated with the tobacco product reported to the applicant;

(2) These records must be legible, in the English language, and available for inspection and copying by officers or employees duly designated by the Secretary. Documents that have been translated from another language into English (*e.g.,* original study documents written in a language other than English) must be accompanied by the original language version of the document, a signed statement by an authorized representative of the manufacturer certifying that the English language translation is complete and accurate, and a brief statement of the qualifications of the person that made the translation.

(3) All records must be retained as follows:

(i) Records related to and including the PMTA must be retained for a period of at least 4 years from the date that the marketing order is issued.

(ii) Records related to postmarket reports, including both periodic and adverse experience reports, must be retained for a period of at least 4 years from the date the report was submitted to FDA or until FDA inspects the records, whichever occurs sooner.

(b) *Record retention by FDA.* FDA will retain information submitted to it in accordance with Federal Agency Records schedules and will provide a copy to persons to whom such information may legally be disclosed on request under the fee schedule in FDA's public information regulations in § 20.45 of this chapter.

§ 1114.47 Confidentiality.

(a) *General.* FDA will determine the public availability of any part of an application and other content related to such an application under this section and part 20 of this chapter.

(b) *Confidentiality of data and information prior to an order.* Prior to issuing an order under this part:

(1) FDA will not publicly disclose the existence of an application unless:

(i) The applicant has publicly disclosed or acknowledged (as such disclosure is defined in § 20.81 of this chapter), or has authorized FDA in writing to publicly disclose or acknowledge, that the applicant has submitted an application to FDA; or

(ii) FDA refers the application to TPSAC.

(2) FDA will not disclose the existence or contents of an FDA communication with an applicant

regarding its application except to the extent that the applicant has publicly disclosed or acknowledged, or authorized FDA in writing to publicly disclose or acknowledge, the existence or contents of that particular FDA communication.

(3) Except as described in paragraph (b)(4) of this section, FDA will not disclose information contained in an application unless the applicant has publicly disclosed or acknowledged, or authorized FDA in writing to publicly disclose or acknowledge, the existence of that particular information. If the applicant has publicly disclosed or acknowledged, or authorized FDA in writing to publicly disclose or acknowledge, the existence of that particular information contained in an application, FDA may disclose the existence of that particular information.

(4) If FDA refers an application to TPSAC, the contents of the application will be available for public disclosure under part 20 of this chapter, except information that has been shown to fall within the exemption established for trade secrets and confidential commercial or financial information in § 20.61, or personal privacy in § 20.63.

(c) *Disclosure of data and information after issuance of a marketing order.* After FDA issues a marketing order, it may make the following information related to the application and order available for public disclosure upon request or at FDA's own initiative, including information from amendments to the application and FDA's reviews of the application:

(1) All data previously disclosed to the public, as such disclosure is defined in § 20.81 of this chapter;

(2) Any protocol for a test or study, unless it is shown to fall within the exemption established for trade secrets and confidential commercial information in § 20.61 of this chapter;

(3) Information and data submitted to demonstrate that the new tobacco product is appropriate for the protection of public health, unless the information is shown to fall within the exemptions established in § 20.61 of this chapter for trade secrets and confidential commercial information, or in § 20.63 of this chapter for personal privacy;

(4) Correspondence between FDA and the applicant, including any requests FDA made for additional information and responses to such requests, and all written summaries of oral discussions between FDA and the applicant, unless it is shown to fall within the exemptions in § 20.61 of this chapter for trade secrets and confidential commercial information, or in § 20.63 of this chapter for personal privacy;

(5) In accordance with § 25.51(b) of this chapter, the environmental assessment or, if applicable, the claim for categorical exclusion from the requirement to submit an environmental assessment under part 25 of this chapter; and

(6) Information and data contained in postmarket reports submitted to FDA, unless the information is shown to fall within the exemptions established in § 20.61 of this chapter for trade secrets and confidential commercial information, or in § 20.63 of this chapter for personal privacy.

(d) *Disclosure of data and information after the issuance of a no marketing order.* After FDA issues a no marketing order, FDA may make certain information related to the application and the order available for public disclosure upon request or at FDA's own initiative unless the information is otherwise exempt from disclosure under part 20 of this chapter. Information FDA may disclose includes, but is not limited to the tobacco product category (*e.g.,* cigarette), tobacco product subcategory (*e.g.,* filtered, combusted cigarette), package size, product quantity, characterizing flavor, and the basis for the no marketing order.

§ 1114.49 Electronic submission.

(a) *Electronic format requirement.* Applicants submitting any documents to the Agency under this part must provide all required information to FDA using the Agency's electronic system, except as provided in paragraph (b) of this section. The application and all supporting information must be in an electronic format that FDA can process, review, and archive.

(b) *Waivers from electronic format requirement.* An applicant may submit a written request, that is legible and in English, to the Center for Tobacco Products asking that FDA waive the requirement for electronic format and content. Waivers will be granted if use of electronic means is not reasonable for the applicant. To request a waiver, applicants can send the written request to the address included on our website (*www.fda.gov/tobaccoproducts*). The request must include the following information:

(1) The name and address of the applicant, a list of individuals authorized by the applicant to serve as the contact person, and contact information. If the applicant has submitted a PMTA previously, the regulatory correspondence should also include any identifying information about the previous submission.

(2) A statement that creation and/or submission of information in electronic format is not reasonable for the applicant, and an explanation of why creation and/or submission in electronic format is not reasonable. This statement must be signed by the applicant or by a representative who is authorized to make the declaration on behalf of the applicant.

(c) *Paper submission.* An applicant who has obtained a waiver from filing electronically must send a written application through the Document Control Center to the address provided in the FDA documentation granting the waiver.

Dated: July 24, 2019.

Norman E. Sharpless,

Acting Commissioner of Food and Drugs.

Dated: September 3, 2019.

Eric D. Hargan,

Deputy Secretary, Department of Health and Human Services.

[FR Doc. 2019–20315 Filed 9–20–19; 8:45 am]

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Part III

Environmental Protection Agency

40 CFR Part 63

National Emission Standards for Hazardous Air Pollutants: Taconite Iron Ore Processing Residual Risk and Technology Review; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2017–0664; FRL–9999–37–OAR]

RIN 2060–AT05

National Emission Standards for Hazardous Air Pollutants: Taconite Iron Ore Processing Residual Risk and Technology Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This proposal presents the results of the U.S. Environmental Protection Agency's (EPA's) residual risk and technology reviews (RTRs) for the National Emission Standards for the Hazardous Air Pollutants (NESHAP) for Taconite Iron Ore Processing, as required under the Clean Air Act (CAA). Based on the results of the risk review, the EPA is proposing that risks from emissions of air toxics from this source category are acceptable and that the existing standards provide an ample margin of safety. Furthermore, under the technology review, the EPA identified no cost-effective developments in controls, practices, or processes to achieve further emissions reductions. Therefore, the EPA is proposing no revisions to the existing standards based on the RTRs. However, in this action the EPA is proposing: The removal of exemptions for periods of startup, shutdown, and malfunction (SSM) and clarifying that the emissions standards apply at all times; the addition of electronic reporting of performance test results and compliance reports; minor technical corrections and amendments to monitoring and testing requirements that would reduce the compliance burden on industry while continuing to be protective of the environment; and that regulation of a certain type compound emitted by one of the facilities, known as elongated mineral particulate, is not required under CAA section 112 because this compound is not a hazardous air pollutant (HAP) pursuant to the CAA. This action, if finalized, would result in improved monitoring, compliance, and implementation of the existing standards.

DATES: *Comments.* Comments must be received on or before November 12, 2019. Under the Paperwork Reduction Act (PRA), comments on the information collection provisions are best assured of consideration if the Office of Management and Budget (OMB) receives a copy of your comments on or before October 25, 2019.

Public hearing. If anyone contacts us requesting a public hearing on or before September 30, 2019, we will hold a hearing. Additional information about the hearing, if requested, will be published in a subsequent **Federal Register** document and posted at *https://www.epa.gov/stationary-sources-air-pollution/taconite-iron-ore-processing-national-emission-standards-hazardous.* See **SUPPLEMENTARY INFORMATION** for information on requesting and registering for a public hearing.

ADDRESSES: You may send comments, identified by Docket ID No. EPA–HQ–OAR–2017–0664, by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov/* (our preferred method). Follow the online instructions for submitting comments.
- *Email: a-and-r-docket@epa.gov.* Include Docket ID No. EPA–HQ–OAR–2017–0664 in the subject line of the message.
- *Fax:* (202) 566–9744. Attention Docket ID No. EPA–HQ–OAR–2017–0664.
- *Mail:* U.S. Environmental Protection Agency, EPA Docket Center, Docket ID No. EPA–HQ–OAR–2017–0664, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.
- *Hand/Courier Delivery:* EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Docket Center's hours of operation are 8:30 a.m.–4:30 p.m., Monday–Friday (except federal holidays).

Instructions: All submissions received must include the Docket ID No. for this rulemaking. Comments received may be posted without change to *https://www.regulations.gov/,* including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: For questions about this proposed action, contact Mr. David Putney, Sector Policies and Programs Division (D243–02), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–2016; fax number: (919) 541–4991; and email address: *putney.david@epa.gov.* For specific information regarding the risk modeling methodology, contact Mr. Chris Sarsony, Health and Environmental Impacts Division (C539–02), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–4843; fax number: (919) 541–0840; and email address: *sarsony.chris@epa.gov.* For questions about monitoring and testing requirements, contact Ms. Gerri Garwood, Sector Policies and Programs Division (D243–05), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–2406; fax number: (919) 541–4991; and email address: *Garwood.gerri@epa.gov.* For information about the applicability of the NESHAP to a particular entity, contact Mr. John Cox, Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency, WJC South Building (Mail Code 2227A), 1200 Pennsylvania Avenue NW, Washington DC 20460; telephone number: (202) 564–1395; and email address: *cox.john@epa.gov.*

SUPPLEMENTARY INFORMATION:

Public hearing. Please contact Ms. Adrian Gates at (919) 541–4860 or by email at *gates.adrian@epa.gov* to request a public hearing, to register to speak at the public hearing, or to inquire as to whether a public hearing will be held.

Docket. The EPA has established a docket for this rulemaking under Docket ID No. EPA–HQ–OAR–2017–0664. All documents in the docket are listed in *Regulations.gov.* Although listed, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *Regulations.gov* or in hard copy at the EPA Docket Center, Room 3334, WJC West Building, 1301 Constitution Avenue NW, Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the EPA Docket Center is (202) 566–1742.

Instructions. Direct your comments to Docket ID No. EPA–HQ–OAR–2017–0664. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *https://*

www.regulations.gov/, including any personal information provided, unless the comment includes information claimed to be CBI or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *https://www.regulations.gov/* or email. This type of information should be submitted by mail as discussed below.

The EPA may publish any comment received to its public docket. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the Web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

The *https://www.regulations.gov/* website allows you to submit your comment anonymously, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *https://www.regulations.gov/,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any digital storage media you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should not include special characters or any form of encryption and be free of any defects or viruses. For additional information about the EPA's public docket, visit the EPA Docket Center homepage at *https://www.epa.gov/dockets.*

Submitting CBI. Do not submit information containing CBI to the EPA through *https://www.regulations.gov/* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information on any digital storage media that you mail to the EPA, mark the outside of the digital storage media as CBI and then identify electronically within the digital storage media the specific information that is claimed as CBI. In addition to one complete version of the comments that includes information claimed as CBI, you must submit a copy of the comments that does not contain the information claimed as CBI directly to the public docket through the procedures outlined in Instructions above. If you submit any digital storage media that does not contain CBI, mark the outside of the digital storage media clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and the EPA's electronic public docket without prior notice. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 Code of Federal Regulations (CFR) part 2. Send or deliver information identified as CBI only to the following address: OAQPS Document Control Officer (C404–02), OAQPS, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, Attention Docket ID No. EPA–HQ–OAR–2017–0664.

Preamble acronyms and abbreviations. We use multiple acronyms and terms in this preamble. While this list may not be exhaustive, to ease the reading of this preamble and for reference purposes, the EPA defines the following terms and acronyms here:

AEGL acute exposure guideline level
AERMOD air dispersion model used by the HEM–3 model
CAA Clean Air Act
CalEPA California EPA
CBI Confidential Business Information
CFR Code of Federal Regulations
D/F dioxins/furans
EMP elongated mineral particulate
EPA Environmental Protection Agency
ERPG emergency response planning guideline
ERT Electronic Reporting Tool
ESP electrostatic precipitator
HAP hazardous air pollutant(s)
HCl hydrochloric acid
HEM–3 Human Exposure Model, Version 1.5.5
HF hydrogen fluoride
HI hazard index
HQ hazard quotient
IRIS Integrated Risk Information System
km kilometer
MACT maximum achievable control technology
mg/m^3 milligrams per cubic meter
MIR maximum individual risk
NAAQS National Ambient Air Quality Standards
NEI National Emissions Inventory
NESHAP national emission standards for hazardous air pollutants
NTTAA National Technology Transfer and Advancement Act
OAQPS Office of Air Quality Planning and Standards
OMB Office of Management and Budget
PB–HAP hazardous air pollutants known to be persistent and bio-accumulative in the environment
pdf portable document format
PM particulate matter
POM polycyclic organic matter
REL reference exposure level
RFA Regulatory Flexibility Act
RfC reference concentration
RTR residual risk and technology review
SAB Science Advisory Board
SSM startup, shutdown, and malfunction
The Court the United States Court of Appeals for the District of Columbia Circuit
TOSHI target organ-specific hazard index
tpy tons per year
TRIM.FaTE Total Risk Integrated Methodology.Fate, Transport, and Ecological Exposure model
UF uncertainty factor
UMRA Unfunded Mandates Reform Act
URE unit risk estimate

Organization of this document. The information in this preamble is organized as follows:

I. General Information
A. Does this action apply to me?
B. Where can I get a copy of this document and other related information?
II. Background
A. What is the statutory authority for this action?
B. What is this source category and how does the current NESHAP regulate its HAP emissions?
C. What data collection activities were conducted to support this action?
D. What other relevant background information and data are available?
III. Analytical Procedures and Decision-Making
A. How do we consider risk in our decision-making?
B. How do we perform the technology review?
C. How do we estimate post-MACT risk posed by the source category?
IV. Analytical Results and Proposed Decisions
A. What are the analytical results and proposed decisions for this source category?
B. What are the results and proposed decisions based on our technology review?
C. What other actions are we proposing?
D. What compliance dates are we proposing?
V. Summary of Cost, Environmental, and Economic Impacts
A. What are the affected sources?
B. What are the air quality impacts?
C. What are the cost impacts?
D. What are the economic impacts?
E. What are the benefits?
VI. Request for Comments
VII. Submitting Data Corrections
VIII. Statutory and Executive Order Reviews
A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review
B. Executive Order 13771: Reducing Regulation and Controlling Regulatory Costs

C. Paperwork Reduction Act (PRA)
D. Regulatory Flexibility Act (RFA)
E. Unfunded Mandates Reform Act (UMRA)
F. Executive Order 13132: Federalism
G. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments
H. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks
I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use
J. National Technology Transfer and Advancement Act (NTTAA)
K. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

I. General Information

A. Does this action apply to me?

Table 1 of this preamble lists the NESHAP and associated regulated industrial source category that is the subject of this proposal. Table 1 is not intended to be exhaustive, but rather provides a guide for readers regarding the entities that this proposed action is likely to affect. The proposed amendments, once promulgated, will be directly applicable to the affected sources. Federal, state, local, and tribal government entities would not be affected by this proposed action. As defined in the *Initial List of Categories of Sources Under Section 112(c)(1) of the Clean Air Act Amendments of 1990* (see 57 FR 31576, July 16, 1992) and *Documentation for Developing the Initial Source Category List, Final Report* (*see* EPA–450/3–91–030, July 1992), the Taconite Iron Ore Processing source category includes any operation engaged in separating and concentrating iron ore from taconite, a low grade iron ore to produce taconite pellets. The category includes, but is not limited to, the following processes: Liberation of the iron ore by wet or dry crushing and grinding in gyratory crushers, cone crushers, rod mills, and ball mills; concentration of the iron ore by magnetic separation or flotation; pelletization by wet tumbling with a balling drum or balling disc; induration using a straight grate or grate kiln furnace, and finished pellet handling.

TABLE 1—NESHAP AND INDUSTRIAL SOURCE CATEGORIES AFFECTED BY THIS PROPOSED ACTION

Source category	NESHAP	NAICS code [1]
Taconite Iron Ore Processing	40 CFR part 63, subpart RRRRR	21221

[1] North American Industry Classification System.

B. Where can I get a copy of this document and other related information?

In addition to being available in the docket, an electronic copy of this action is available on the internet. Following signature by the EPA Administrator, the EPA will post a copy of this proposed action at *https://www.epa.gov/taconite-iron-ore-processing-national-emission-standards-hazardous.* Following publication in the **Federal Register**, the EPA will post the **Federal Register** version of the proposal and key technical documents at this same website. Information on the overall RTR program is available at *https://www3.epa.gov/ttn/atw/rrisk/rtrpg.html.*

A redline version of the regulatory language that incorporates the proposed changes in this action is available in the docket for this action (Docket ID No. EPA–HQ–OAR–2017–0664).

II. Background

A. What is the statutory authority for this action?

The statutory authority for this action is provided by sections 112 and 301 of the CAA, as amended (42 U.S.C. 7401 *et seq.*). Section 112 of the CAA establishes a two-stage regulatory process to develop standards for emissions of HAP from stationary sources. Generally, the first stage involves establishing technology-based standards and the second stage involves evaluating those standards that are based on maximum achievable control technology (MACT) to determine whether additional standards are needed to address any remaining risk associated with HAP emissions. This second stage is commonly referred to as the ''residual risk review.'' In addition to the residual risk review, the CAA also requires the EPA to review standards set under CAA section 112 every 8 years to determine if there are ''developments in practices, processes, or control technologies'' that may be appropriate to incorporate into the standards. This review is commonly referred to as the ''technology review.'' When the two reviews are combined into a single rulemaking, it is commonly referred to as the ''risk and technology review.'' The discussion that follows identifies the most relevant statutory sections and briefly explains the contours of the methodology used to implement these statutory requirements. A more comprehensive discussion appears in the document titled *CAA Section 112 Risk and Technology Reviews: Statutory Authority and Methodology,* in the docket for this rulemaking.

In the first stage of the CAA section 112 standard setting process, the EPA promulgates technology-based standards under CAA section 112(d) for categories of sources identified as emitting one or more of the HAP listed in CAA section 112(b). Sources of HAP emissions are either major sources or area sources, and CAA section 112 establishes different requirements for major source standards and area source standards. ''Major sources'' are those that emit or have the potential to emit 10 tons per year (tpy) or more of a single HAP or 25 tpy or more of any combination of HAP. All other sources are ''area sources.'' For major sources, CAA section 112(d)(2) provides that the technology-based NESHAP must reflect the maximum degree of emission reductions of HAP achievable (after considering cost, energy requirements, and non-air quality health and environmental impacts). These standards are commonly referred to as MACT standards. CAA section 112(d)(3) also establishes a minimum control level for MACT standards, known as the MACT ''floor.'' The EPA must also consider control options that are more stringent than the floor. Standards more stringent than the floor are commonly referred to as beyond-the-floor standards. In certain instances, as provided in CAA section 112(h), the EPA may set work practice standards where it is not feasible to prescribe or enforce a numerical emission standard. For area sources, CAA section 112(d)(5) gives the EPA discretion to set standards based on generally available control technologies or management practices (GACT standards) in lieu of MACT standards.

The second stage in standard-setting focuses on identifying and addressing any remaining (*i.e.,* ''residual'') risk according to CAA section 112(f). For source categories subject to MACT standards, section 112(f)(2) of the CAA requires the EPA to determine whether promulgation of additional standards or revised standards is needed to provide

an ample margin of safety to protect public health or to prevent an adverse environmental effect. Section 112(d)(5) of the CAA provides that this residual risk review is not required for categories of area sources subject to GACT standards. Section 112(f)(2)(B) of the CAA further expressly preserves the EPA's use of the two-step approach for developing standards to address any residual risk and the Agency's interpretation of ''ample margin of safety'' developed in the *National Emissions Standards for Hazardous Air Pollutants: Benzene Emissions from Maleic Anhydride Plants, Ethylbenzene/Styrene Plants, Benzene Storage Vessels, Benzene Equipment Leaks, and Coke By-Product Recovery Plants* (Benzene NESHAP) (54 FR 38044, September 14, 1989). The EPA notified Congress in the Risk Report that the Agency intended to use the Benzene NESHAP approach in making CAA section 112(f) residual risk determinations (EPA–453/R–99–001, p. ES–11). The EPA subsequently adopted this approach in its residual risk determinations and the United States Court of Appeals for the District of Columbia Circuit (the Court) upheld the EPA's interpretation that CAA section 112(f)(2) incorporates the approach established in the Benzene NESHAP. See *NRDC* v. *EPA,* 529 F.3d 1077, 1083 (D.C. Cir. 2008).

The approach incorporated into the CAA and used by the EPA to evaluate residual risk and to develop standards under CAA section 112(f)(2) is a two-step approach. In the first step, the EPA determines whether risks are acceptable. This determination ''considers all health information, including risk estimation uncertainty, and includes a presumptive limit on maximum individual lifetime [cancer] risk (MIR) [1] of approximately 1 in 10 thousand.'' 54 FR 38045, September 14, 1989. If risks are unacceptable, the EPA must determine the emissions standards necessary to reduce risk to an acceptable level without considering costs. In the second step of the approach, the EPA considers whether the emissions standards provide an ample margin of safety to protect public health ''in consideration of all health information, including the number of persons at risk levels higher than approximately 1 in 1 million, as well as other relevant factors, including costs and economic impacts, technological feasibility, and other factors relevant to each particular decision.'' *Id.* The EPA must promulgate emission standards necessary to provide an ample margin of safety to protect public health or determine that the standards being reviewed provide an ample margin of safety without any revisions. After conducting the ample margin of safety analysis, we consider whether a more stringent standard is necessary to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect.

CAA section 112(d)(6) separately requires the EPA to review standards promulgated under CAA section 112 and revise them ''as necessary (taking into account developments in practices, processes, and control technologies)'' no less often than every 8 years. In conducting this review, which we call the ''technology review,'' the EPA is not required to recalculate the MACT floor. *Natural Resources Defense Council (NRDC)* v. *EPA,* 529 F.3d 1077, 1084 (D.C. Cir. 2008). *Association of Battery Recyclers, Inc.* v. *EPA,* 716 F.3d 667 (D.C. Cir. 2013). The EPA may consider cost in deciding whether to revise the standards pursuant to CAA section 112(d)(6).

B. What is this source category and how does the current NESHAP regulate its HAP emissions?

The EPA initially promulgated the Taconite Iron Ore Processing NESHAP on October 30, 2003 (68 FR 61869), and it is codified at 40 CFR part 63, subpart RRRRR. This NESHAP regulates HAP emissions from new and existing taconite iron ore processing plants that are major sources of HAP. The Taconite Iron Ore Processing source category consists of eight individual facilities. Six of these facilities are in Minnesota and two are in Michigan.

A taconite iron ore processing plant separates and concentrates iron ore from taconite, a low-grade iron ore containing 20- to 25-percent iron, and produces taconite pellets, which are 60- to 65-percent iron. Most of these pellets, nearly 98 percent, are sent to iron and steel manufacturers for use as feed material. The regulated sources are each new or existing ore crushing and handling operation, ore dryer, pellet indurating furnace, and finished pellet handling operation at a taconite iron ore processing plant that is (or is part of) a major source of HAP emissions. The NESHAP also regulates fugitive emissions from stockpiles (including uncrushed and crushed ore and finished pellets), material transfer points, plant roadways, tailings basin, pellet loading areas, and yard areas.

Taconite iron ore processing includes crushing and handling of the crude ore; concentrating (milling, magnetic separation, chemical flotation, etc.); agglomerating (dewatering, drying, and balling); indurating; and finished pellet handling.

Taconite ore is obtained using a strip-mining process. Surface material and rock are removed to expose the taconite ore-bearing rock layers. Blasting is used to break up the taconite ore, which is then scooped up using large cranes with shovels and loaded into trucks or railcars. The ore is transported from the mine to the primary crushers.

The ore crushing process begins when the taconite ore is dumped into the primary crusher which reduces the crude ore to a diameter of about 6 inches. Additional fine crushing further reduces the material to a size approximately ¾ of an inch in diameter. Intermediate vibratory screens remove the undersized material from the feed before it enters the next crusher. After it is adequately crushed, the ore is conveyed to storage bins at the concentrator building.

In the concentrator building, water is typically added to the ore as it is conveyed into rod and ball mills which further grind the taconite ore to the consistency of coarse beach sand. Taconite ore is then separated from the waste rock material using magnetic separation. The iron content of the slurry is further increased using a combination of hydraulic concentration (gravity settling) and chemical flotation. Typically, application of water is utilized to suppress particulate and HAP metal emissions from the concentrating processes.

From the concentration process, the taconite slurry enters the agglomerating process. In this part of the process, water is removed from the taconite slurry using vacuum disk filters or similar equipment and, at one plant, rotary dryers follow the disc filters and provide additional drying of the ore. The taconite is then mixed with binding agents in a balling drum which tumbles and rolls the taconite into unfired pellets. From the balling drum, the unfired pellets are conveyed to the indurating furnace.

The unfired taconite pellets enter the induration furnace where they are hardened and oxidized at a temperature of between 2,290 to 2,550 degrees Fahrenheit. Indurating furnaces are either straight grate furnaces or grate kiln furnaces. The hardened, finished pellets exit through the indurating furnace cooler.

The finished pellet handling process begins at the point where the fired

[1] Although defined as ''maximum individual risk,'' MIR refers only to cancer risk. MIR, one metric for assessing cancer risk, is the estimated risk if an individual were exposed to the maximum level of a pollutant for a lifetime.

taconite pellets exit the indurating furnace cooler (*i.e.,* pellet loadout) and ends at the finished pellet stockpile. The finished pellet handling process includes finished pellet screening, transfer, and storage.

Ore crushing and handling, ore drying, and finished pellet handling are all potentially significant points of particulate matter (PM) emissions. Taconite ore inherently contains trace metals, such as manganese, chromium, cobalt, arsenic, and lead, which are listed as HAP under CAA section 112(b) and the PM emissions from these three operations can contain these metal compounds. Manganese compounds are the predominant metal HAP emitted from ore crushing and handling, ore drying, and finished pellet handling.

The indurating furnaces are the most significant sources of HAP emissions, accounting for about 99 percent of the total HAP emissions from the Taconite Iron Ore Processing source category. Three types of HAP are emitted from the waste gas stacks of indurating furnaces. The first type of HAP is metallic HAP existing as a portion of PM from the taconite ore or from fuel (such as coal) fed into the furnaces. Manganese and arsenic compounds are the predominant metal HAP emitted by indurating furnaces. Other metal HAP emitted from these furnaces include chromium, lead, nickel, cadmium, and mercury. The second type of HAP is organic HAP, primarily formaldehyde, resulting as a product of incomplete fuel combustion. The third type of HAP is acid gases, such as hydrochloric acid (HCl) and hydrofluoric acid (HF). Fluorine and chlorine compounds in the raw materials are liberated during the indurating process and combine with moisture in the exhaust to form HCl and HF.

The current rule requires compliance with emission limits, operating limits for control devices, and work practice standards at all times except during periods of SSM. The emission limits are in the form of PM limits, which are a surrogate for metal HAP emissions as well as for HCl and HF for indurating furnaces. Emission limitations, shown in Table 2, apply to each ore crushing and handling operation, ore dryer, indurating furnace, and finished pellet handling operation.

TABLE 2—PM EMISSION LIMITS FOR TACONITE IRON ORE PROCESSING

Affected source	Affected source is new or existing	Emission limits [1]
Ore crushing and handling emission units	Existing	0.008 gr/dscf
	New	0.005 gr/dscf.
Straight grate indurating furnace processing magnetite	Existing	0.01 gr/dscf
	New	0.006 gr/dscf.
Grate kiln indurating furnace processing magnetite	Existing	0.01 gr/dscf.
	New	0.006 gr/dscf.
Grate kiln indurating furnace processing hematite	Existing	0.03 gr/dscf.
	New	0.018 gr/dscf.
Finished pellet handling emission units	Existing	0.008 gr/dscf.
	New	0.005 gr/dscf.
Ore dryer	Existing	0.052 gr/dscf.
	New	0.025 gr/dscf.

[1] gr/dscf = grains per dry standard cubic foot.

Performance tests are required to demonstrate compliance with the emission limits and must be conducted twice per 5-year period. The rule also requires that site-specific operating limits be established during the performance test for each control device and monitored continuously to demonstrate continuous compliance. Table 3 lists the operating parameters that must be established during the performance test and then monitored continuously.

TABLE 3—OPERATING PARAMETERS MONITORED TO DEMONSTRATE CONTINUOUS COMPLIANCE

Control device [1]	Monitoring device [2]	Parameters monitored
Baghouse	Bag leak detection system	Relative change in PM loading.
Dynamic wet scrubber	CPMS	Scrubber water flow rate and either fan amperage or pressure drop.
Wet scrubbers (other than dynamic wet scrubbers)	CPMS	Pressure drop and scrubber water flow rate.
Dry ESP	COMS, or CPMS	Opacity Secondary voltage and secondary current.
Wet ESP	CPMS	Secondary voltage, stack outlet temperature, and water flow rate.

[1] ESP = electrostatic precipitator.
[2] CPMS = continuous parameter monitoring system, COMS = continuous opacity monitor.

The current rule also includes operation and maintenance requirements for pellet indurating furnaces to ensure good combustion practices to minimize emissions of organic HAP (combustion-related HAP such as formaldehyde) and requires that sources of fugitive dust emissions at taconite iron ore processing plants be controlled using work practices described in detail in a facility's fugitive dust emissions control plan. The plan must address fugitive emissions from stockpiles (including uncrushed and crushed ore and finished pellets), material transfer points, plant roadways, tailings basin, pellet loading areas, and yard areas.

C. What data collection activities were conducted to support this action?

For the Taconite Iron Ore Processing source category, the EPA did not use data collection requests to gather emissions and other related data used in the analysis of risks. The data and data sources used to support this action are described in section II.D below.

D. What other relevant background information and data are available?

Information used to estimate emissions from taconite iron ore processing plants was obtained primarily from the EPA's 2014 National Emissions Inventory (NEI) database (*https://www.epa.gov/air-emissions-inventories/2014-national-emissions-inventory-nei-data*) and supplemental information submitted by industry. Data on the numbers, types, dimensions, and locations of the emission points for each facility were obtained from the NEI, state agencies, Google Earth™, and taconite iron ore processing industry staff. The HAP emissions from taconite iron ore processing plants were categorized by source into one of the five emission process groups as follows: Ore crushing and handling operations; ore drying; pellet induration; pellet handling operations; and fugitive sources. Data on HAP emissions, including the HAP emitted, emission source, emission rates, stack parameters (such as temperature, velocity, flow, etc.), and latitude and longitude were compiled into a draft modeling file.

To ensure the quality of the emissions data, the EPA subjected the draft modeling file to a variety of quality checks. The draft modeling file for each facility was made available to the facility to review the emission release parameters and the emission rates for their facilities. Source latitudes and longitudes reported by facilities were checked in Google Earth™ to verify accuracy and were corrected as needed. These and other quality control efforts resulted in a more accurate emissions dataset. The document, *Development of the Residual Risk Review Emissions Dataset for the Taconite Iron Ore Processing Source Category,* provides a detailed description of the development of the modeling dataset and is available in the docket for this rulemaking.

III. Analytical Procedures and Decision-Making

In this section, we describe the analyses performed to support the proposed decisions for the RTR and other issues addressed in this action.

A. How do we consider risk in our decision-making?

As discussed in section II.A of this preamble and in the Benzene NESHAP, in evaluating and developing standards under CAA section 112(f)(2), we apply a two-step approach to determine whether or not risks are acceptable and to determine if the standards provide an ample margin of safety to protect public health. As explained in the Benzene NESHAP, ''the first step judgment on acceptability cannot be reduced to any single factor'' and, thus, ''[t]he Administrator believes that the acceptability of risk under section 112 is best judged on the basis of a broad set of health risk measures and information.'' 54 FR 38046, September 14, 1989. Similarly, with regard to the ample margin of safety determination, ''the Agency again considers all of the health risk and other health information considered in the first step. Beyond that information, additional factors relating to the appropriate level of control will also be considered, including cost and economic impacts of controls, technological feasibility, uncertainties, and any other relevant factors.'' *Id.*

The Benzene NESHAP approach provides flexibility regarding factors the EPA may consider in making determinations and how the EPA may weigh those factors for each source category. The EPA conducts a risk assessment that provides estimates of the MIR posed by the HAP emissions from each source in the source category, the hazard index (HI) for chronic exposures to HAP with the potential to cause noncancer health effects, and the hazard quotient (HQ) for acute exposures to HAP with the potential to cause noncancer health effects.[2] The assessment also provides estimates of the distribution of cancer risk within the exposed populations, cancer incidence, and an evaluation of the potential for an adverse environmental effect. The scope of the EPA's risk analysis is consistent with the EPA's response to comments on our policy under the Benzene NESHAP where the EPA explained that:

> ''[t]he policy chosen by the Administrator permits consideration of multiple measures of health risk. Not only can the MIR figure be considered, but also incidence, the presence of non-cancer health effects, and the uncertainties of the risk estimates. In this way, the effect on the most exposed individuals can be reviewed as well as the impact on the general public. These factors can then be weighed in each individual case. This approach complies with the *Vinyl Chloride* mandate that the Administrator ascertain an acceptable level of risk to the public by employing his expertise to assess available data. It also complies with the Congressional intent behind the CAA, which did not exclude the use of any particular measure of public health risk from the EPA's consideration with respect to CAA section 112 regulations, and thereby implicitly permits consideration of any and all measures of health risk which the Administrator, in his judgment, believes are appropriate to determining what will 'protect the public health'.''

See 54 FR 38057, September 14, 1989. Thus, the level of the MIR is only one factor to be weighed in determining acceptability of risk. The Benzene NESHAP explained that ''an MIR of approximately one in 10 thousand should ordinarily be the upper end of the range of acceptability. As risks increase above this benchmark, they become presumptively less acceptable under CAA section 112, and would be weighed with the other health risk measures and information in making an overall judgment on acceptability. Or, the Agency may find, in a particular case, that a risk that includes an MIR less than the presumptively acceptable level is unacceptable in the light of other health risk factors.'' *Id.* at 38045. In other words, risks that include an MIR above 100-in-1 million may be determined to be acceptable, and risks with an MIR below that level may be determined to be unacceptable, depending on all of the available health information. Similarly, with regard to the ample margin of safety analysis, the EPA stated in the Benzene NESHAP that: ''EPA believes the relative weight of the many factors that can be considered in selecting an ample margin of safety can only be determined for each specific source category. This occurs mainly because technological and economic factors (along with the health-related factors) vary from source category to source category.'' *Id.* at 38061. We also consider the uncertainties associated with the various risk analyses, as discussed earlier in this preamble, in our determinations of acceptability and ample margin of safety.

The EPA notes that it has not considered certain health information to date in making residual risk determinations. At this time, we do not attempt to quantify the HAP risk that may be associated with emissions from other facilities that do not include the source category under review, mobile source emissions, natural source emissions, persistent environmental pollution, or atmospheric transformation in the vicinity of the sources in the category.

The EPA understands the potential importance of considering an individual's total exposure to HAP in addition to considering exposure to HAP emissions from the source category and facility. We recognize that such consideration may be particularly important when assessing noncancer

[2] The MIR is defined as the cancer risk associated with a lifetime of exposure at the highest concentration of HAP where people are likely to live. The HQ is the ratio of the potential HAP exposure concentration to the noncancer dose-response value; the HI is the sum of HQs for HAP that affect the same target organ or organ system.

risk, where pollutant-specific exposure health reference levels (*e.g.,* reference concentrations (RfCs)) are based on the assumption that thresholds exist for adverse health effects. For example, the EPA recognizes that, although exposures attributable to emissions from a source category or facility alone may not indicate the potential for increased risk of adverse noncancer health effects in a population, the exposures resulting from emissions from the facility in combination with emissions from all of the other sources (*e.g.,* other facilities) to which an individual is exposed may be sufficient to result in an increased risk of adverse noncancer health effects. In May 2010, the Science Advisory Board (SAB) advised the EPA ''that RTR assessments will be most useful to decision makers and communities if results are presented in the broader context of aggregate and cumulative risks, including background concentrations and contributions from other sources in the area.'' [3]

In response to the SAB recommendations, the EPA incorporates cumulative risk analyses into its RTR risk assessments, including those reflected in this action. The Agency (1) conducts facility-wide assessments, which include source category emission points, as well as other emission points within the facilities; (2) combines exposures from multiple sources in the same category that could affect the same individuals; and (3) for some persistent and bioaccumulative pollutants, analyzes the ingestion route of exposure. In addition, the RTR risk assessments consider aggregate cancer risk from all carcinogens and aggregated noncancer HQs for all noncarcinogens affecting the same target organ or target organ system.

Although we are interested in placing source category and facility-wide HAP risk in the context of total HAP risk from all sources combined in the vicinity of each source, we are concerned about the uncertainties of doing so. Estimates of total HAP risk from emission sources other than those that we have studied in depth during this RTR review would have significantly greater associated uncertainties than the source category or facility-wide estimates. Such aggregate or cumulative assessments would compound those uncertainties, making the assessments too unreliable.

[3] Recommendations of the SAB Risk and Technology Review Methods Panel are provided in their report, which is available at: *https://yosemite.epa.gov/sab/sabproduct.nsf/4AB3966E263D943A8525771F00668381/$File/EPA-SAB-10-007-unsigned.pdf.*

B. How do we perform the technology review?

Our technology review focuses on the identification and evaluation of developments in practices, processes, and control technologies that have occurred since the MACT standards were promulgated. Where we identify such developments, we analyze their technical feasibility, estimated costs, energy implications, and non-air environmental impacts. We also consider the emission reductions associated with applying each development. This analysis informs our decision of whether it is ''necessary'' to revise the emissions standards. In addition, we consider the appropriateness of applying controls to new sources versus retrofitting existing sources. For this exercise, we consider any of the following to be a ''development'':

- Any add-on control technology or other equipment that was not identified and considered during development of the original MACT standards;
- Any improvements in add-on control technology or other equipment (that were identified and considered during development of the original MACT standards) that could result in additional emissions reduction;
- Any work practice or operational procedure that was not identified or considered during development of the original MACT standards;
- Any process change or pollution prevention alternative that could be broadly applied to the industry and that was not identified or considered during development of the original MACT standards; and
- Any significant changes in the cost (including cost effectiveness) of applying controls (including controls the EPA considered during the development of the original MACT standards).

In addition to reviewing the practices, processes, and control technologies that were considered at the time we originally developed the NESHAP, we review a variety of data sources in our investigation of potential practices, processes, or controls to consider. See sections II.C and II.D of this preamble for information on the specific data sources that were reviewed as part of the technology review.

C. How do we estimate post-MACT risk posed by the source category?

In this section, we provide a complete description of the types of analyses that we generally perform during the risk assessment process. In some cases, we do not perform a specific analysis because it is not relevant. For example, in the absence of emissions of HAP known to be persistent and bioaccumulative in the environment (PB–HAP), we would not perform a multipathway exposure assessment. Where we do not perform an analysis, we state that we do not and provide the reason. While we present all of our risk assessment methods, we only present risk assessment results for the analyses actually conducted (see section IV.A of this preamble).

The EPA conducts a risk assessment that provides estimates of the MIR for cancer posed by the HAP emissions from each source in the source category, the HI for chronic exposures to HAP with the potential to cause noncancer health effects, and the HQ for acute exposures to HAP with the potential to cause noncancer health effects. The assessment also provides estimates of the distribution of cancer risk within the exposed populations, cancer incidence, and an evaluation of the potential for an adverse environmental effect. The seven sections that follow this paragraph describe how we estimated emissions and conducted the risk assessment. The docket for this rulemaking contains the following document which provides more information on the risk assessment inputs and models: *Residual Risk Assessment for the Taconite Iron Ore Processing Source Category in Support of the 2019 Risk and Technology Review Proposed Rule* (also referred to as the Taconite Risk Report in this preamble, and available in Docket ID No. EPA–HQ–OAR–2017–0664). The methods used to assess risk (as described in the seven primary steps below) are consistent with those described by the EPA in the document reviewed by a panel of the EPA's SAB in 2009; [4] and described in the SAB review report issued in 2010. They are also consistent with the key recommendations contained in that report.

1. How did we estimate actual emissions and identify the emissions release characteristics?

The HAP emissions from taconite iron ore processing plants fall into the following pollutant categories: Metals (HAP metals), acid gases (*i.e.,* HCl and HF), and combustion-related organic HAP, such as polycyclic aromatic hydrocarbons, dioxins/furans (D/F), benzene, and formaldehyde. The HAP

[4] U.S. EPA. *Risk and Technology Review (RTR) Risk Assessment Methodologies: For Review by the EPA's Science Advisory Board with Case Studies—MACT I Petroleum Refining Sources and Portland Cement Manufacturing,* June 2009. EPA–452/R–09–006. *https://www3.epa.gov/airtoxics/rrisk/rtrpg.html.*

are emitted from several emission sources at taconite iron ore processing plants which, for the purposes of the source category risk assessment, have been categorized into five emission process groups as follows: ore crushing and handling operations, ore drying, pellet induration, finished pellet handling operations, and fugitive dust emissions control plan sources.

The main sources of emissions data include the NEI data submitted for calendar year 2014 and supplemental information submitted by industry (available in Docket ID No. EPA–HQ–OAR–2017–0664). Data on the numbers, types, dimensions, and locations of the emission points for each facility were obtained from the NEI, state agencies (*i.e.,* the Minnesota Pollution Control Agency and the Michigan Department of Environmental Quality), Google Earth™, and from representatives of the taconite iron ore processing industry. A description of the data, approach, and rationale used to develop actual HAP emissions estimates is discussed in more detail in the document, *Development of the Residual Risk Review Emissions Dataset for the Taconite Iron Ore Processing Source Category,* which is available in the docket (Docket ID No. EPA–HQ–OAR–2017–0664).

2. How did we estimate MACT-allowable emissions?

The available emissions data in the RTR emissions dataset include estimates of the mass of HAP emitted during a specified annual time period. These ''actual'' emission levels are often lower than the emission levels allowed under the requirements of the current MACT standards. The emissions allowed under the MACT standards are referred to as the ''MACT-allowable'' emissions. We discussed the consideration of both MACT-allowable and actual emissions in the final Coke Oven Batteries RTR (70 FR 19998–19999, April 15, 2005) and in the proposed and final Hazardous Organic NESHAP RTR (71 FR 34428, June 14, 2006, and 71 FR 76609, December 21, 2006, respectively). In those actions, we noted that assessing the risk at the MACT-allowable level is inherently reasonable since that risk reflects the maximum level facilities could emit and still comply with national emission standards. We also explained that it is reasonable to consider actual emissions, where such data are available, in both steps of the risk analysis, in accordance with the Benzene NESHAP approach. (54 FR 38044, September 14, 1989.)

Allowable emission rates for the taconite iron ore processing plants were developed by scaling the actual emission rates. Specifically, once the actual emission rates were developed for a given facility, the allowable emission rate of each emission process group at a given facility was estimated by multiplying the actual emission rate of the emission process group by the ratio of the effective (maximum) production rate of that facility to the actual production rate of that facility during calendar year 2014. The ratios all exceeded 1.0 resulting in all allowable emissions being greater than actual emissions. For a detailed description of the estimation of allowable emissions, see the document, *Development of the Residual Risk Review Emissions Dataset for the Taconite Iron Ore Processing Source Category,* which is available in the docket (Docket ID No. EPA–HQ–OAR–2017–0664).

3. How do we conduct dispersion modeling, determine inhalation exposures, and estimate individual and population inhalation risk?

Both long-term and short-term inhalation exposure concentrations and health risk from the source category addressed in this action were estimated using the Human Exposure Model (HEM–3).[5] The HEM–3 performs three primary risk assessment activities: (1) Conducting dispersion modeling to estimate the concentrations of HAP in ambient air, (2) estimating long-term and short-term inhalation exposures to individuals residing within 50 kilometers (km) of the modeled sources, and (3) estimating individual and population-level inhalation risk using the exposure estimates and quantitative dose-response information.

a. Dispersion Modeling

The air dispersion model AERMOD, used by the HEM–3 model, is one of the EPA's preferred models for assessing air pollutant concentrations from industrial facilities.[6] To perform the dispersion modeling and to develop the preliminary risk estimates, HEM–3 draws on three data libraries. The first is a library of meteorological data, which is used for dispersion calculations. This library includes 1 year (2016) of hourly surface and upper air observations from 824 meteorological stations, selected to provide coverage of the United States and Puerto Rico. A second library of United States Census Bureau census block[7] internal point locations and populations provides the basis of human exposure calculations (U.S. Census, 2010). In addition, for each census block, the census library includes the elevation and controlling hill height, which are also used in dispersion calculations. A third library of pollutant-specific dose-response values is used to estimate health risk. These are discussed below.

b. Risk From Chronic Exposure to HAP

In developing the risk assessment for chronic exposures, we use the estimated annual average ambient air concentrations of each HAP emitted by each source in the source category. The HAP air concentrations at each nearby census block centroid located within 50 km of the facility are a surrogate for the chronic inhalation exposure concentration for all the people who reside in that census block. A distance of 50 km is consistent with both the analysis supporting the 1989 Benzene NESHAP (54 FR 38044, September 14, 1989) and the limitations of Gaussian dispersion models, including AERMOD.

For each facility, we calculate the MIR as the cancer risk associated with a continuous lifetime (24 hours per day, 7 days per week, 52 weeks per year, 70 years) exposure to the maximum concentration at the centroid of each inhabited census block. We calculate individual cancer risk by multiplying the estimated lifetime exposure to the ambient concentration of each HAP (in micrograms per cubic meter ($\mu g/m^3$)) by its unit risk estimate (URE). The URE is an upper-bound estimate of an individual's incremental risk of contracting cancer over a lifetime of exposure to a concentration of 1 microgram of the pollutant per cubic meter of air. For residual risk assessments, we generally use UREs from the EPA's Integrated Risk Information System (IRIS). For carcinogenic pollutants without IRIS values, we look to other reputable sources of cancer dose-response values, often using California EPA (CalEPA) UREs, where available. In cases where new, scientifically credible dose-response values have been developed in a manner consistent with EPA guidelines and have undergone a peer review process similar to that used by the EPA, we may use such dose-response values in place of, or in addition to, other values, if appropriate. The pollutant-specific dose-response

[5] For more information about HEM–3, go to *https://www.epa.gov/fera/risk-assessment-and-modeling-human-exposure-model-hem.*

[6] U.S. EPA. Revision to the *Guideline on Air Quality Models: Adoption of a Preferred General Purpose (Flat and Complex Terrain) Dispersion Model and Other Revisions* (70 FR 68218, November 9, 2005).

[7] A census block is the smallest geographic area for which census statistics are tabulated.

values used to estimate health risk are available at *https://www.epa.gov/fera/dose-response-assessment-assessing-health-risks-associated-exposure-hazardous-air-pollutants.*

To estimate individual lifetime cancer risks associated with exposure to HAP emissions from each facility in the source category, we sum the risks for each of the carcinogenic HAP [8] emitted by the modeled facility. We estimate cancer risk at every census block within 50 km of every facility in the source category. The MIR is the highest individual lifetime cancer risk estimated for any of those census blocks. In addition to calculating the MIR, we estimate the distribution of individual cancer risks for the source category by summing the number of individuals within 50 km of the sources whose estimated risk falls within a specified risk range. We also estimate annual cancer incidence by multiplying the estimated lifetime cancer risk at each census block by the number of people residing in that block, summing results for all of the census blocks, and then dividing this result by a 70-year lifetime.

To assess the risk of noncancer health effects from chronic exposure to HAP, we calculate either an HQ or a target organ-specific hazard index (TOSHI). We calculate an HQ when a single noncancer HAP is emitted. Where more than one noncancer HAP is emitted, we sum the HQ for each of the HAP that affects a common target organ or target organ system to obtain a TOSHI. The HQ is the estimated exposure divided by the chronic noncancer dose-response value, which is a value selected from one of several sources. The preferred chronic noncancer dose-response value is the EPA RfC, defined as ''an estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime'' (*https://iaspub.epa.gov/sor_internet/registry/termreg/searchandretrieve/glossariesandkeywordlists/search.do?details=&vocabName=IRIS%20Glossary*). In cases where an RfC from the EPA's IRIS is not available or where the EPA determines that using a value other than the RfC is appropriate, the chronic noncancer dose-response value can be a value from the following prioritized sources, which define their dose-response values similarly to the EPA: (1) The Agency for Toxic Substances and Disease Registry (ATSDR) Minimum Risk Level (*https://www.atsdr.cdc.gov/mrls/index.asp*); (2) the CalEPA Chronic Reference Exposure Level (REL) (*https://oehha.ca.gov/air/crnr/notice-adoption-air-toxics-hot-spots-program-guidance-manual-preparation-health-risk-0*); or (3) as noted above, a scientifically credible dose-response value that has been developed in a manner consistent with the EPA guidelines and has undergone a peer review process similar to that used by the EPA. The pollutant-specific dose-response values used to estimate health risks are available at *https://www.epa.gov/fera/dose-response-assessment-assessing-health-risks-associated-exposure-hazardous-air-pollutants.*

c. Risk From Acute Exposure to HAP That May Cause Health Effects Other Than Cancer

For each HAP for which appropriate acute inhalation dose-response values are available, the EPA also assesses the potential health risks due to acute exposure. For these assessments, the EPA makes conservative assumptions about emission rates, meteorology, and exposure location. In this proposed rulemaking, as part of our efforts to continually improve our methodologies to evaluate the risks that HAP emitted from categories of industrial sources pose to human health and the environment,[9] we are revising our treatment of meteorological data to use reasonable worst-case air dispersion conditions in our acute risk screening assessments instead of worst-case air dispersion conditions. This revised treatment of meteorological data and the supporting rationale are described in more detail in *Residual Risk Assessment for Taconite Iron Ore Processing Source Category in Support of the 2019 Risk and Technology Review Proposed Rule* and in Appendix 5 of the report: *Technical Support Document for Acute Risk Screening Assessment.* We will be applying this revision in RTR rulemakings proposed on or after June 3, 2019.

To assess the potential acute risk to the maximally exposed individual, we use the peak hourly emission rate for each emission point,[10] reasonable worst-case air dispersion conditions (*i.e.,* 99th percentile), and the point of highest off-site exposure. Specifically, we assume that peak emissions from the source category and reasonable worst-case air dispersion conditions co-occur and that a person is present at the point of maximum exposure.

To characterize the potential health risks associated with estimated acute inhalation exposures to a HAP, we generally use multiple acute dose-response values, including acute RELs, acute exposure guideline levels (AEGLs), and emergency response planning guidelines (ERPG) for 1-hour exposure durations, if available, to calculate acute HQs. The acute HQ is calculated by dividing the estimated acute exposure concentration by the acute dose-response value. For each HAP for which acute dose-response values are available, the EPA calculates acute HQs.

An acute REL is defined as ''the concentration level at or below which no adverse health effects are anticipated for a specified exposure duration.'' [11] Acute RELs are based on the most sensitive, relevant, adverse health effect reported in the peer-reviewed medical and toxicological literature. They are designed to protect the most sensitive individuals in the population through the inclusion of margins of safety. Because margins of safety are incorporated to address data gaps and

[8] The EPA's 2005 *Guidelines for Carcinogen Risk Assessment* classifies carcinogens as: ''carcinogenic to humans,'' ''likely to be carcinogenic to humans,'' and ''suggestive evidence of carcinogenic potential.'' These classifications also coincide with the terms ''known carcinogen, probable carcinogen, and possible carcinogen,'' respectively, which are the terms advocated in the EPA's *Guidelines for Carcinogen Risk Assessment,* published in 1986 (51 FR 33992, September 24, 1986). In August 2000, the document, *Supplemental Guidance for Conducting Health Risk Assessment of Chemical Mixtures* (EPA/630/R–00/002), was published as a supplement to the 1986 document. Copies of both documents can be obtained from *https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=20533&CFID=70315376&CFTOKEN=71597944.* Summing the risk of these individual compounds to obtain the cumulative cancer risk is an approach that was recommended by the EPA's SAB in their 2002 peer review of the EPA's National Air Toxics Assessment (NATA) titled *NATA—Evaluating the National-scale Air Toxics Assessment 1996 Data—an SAB Advisory,* available at *https://yosemite.epa.gov/sab/sabproduct.nsf/214C6E915BB04E14852570CA007A682C/$File/ecadv02001.pdf.*

[9] See, *e.g.,* U.S. EPA. *Screening Methodologies to Support Risk and Technology Reviews (RTR): A Case Study Analysis* (Draft Report, May 2017. *https://www3.epa.gov/ttn/atw/rrisk/rtrpg.html*).

[10] In the absence of hourly emission data, we develop estimates of maximum hourly emission rates by multiplying the average actual annual emissions rates by a factor (either a category-specific factor or a default factor of 10) to account for variability. This is documented in *Residual Risk Assessment for Taconite Iron Ore Processing Source Category in Support of the 2019 Risk and Technology Review Proposed Rule* and in Appendix 5 of the report: *Technical Support Document for Acute Risk Screening Assessment.* Both are available in the docket for this rulemaking.

[11] CalEPA issues acute RELs as part of its Air Toxics Hot Spots Program, and the 1-hour and 8-hour values are documented in *Air Toxics Hot Spots Program Risk Assessment Guidelines, Part I, The Determination of Acute Reference Exposure Levels for Airborne Toxicants,* which is available at *https://oehha.ca.gov/air/general-info/oehha-acute-8-hour-and-chronic-reference-exposure-level-rel-summary.*

uncertainties, exceeding the REL does not automatically indicate an adverse health impact. AEGLs represent threshold exposure limits for the general public and are applicable to emergency exposures ranging from 10 minutes to 8 hours.[12] They are guideline levels for ''once-in-a-lifetime, short-term exposures to airborne concentrations of acutely toxic, high-priority chemicals.'' *Id.* at 21. The AEGL–1 is specifically defined as ''the airborne concentration (expressed as ppm (parts per million) or mg/m^3 (milligrams per cubic meter)) of a substance above which it is predicted that the general population, including susceptible individuals, could experience notable discomfort, irritation, or certain asymptomatic nonsensory effects. However, the effects are not disabling and are transient and reversible upon cessation of exposure.'' The document also notes that ''Airborne concentrations below AEGL–1 represent exposure levels that can produce mild and progressively increasing but transient and nondisabling odor, taste, and sensory irritation or certain asymptomatic, nonsensory effects.'' *Id.* AEGL–2 are defined as ''the airborne concentration (expressed as parts per million or milligrams per cubic meter) of a substance above which it is predicted that the general population, including susceptible individuals, could experience irreversible or other serious, long-lasting adverse health effects or an impaired ability to escape.'' *Id.*

ERPGs are ''developed for emergency planning and are intended as health-based guideline concentrations for single exposures to chemicals.''[13] *Id.* at 1. The ERPG–1 is defined as ''the maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to 1 hour without experiencing other than mild transient adverse health effects or without perceiving a clearly defined, objectionable odor.'' *Id.* at 2. Similarly, the ERPG–2 is defined as ''the maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to one hour without experiencing or developing irreversible or other serious health effects or symptoms which could impair an individual's ability to take protective action.'' *Id.* at 1.

An acute REL for 1-hour exposure durations is typically lower than its corresponding AEGL–1 and ERPG–1. Even though their definitions are slightly different, AEGL–1s are often the same as the corresponding ERPG–1s, and AEGL–2s are often equal to ERPG–2s. The maximum HQs from our acute inhalation screening risk assessment typically result when we use the acute REL for a HAP. In cases where the maximum acute HQ exceeds 1, we also report the HQ based on the next highest acute dose-response value (usually the AEGL–1 and/or the ERPG–1).

For this source category, ore crushing and handling, ore drying, and pellet handling operations may have batch operation cycles with peak emissions as high as 10 times the average hourly actual emissions occurring for part of that cycle. Therefore, a factor of 10 was used to estimate peak hourly emissions for these sources. With regard to fugitive dust emissions (*e.g.,* stockpiles, material transfer points, plant roadways, tailings basin, pellet loading areas, and yard areas), we assumed peak hourly emissions could be as high as 10 times the average (*i.e.,* the default value described in footnote number 10) because we did not have sufficient data or information to derive a different value. However, with regard to indurating furnaces, which typically operate continuously for long periods of time with relatively minor fluctuations, it is estimated that emission rates could occasionally increase by a factor of up to two times the average hourly actual emission. Therefore, the EPA selected two as the appropriate multiplier to estimate maximum acute emissions from indurating furnaces. A more detailed discussion of the selection of the acute emission factors is available in the document *Development of the Residual Risk Review Emissions Dataset for the Taconite Iron Ore Processing Source Category,* available in the docket (Docket ID No. EPA–HQ–OAR–2017–0664).

In our acute inhalation screening risk assessment, acute impacts are deemed negligible for HAP for which acute HQs are less than or equal to 1, and no further analysis is performed for these HAP. In cases where an acute HQ from the screening analysis is greater than 1, we assess the site-specific data to ensure that the acute HQ is at an off-site location. For this source category, for each HAP with an acute HQ value greater than 1, the data refinements employed consisted of plotting the HEM–3 polar grid results on aerial photographs of the facilities. We then assessed whether the highest acute HQs were off-site and at locations that may be accessible to the public (*e.g.,* roadways and public buildings). These refinements are discussed more fully in the Taconite Risk Report, which is available in the docket for this source category.

4. How do we conduct the multipathway exposure and risk screening assessment?

The EPA conducts a tiered screening assessment examining the potential for significant human health risks due to exposures via routes other than inhalation (*i.e.,* ingestion). We first determine whether any sources in the source category emit any HAP known to be persistent and bioaccumulative in the environment, as identified in the EPA's Air Toxics Risk Assessment Library (see Volume 1, Appendix D, at *https://www.epa.gov/fera/risk-assessment-and-modeling-air-toxics-risk-assessment-reference-library.*

For the Taconite Iron Ore Processing source category, we identified PB–HAP emissions of arsenic, cadmium, D/F, lead, mercury, and polycyclic organic matter (POM), so we proceeded to the next step of the evaluation. Except for lead, the human health risk screening assessment for PB–HAP consists of three progressive tiers. In a Tier 1 screening assessment, we determine whether the magnitude of the facility-specific emissions of PB–HAP warrants further evaluation to characterize human health risk through ingestion exposure. To facilitate this step, we evaluate emissions against previously developed screening threshold emission rates for several PB–HAP that are based on a hypothetical upper-end screening exposure scenario developed for use in conjunction with the EPA's Total Risk Integrated Methodology. Fate, Transport, and Ecological Exposure (TRIM.FaTE) model. The PB–HAP with screening threshold emission rates are arsenic compounds, cadmium compounds, chlorinated dibenzodioxins and furans, mercury compounds, and POM. Based on the EPA estimates of toxicity and bioaccumulation potential, these pollutants represent a conservative list for inclusion in multipathway risk assessments for RTR rules. (See Volume 1, Appendix D at *https://www.epa.gov/sites/production/files/2013-08/documents/volume_1_reflibrary.pdf.*) In this assessment, we

[12] National Academy of Sciences, 2001. *Standing Operating Procedures for Developing Acute Exposure Levels for Hazardous Chemicals,* page 2. Available at *https://www.epa.gov/sites/production/files/2015-09/documents/sop_final_standing_operating_procedures_2001.pdf.* Note that the National Advisory Committee for Acute Exposure Guideline Levels for Hazardous Substances ended in October 2011, but the AEGL program continues to operate at the EPA and works with the National Academies to publish final AEGLs (*https://www.epa.gov/aegl*).

[13] *ERPGS Procedures and Responsibilities.* March 2014. American Industrial Hygiene Association. Available at: *https://www.aiha.org/get-involved/AIHAGuidelineFoundation/EmergencyResponsePlanningGuidelines/Documents/ERPG%20Committee%20Standard%20Operating%20Procedures%20%20-%20March%202014%20Revision%20%28Updated%2010-2-2014%29.pdf.*

compare the facility-specific emission rates of these PB–HAP to the screening threshold emission rates for each PB–HAP to assess the potential for significant human health risks via the ingestion pathway. The ratio of a facility's actual emission rate to the Tier 1 screening threshold emission rate is a ''screening value.''

We derive the Tier 1 screening threshold emission rates for these PB–HAP (other than lead compounds) to correspond to a maximum excess lifetime cancer risk of 1-in-1 million (*i.e.,* for arsenic compounds, polychlorinated dibenzodioxins and furans and POM) or, for HAP that cause noncancer health effects (*i.e.,* cadmium compounds and mercury compounds), a maximum HQ of 1. If the emission rate of any one PB–HAP or combination of carcinogenic PB–HAP in the Tier 1 screening assessment exceeds the Tier 1 screening threshold emission rate for any facility (*i.e.,* the screening value is greater than 1), we conduct a second screening assessment, which we call the Tier 2 screening assessment. The Tier 2 screening assessment separates the Tier 1 combined fisher and farmer exposure scenario into fisher, farmer, and gardener scenarios that retain upper-bound ingestion rates.

In the Tier 2 screening assessment, the location of each facility that exceeds a Tier 1 screening threshold emission rate is used to refine the assumptions associated with the Tier 1 fisher and farmer exposure scenarios at that facility. A key assumption in the Tier 1 screening assessment is that a lake and/or farm is located near the facility. As part of the Tier 2 screening assessment, we use a U.S. Geological Survey (USGS) database to identify actual waterbodies within 50 km of each facility and assume the fisher only consumes fish from lakes within that 50 km zone. We also examine the differences between local meteorology near the facility and the meteorology used in the Tier 1 screening assessment. We then adjust the previously-developed Tier 1 screening threshold emission rates for each PB–HAP for each facility based on an understanding of how exposure concentrations estimated for the screening scenario change with the use of local meteorology and USGS lakes database.

In the Tier 2 farmer scenario, we maintain an assumption that the farm is located within 0.5 km of the facility and that the farmer consumes meat, eggs, dairy, vegetables, and fruit produced near the facility. We may further refine the Tier 2 screening analysis by assessing a gardener scenario to characterize a range of exposures, with the gardener scenario being more plausible in RTR evaluations. Under the gardener scenario, we assume the gardener consumes home-produced eggs, vegetables, and fruit products at the same ingestion rate as the farmer. The Tier 2 screen continues to rely on the high-end food intake assumptions that were applied in Tier 1 for local fish (adult female angler at 99th percentile fish consumption), [14] and locally grown or raised foods (90th percentile consumption of locally grown or raised foods for the farmer and gardener scenarios).[15] If PB–HAP emission rates do not result in a Tier 2 screening value greater than 1, we consider those PB–HAP emissions to pose risks below a level of concern. If the PB–HAP emission rates for a facility exceed the Tier 2 screening threshold emission rates, we may conduct a Tier 3 screening assessment.

There are several analyses that can be included in a Tier 3 screening assessment, depending upon the extent of refinement warranted, including validating that the lakes are fishable, locating residential/garden locations for urban and/or rural settings, considering plume-rise to estimate emissions lost above the mixing layer, and considering hourly effects of meteorology and plume-rise on chemical fate and transport (a time-series analysis). If necessary, the EPA may further refine the screening assessment through a site-specific assessment.

There are several analyses that can be included in a Tier 3 screening assessment, depending upon the extent of refinement warranted, including validating that the lakes are fishable, locating residential/garden locations for urban and/or rural settings, considering plume-rise to estimate emissions lost above the mixing layer, and considering hourly effects of meteorology and plume rise on chemical fate and transport (a time-series analysis). If necessary, the EPA may further refine the screening assessment through a site-specific assessment.

In evaluating the potential multipathway risk from emissions of lead compounds, rather than developing a screening threshold emission rate, we compare maximum estimated chronic inhalation exposure concentrations to the level of the current National Ambient Air Quality Standard (NAAQS) for lead.[16] Values below the level of the primary (health-based) lead NAAQS are considered to have a low potential for multipathway risk.

For further information on the multipathway assessment approach, see the Taconite Risk Report, which is available in the docket for this action.

5. How do we conduct the environmental risk screening assessment?

a. Adverse Environmental Effect, Environmental HAP, and Ecological Benchmarks

The EPA conducts a screening assessment to examine the potential for an adverse environmental effect as required under section 112(f)(2)(A) of the CAA. Section 112(a)(7) of the CAA defines ''adverse environmental effect'' as ''any significant and widespread adverse effect, which may reasonably be anticipated, to wildlife, aquatic life, or other natural resources, including adverse impacts on populations of endangered or threatened species or significant degradation of environmental quality over broad areas.''

The EPA focuses on eight HAP, which are referred to as ''environmental HAP,'' in its screening assessment: Six PB–HAP and two acid gases. The PB–HAP included in the screening assessment are arsenic compounds, cadmium compounds, D/F, POM, mercury (both inorganic mercury and methyl mercury), and lead compounds. The acid gases included in the screening assessment are HCl and HF.

HAP that persist and bioaccumulate are of particular environmental concern because they accumulate in the soil, sediment, and water. The acid gases, HCl and HF, are included due to their well-documented potential to cause direct damage to terrestrial plants. In the environmental risk screening assessment, we evaluate the following four exposure media: Terrestrial soils, surface water bodies (includes water-column and benthic sediments), fish

[14] Burger, J. 2002. Daily consumption of wild fish and game: Exposures of high end recreationists. *International Journal of Environmental Health Research* 12:343–354.

[15] U.S. EPA. *Exposure Factors Handbook 2011 Edition (Final).* U.S. Environmental Protection Agency, Washington, DC, EPA/600/R–09/052F, 2011.

[16] In doing so, the EPA notes that the legal standard for a primary NAAQS—that a standard is requisite to protect public health and provide an adequate margin of safety (CAA section 109(b))—differs from the CAA section 112(f) standard (requiring, among other things, that the standard provide an ''ample margin of safety to protect public health''). However, the primary lead NAAQS is a reasonable measure of determining risk acceptability (*i.e.,* the first step of the Benzene NESHAP analysis) since it is designed to protect the most susceptible group in the human population—children, including children living near major lead emitting sources. 73 FR 67002/3; 73 FR 67000/3; 73 FR 67005/1. In addition, applying the level of the primary lead NAAQS at the risk acceptability step is conservative, since that primary lead NAAQS reflects an adequate margin of safety.

consumed by wildlife, and air. Within these four exposure media, we evaluate nine ecological assessment endpoints, which are defined by the ecological entity and its attributes. For PB–HAP (other than lead), both community-level and population-level endpoints are included. For acid gases, the ecological assessment evaluated is terrestrial plant communities.

An ecological benchmark represents a concentration of HAP that has been linked to a particular environmental effect level. For each environmental HAP, we identified the available ecological benchmarks for each assessment endpoint. We identified, where possible, ecological benchmarks at the following effect levels: Probable effect levels, lowest-observed-adverse-effect level, and no-observed-adverse-effect level. In cases where multiple effect levels were available for a particular PB–HAP and assessment endpoint, we use all of the available effect levels to help us to determine whether ecological risks exist and, if so, whether the risks could be considered significant and widespread.

For further information on how the environmental risk screening assessment was conducted, including a discussion of the risk metrics used, how the environmental HAP were identified, and how the ecological benchmarks were selected, see Appendix 9 of the Taconite Risk Report, which is available in Docket ID No. EPA–HQ–OAR–2017–0664.

b. Environmental Risk Screening Methodology

For the environmental risk screening assessment, the EPA first determined whether any facilities in the Taconite Iron Ore Processing source category emitted any of the environmental HAP. For the Taconite Iron Ore Processing source category, we identified emissions of arsenic, cadmium, D/F, HCl, HF, lead, mercury, and POM. Because one or more of the environmental HAP evaluated are emitted by at least one facility in the source category, we proceeded to the second step of the evaluation.

c. PB–HAP Methodology

The environmental screening assessment includes six PB–HAP, arsenic compounds, cadmium compounds, D/F, POM, mercury (both inorganic mercury and methyl mercury), and lead compounds. With the exception of lead, the environmental risk screening assessment for PB–HAP consists of three tiers. The first tier of the environmental risk screening assessment uses the same health-protective conceptual model that is used for the Tier 1 human health screening assessment. TRIM.FaTE simulations were used to back-calculate Tier 1 screening threshold emission rates. The screening threshold emission rates represent the emission rate in tons of pollutant per year that results in media concentrations at the facility that equal the relevant ecological benchmark. To assess emissions from each facility in the category, the reported emission rate for each PB–HAP was compared to the Tier 1 screening threshold emission rate for that PB–HAP for each assessment endpoint and effect level. If emissions from a facility do not exceed the Tier 1 screening threshold emission rate, the facility ''passes'' the screening assessment, and, therefore, is not evaluated further under the screening approach. If emissions from a facility exceed the Tier 1 screening threshold emission rate, we evaluate the facility further in Tier 2.

In Tier 2 of the environmental screening assessment, the screening threshold emission rates are adjusted to account for local meteorology and the actual location of lakes in the vicinity of facilities that did not pass the Tier 1 screening assessment. For soils, we evaluate the average soil concentration for all soil parcels within a 7.5-km radius for each facility and PB–HAP. For the water, sediment, and fish tissue concentrations, the highest value for each facility for each pollutant is used. If emission concentrations from a facility do not exceed the Tier 2 screening threshold emission rate, the facility ''passes'' the screening assessment and typically is not evaluated further. If emissions from a facility exceed the Tier 2 screening threshold emission rate, we evaluate the facility further in Tier 3.

As in the multipathway human health risk assessment, in Tier 3 of the environmental screening assessment, we examine the suitability of the lakes around the facilities to support life and remove those that are not suitable (*e.g.,* lakes that have been filled in or are industrial ponds), adjust emissions for plume-rise, and conduct hour-by-hour time-series assessments. If these Tier 3 adjustments to the screening threshold emission rates still indicate the potential for an adverse environmental effect (*i.e.,* facility emission rate exceeds the screening threshold emission rate), we may elect to conduct a more refined assessment using more site-specific information. If, after additional refinement, the facility emission rate still exceeds the screening threshold emission rate, the facility may have the potential to cause an adverse environmental effect.

To evaluate the potential for an adverse environmental effect from lead, we compared the average modeled air concentrations (from HEM–3) of lead around each facility in the source category to the level of the secondary NAAQS for lead. The secondary lead NAAQS is a reasonable means of evaluating environmental risk because it is set to provide substantial protection against adverse welfare effects which can include ''effects on soils, water, crops, vegetation, man-made materials, animals, wildlife, weather, visibility and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being.''

d. Acid Gas Environmental Risk Methodology

The environmental screening assessment for acid gases evaluates the potential phytotoxicity and reduced productivity of plants due to chronic exposure to HF and HCl. The environmental risk screening methodology for acid gases is a single-tier screening assessment that compares modeled ambient air concentrations (from AERMOD) to the ecological benchmarks for each acid gas. To identify a potential adverse environmental effect (as defined in section 112(a)(7) of the CAA) from emissions of HF and HCl, we evaluate the following metrics: The size of the modeled area around each facility that exceeds the ecological benchmark for each acid gas, in acres and km^2; the percentage of the modeled area around each facility that exceeds the ecological benchmark for each acid gas; and the area-weighted average screening value around each facility (calculated by dividing the area-weighted average concentration over the 50-km modeling domain by the ecological benchmark for each acid gas). For further information on the environmental screening assessment approach, see Appendix 9 of the Taconite Risk Report, which is available in Docket ID No. EPA–HQ–OAR–2017–0664.

6. How do we conduct facility-wide assessments?

To put the source category risks in context, we typically examine the risks from the entire ''facility,'' where the facility includes all HAP-emitting operations within a contiguous area and under common control. In other words, we examine the HAP emissions not only from the source category emission points of interest, but also emissions of

HAP from all other emission sources at the facility for which we have data. For this source category, we conducted the facility-wide assessment using a dataset compiled from the 2014 NEI and supplemental information submitted by industry. The source category records of that dataset were evaluated and updated as described in section II.D of this preamble. Once a quality assured source category dataset was available, it was placed back with the remaining records from the NEI for that facility. The facility-wide file was then used to analyze risks due to the inhalation of HAP that are emitted ''facility-wide'' for the populations residing within 50 km of each facility, consistent with the methods used for the source category analysis described above. For these facility-wide risk analyses, the modeled source category risks were compared to the facility-wide risks to determine the portion of the facility-wide risks that could be attributed to the source category addressed in this action. We also specifically examined the facility that was associated with the highest estimate of risk and determined the percentage of that risk attributable to the source category of interest. The Taconite Risk Report, available in Docket ID No. EPA–HQ–OAR–2017–0664, provides the methodology and results of the facility-wide analyses, including all facility-wide risks and the percentage of source category contribution to facility-wide risks.

7. How do we consider uncertainties in risk assessment?

Uncertainty and the potential for bias are inherent in all risk assessments, including those performed for this proposal. Although uncertainty exists, we believe that our approach, which used conservative tools and assumptions, ensures that our decisions are health and environmentally protective. A brief discussion of the uncertainties in the RTR emissions dataset, dispersion modeling, inhalation exposure estimates, and dose-response relationships follows below. Also included are those uncertainties specific to our acute screening assessments, multipathway screening assessments, and our environmental risk screening assessments. A more thorough discussion of these uncertainties is included in the Taconite Risk Report, which is available in the docket for this action. If a multipathway site-specific assessment was performed for this source category, a full discussion of the uncertainties associated with that assessment can be found in Appendix 11 of that document, *Site-Specific Human Health Multipathway Residual Risk Assessment Report.*

a. Uncertainties in the RTR Emissions Dataset

Although the development of the RTR emissions dataset involved quality assurance/quality control (QA/QC) processes, the accuracy of emissions values will vary depending on the source of the data, the degree to which data are incomplete or missing, the degree to which assumptions made to complete the datasets are accurate, errors in emission estimates, and other factors. The emission estimates considered in this analysis generally are annual totals for certain years, and they do not reflect short-term fluctuations during the course of a year or variations from year to year. The estimates of peak hourly emission rates for the acute effects screening assessment were based on an emission adjustment factor applied to the average annual hourly emission rates, which are intended to account for emission fluctuations due to normal facility operations.

b. Uncertainties in Dispersion Modeling

We recognize there is uncertainty in ambient concentration estimates associated with any model, including the EPA's recommended regulatory dispersion model, AERMOD. In using a model to estimate ambient pollutant concentrations, the user chooses certain options to apply. For RTR assessments, we select some model options that have the potential to overestimate ambient air concentrations (*e.g.,* not including plume depletion or pollutant transformation). We select other model options that have the potential to underestimate ambient impacts (*e.g.,* not including building downwash). Other options that we select have the potential to either under- or overestimate ambient levels (*e.g.,* meteorology and receptor locations). On balance, considering the directional nature of the uncertainties commonly present in ambient concentrations estimated by dispersion models, the approach we apply in the RTR assessments should yield unbiased estimates of ambient HAP concentrations. We also note that the selection of meteorology dataset location could have an impact on the risk estimates. As we continue to update and expand our library of meteorological station data used in our risk assessments, we expect to reduce this variability.

c. Uncertainties in Inhalation Exposure Assessment

Although every effort is made to identify all of the relevant facilities and emission points, as well as to develop accurate estimates of the annual emission rates for all relevant HAP, the uncertainties in our emission inventory likely dominate the uncertainties in the exposure assessment. Some uncertainties in our exposure assessment include human mobility, using the centroid of each census block, assuming lifetime exposure, and assuming only outdoor exposures. For most of these factors, there is neither an under- nor overestimate when looking at the maximum individual risk or the incidence, but the shape of the distribution of risks may be affected. With respect to outdoor exposures, actual exposures may not be as high if people spend time indoors, especially for very reactive pollutants or larger particles. For all factors, we reduce uncertainty when possible. For example, with respect to census-block centroids, we analyze large blocks using aerial imagery and adjust locations of the block centroids to better represent the population in the blocks. We also add additional receptor locations where the population of a block is not well represented by a single location.

d. Uncertainties in Dose-Response Relationships

There are uncertainties inherent in the development of the dose-response values used in our risk assessments for cancer effects from chronic exposures and noncancer effects from both chronic and acute exposures. Some uncertainties are generally expressed quantitatively, and others are generally expressed in qualitative terms. We note, as a preface to this discussion, a point on dose-response uncertainty that is stated in the EPA's *2005 Guidelines for Carcinogen Risk Assessment;* namely, that ''the primary goal of EPA actions is protection of human health; accordingly, as an Agency policy, risk assessment procedures, including default options that are used in the absence of scientific data to the contrary, should be health protective'' (the EPA's *2005 Guidelines for Carcinogen Risk Assessment,* page 1–7). This is the approach followed here as summarized in the next paragraphs.

Cancer UREs used in our risk assessments are those that have been developed to generally provide an upper bound estimate of risk.[17] That is, they represent a ''plausible upper limit to the true value of a quantity'' (although this is usually not a true statistical

[17] IRIS glossary (*https://ofmpub.epa.gov/sor_internet/registry/termreg/searchandretrieve/glossariesandkeywordlists/search.do?details=&glossaryName=IRIS%20Glossary*).

confidence limit). In some circumstances, the true risk could be as low as zero; however, in other circumstances the risk could be greater.[18] Chronic noncancer RfC and reference dose (RfD) values represent chronic exposure levels that are intended to be health-protective levels. To derive dose-response values that are intended to be ''without appreciable risk,'' the methodology relies upon an uncertainty factor (UF) approach,[19] which considers uncertainty, variability, and gaps in the available data. The UFs are applied to derive dose-response values that are intended to protect against appreciable risk of deleterious effects.

Many of the UFs used to account for variability and uncertainty in the development of acute dose-response values are quite similar to those developed for chronic durations. Additional adjustments are often applied to account for uncertainty in extrapolation from observations at one exposure duration (*e.g.,* 4 hours) to derive an acute dose-response value at another exposure duration (*e.g.,* 1 hour). Not all acute dose-response values are developed for the same purpose, and care must be taken when interpreting the results of an acute assessment of human health effects relative to the dose-response value or values being exceeded. Where relevant to the estimated exposures, the lack of acute dose-response values at different levels of severity should be factored into the risk characterization as potential uncertainties.

Uncertainty also exists in the selection of ecological benchmarks for the environmental risk screening assessment. We established a hierarchy of preferred benchmark sources to allow selection of benchmarks for each environmental HAP at each ecological assessment endpoint. We searched for benchmarks for three effect levels (*i.e.,* no-effects level, threshold-effect level, and probable effect level), but not all combinations of ecological assessment/environmental HAP had benchmarks for all three effect levels. Where multiple effect levels were available for a particular HAP and assessment endpoint, we used all of the available effect levels to help us determine whether risk exists and whether the risk could be considered significant and widespread.

Although we make every effort to identify appropriate human health effect dose-response values for all pollutants emitted by the sources in this risk assessment, some HAP emitted by this source category are lacking dose-response assessments. Accordingly, these pollutants cannot be included in the quantitative risk assessment, which could result in quantitative estimates understating HAP risk. To help to alleviate this potential underestimate, where we conclude similarity with a HAP for which a dose-response value is available, we use that value as a surrogate for the assessment of the HAP for which no value is available. To the extent use of surrogates indicates appreciable risk, we may identify a need to increase priority for an IRIS assessment for that substance. We additionally note that, generally speaking, HAP of greatest concern due to environmental exposures and hazard are those for which dose-response assessments have been performed, reducing the likelihood of understating risk. Further, HAP not included in the quantitative assessment are assessed qualitatively and considered in the risk characterization that informs the risk management decisions, including consideration of HAP reductions achieved by various control options.

For a group of compounds that are unspeciated (*e.g.,* glycol ethers), we conservatively use the most protective dose-response value of an individual compound in that group to estimate risk. Similarly, for an individual compound in a group (*e.g.,* ethylene glycol diethyl ether) that does not have a specified dose-response value, we also apply the most protective dose-response value from the other compounds in the group to estimate risk.

e. Uncertainties in Acute Inhalation Screening Assessments

In addition to the uncertainties highlighted above, there are several factors specific to the acute exposure assessment that the EPA conducts as part of the risk review under section 112 of the CAA. The accuracy of an acute inhalation exposure assessment depends on the simultaneous occurrence of independent factors that may vary greatly, such as hourly emission rates, meteorology, and the presence of a person. In the acute screening assessment that we conduct under the RTR program, we assume that peak emissions from the source category and reasonable worst-case air dispersion conditions (*i.e.,* 99th percentile) co-occur. We then include the additional assumption that a person is located at this point at the same time. Together, these assumptions represent a reasonable worst-case exposure scenario. In most cases, it is unlikely that a person would be located at the point of maximum exposure during the time when peak emissions and reasonable worst-case air dispersion conditions occur simultaneously.

f. Uncertainties in the Multipathway and Environmental Risk Screening Assessments

For each source category, we generally rely on site-specific levels of PB–HAP or environmental HAP emissions to determine whether a refined assessment of the impacts from multipathway exposures is necessary or whether it is necessary to perform an environmental screening assessment. This determination is based on the results of a three-tiered screening assessment that relies on the outputs from models—TRIM.FaTE and AERMOD—that estimate environmental pollutant concentrations and human exposures for five PB–HAP (dioxins, POM, mercury, cadmium, and arsenic) and two acid gases (HF and HCl). For lead, we use AERMOD to determine ambient air concentrations, which are then compared to the secondary NAAQS standard for lead. Two important types of uncertainty associated with the use of these models in RTR risk assessments and inherent to any assessment that relies on environmental modeling are model uncertainty and input uncertainty.[20]

Model uncertainty concerns whether the model adequately represents the actual processes (*e.g.,* movement and accumulation) that might occur in the environment. For example, does the model adequately describe the movement of a pollutant through the soil? This type of uncertainty is difficult to quantify. However, based on feedback received from previous EPA SAB reviews and other reviews, we are confident that the models used in the screening assessments are appropriate and state-of-the-art for the multipathway and environmental screening risk assessments conducted in support of RTR.

Input uncertainty is concerned with how accurately the models have been configured and parameterized for the

[18] An exception to this is the URE for benzene, which is considered to cover a range of values, each end of which is considered to be equally plausible, and which is based on maximum likelihood estimates.

[19] See *A Review of the Reference Dose and Reference Concentration Processes,* U.S. EPA, December 2002, and *Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry,* U.S. EPA, 1994.

[20] In the context of this discussion, the term ''uncertainty'' as it pertains to exposure and risk encompasses both *variability* in the range of expected inputs and screening results due to existing spatial, temporal, and other factors, as well as *uncertainty* in being able to accurately estimate the true result.

assessment at hand. For Tier 1 of the multipathway and environmental screening assessments, we configured the models to avoid underestimating exposure and risk. This was accomplished by selecting upper-end values from nationally representative datasets for the more influential parameters in the environmental model, including selection and spatial configuration of the area of interest, lake location and size, meteorology, surface water, soil characteristics, and structure of the aquatic food web. We also assume an ingestion exposure scenario and values for human exposure factors that represent reasonable maximum exposures.

In Tier 2 of the multipathway and environmental screening assessments, we refine the model inputs to account for meteorological patterns in the vicinity of the facility versus using upper-end national values, and we identify the actual location of lakes near the facility rather than the default lake location that we apply in Tier 1. By refining the screening approach in Tier 2 to account for local geographical and meteorological data, we decrease the likelihood that concentrations in environmental media are overestimated, thereby increasing the usefulness of the screening assessment. In Tier 3 of the screening assessments, we refine the model inputs again to account for hour-by-hour plume-rise and the height of the mixing layer. We can also use those hour-by-hour meteorological data in a TRIM.FaTE run using the screening configuration corresponding to the lake location. These refinements produce a more accurate estimate of chemical concentrations in the media of interest, thereby reducing the uncertainty with those estimates. The assumptions and the associated uncertainties regarding the selected ingestion exposure scenario are the same for all three tiers.

For the environmental screening assessment for acid gases, we employ a single-tiered approach. We use the modeled air concentrations and compare those with ecological benchmarks.

For all tiers of the multipathway and environmental screening assessments, our approach to addressing model input uncertainty is generally cautious. We choose model inputs from the upper end of the range of possible values for the influential parameters used in the models, and we assume that the exposed individual exhibits ingestion behavior that would lead to a high total exposure. This approach reduces the likelihood of not identifying high risks for adverse impacts.

Despite the uncertainties, when individual pollutants or facilities do not exceed screening threshold emission rates (*i.e.,* screen out), we are confident that the potential for adverse multipathway impacts on human health is very low. On the other hand, when individual pollutants or facilities do exceed screening threshold emission rates, it does not mean that impacts are significant, only that we cannot rule out that possibility and that a refined assessment for the site might be necessary to obtain a more accurate risk characterization for the source category.

The EPA evaluates the following HAP in the multipathway and/or environmental risk screening assessments, where applicable: arsenic, cadmium, D/F, lead, mercury (both inorganic and methyl mercury), POM, HCl, and HF. These HAP represent pollutants that can cause adverse impacts either through direct exposure to HAP in the air or through exposure to HAP that are deposited from the air onto soils and surface waters and then through the environment into the food web. These HAP represent those HAP for which we can conduct a meaningful multipathway or environmental screening risk assessment. For other HAP not included in our screening assessments, the model has not been parameterized such that it can be used for that purpose. In some cases, depending on the HAP, we may not have appropriate multipathway models that allow us to predict the concentration of that pollutant. The EPA acknowledges that other HAP beyond these that we are evaluating may have the potential to cause adverse effects and, therefore, the EPA may evaluate other relevant HAP in the future, as modeling science and resources allow.

IV. Analytical Results and Proposed Decisions

A. What are the analytical results and proposed decisions for this source category?

1. What are the results of the risk assessment and analyses?

As described in section III of this preamble, for the Taconite Iron Ore Processing source category, we conducted a risk assessment for all HAP emitted. We present results of the risk assessment briefly below and in more detail in the Taconite Risk Report, which is available in Docket ID No. EPA–HQ–OAR–2017–0664.

a. Chronic Inhalation Risk Assessment Results

Table 4 below provides a summary of the results of the inhalation risk assessment for the source category. For more details about the estimated emission levels for actual and allowable emissions rates and the risk assessment methods and results, see the Taconite Risk Report, available in Docket ID No. EPA–HQ–OAR–2017–0664.

TABLE 4—TACONITE IRON ORE PROCESSING SOURCE CATEGORY INHALATION RISK ASSESSMENT RESULTS

Risk assessment	Maximum individual cancer risk (in 1 million)		Estimated population at increased risk of cancer ≥ 1-in-1 million		Estimated annual cancer incidence (cases per year)		Maximum chronic noncancer TOSHI [1]		Maximum screening acute noncancer HQ [2]
	Based on actual emissions	Based on allowable emissions	Based on actual emissions	Based on allowable emissions	Based on actual emissions	Based on allowable emissions	Based on actual emissions	Based on allowable emissions	Based on actual emissions
Source Category	2	6	38,000	43,000	0.001	0.001	0.2	0.2	HQREL = <1
Whole Facility	2	.....	40,000	.....	0.001	.....	0.2	.....	

[1] The TOSHI is the sum of the chronic noncancer HQs for substances that affect the same target organ or organ system.
[2] The maximum estimated acute exposure concentration was divided by available short-term threshold values to develop HQ values.

Based on the results of the inhalation risk modeling using the actual emissions estimates, as shown in Table 4 of this preamble, the maximum individual cancer risk based on actual emissions (lifetime) is estimated to be 2-in-1 million (driven by arsenic and nickel from fugitive dust and indurating sources), the estimated maximum chronic noncancer TOSHI value based on actual emissions is 0.2 (driven by manganese compounds from fugitive dust and ore crushing sources), and the maximum screening acute noncancer HQ value (off-facility site) is less than 1 (driven by arsenic from fugitive dust and ore crushing sources). The total estimated annual cancer incidence

(national) from these facilities based on actual emission levels is 0.001 excess cancer cases per year or 1 case in every 1,000 years. The results using allowable emissions indicate that the estimated maximum individual cancer risk based on allowable emissions (lifetime) is 6-in-1 million (driven by arsenic and nickel from fugitive dust and indurating sources) and the maximum chronic noncancer TOSHI value is 0.2 (driven by manganese compounds from fugitive dust and ore crushing sources).

b. Screening Level Acute Risk Assessment Results

Table 4 of this preamble shows the estimated acute risk results for the Taconite Iron Ore Processing source category. To estimate the peak emission rates from average emission rates, the screening analysis for acute impacts was based on an industry specific multiplier of 2 for indurating furnaces and a factor of 10 for all other emissions sources. For more detailed acute risk results, refer to the Taconite Risk Report, available in Docket ID No. EPA–HQ–OAR–2017–0664.

c. Multipathway Risk Screening Results

Results of the worst-case Tier 1 multipathway screening analysis indicate that PB–HAP emissions (based on estimates of actual emissions) from each of the eight facilities in the source category exceed the screening threshold emissions rate for the carcinogenic PB–HAP (combined D/F, POM, and arsenic screening values) with a maximum screening value of 3,000 for arsenic emissions. For the noncarcinogenic PB–HAP, all eight facilities have screening values greater than 1 for cadmium emissions with a maximum screening value of 20, and seven facilities have screening values greater than 1 for mercury emissions with a maximum screening value of 40. For the PB–HAP and facilities that did not screen out at Tier 1, we conducted a Tier 2 multipathway screening analysis.

The Tier 2 multipathway screen replaces some of the assumptions used in Tier 1 with site-specific data, the location of fishable lakes, and local wind direction and speed. In Tier 2, the gardener scenario is included to represent consumption of produce grown in rural gardens. It is important to note that, even with the inclusion of some site-specific information in the Tier 2 analysis, the multipathway screening analysis is still a very conservative, health-protective assessment (*i.e.,* upper-bound consumption of local fish, locally grown, and/or raised foods) and in all likelihood will yield results that serve as an upper-bound multipathway risk associated with a facility.

Based on the Tier 2 screening analysis, seven facilities emitting arsenic, D/F, and POM emissions have Tier 2 cancer screening values greater than 1 for the farmer scenario with a maximum screening value of 300. Arsenic emissions are driving the risk for the farmer scenario as well as the gardener scenario with a maximum Tier 2 gardener scenario cancer screening value of 200. The maximum Tier 2 cancer screening value for the fisher scenario is 30, with arsenic driving the risk. When we considered the effect multiple facilities within the source category could have on common lake(s) in the modeling domain, the maximum cancer screening value is 40.

For mercury, four facilities emit mercury emissions above the Tier 2 noncancer screening threshold emissions rate, with at least one facility with a screening value of 10 for the fisher scenario. When we considered the effect multiple facilities within the source category could have on common lake(s) in the modeling domain, mercury emissions resulted in a noncancer screening value of 20, with seven facilities contributing to the risk levels at common lakes. For cadmium, two facilities emit cadmium emissions above the Tier 2 noncancer screening threshold emissions rate, with at least one facility with a screening value of 2 for the fisher scenario. When we considered the effect multiple facilities within the source category could have on common lake(s) in the modeling domain, cadmium emissions exceeded the noncancer screening threshold emissions rate by a factor of 3, with seven facilities contributing to the risk levels at common lakes.

An exceedance of a screening threshold emissions rate (*i.e.,* a screening value greater than 1) in any of the tiers cannot be equated with a risk value or a HQ or HI. Rather, it represents a high-end estimate of what the risk or hazard may be. It represents the high-end estimate of risk because we choose inputs from the upper end of the range of possible values for the influential parameters used in the screens; and we assume that the exposed individual exhibits ingestion behavior that would lead to a high total exposure. For more details on the multipathway screening results, refer to Appendix 10 of the Taconite Risk Report, available in Docket ID No. EPA–HQ–OAR–2017–0664. Thus, facility emissions exceeding the screening threshold emissions rate by a factor of 2 (*i.e.,* a screening value of 2) for a non-carcinogen can be interpreted to mean that we are confident that the HQ would be lower than 2. Similarly, facility emissions exceeding the cancer screening threshold emissions rate by a factor of 20 (*i.e.,* a screening value of 20) for a carcinogen means that we are confident that the risk is lower than 20-in-1 million.

Based upon the maximum Tier 2 screening values for mercury (fisher scenario) and arsenic (fisher and gardener scenario) occurring from the same location, we proceeded to a site-specific assessment using TRIM.FaTE versus conducting a Tier 3 screen. We also selected this site for assessing noncancer risks from cadmium utilizing the fisher scenario as the site was comparable to the maximum Tier 2 location. The selected site represents the combined contribution of mercury, arsenic and cadmium emissions from five taconite iron ore processing plants.

The site selected was modeled using TRIM.FaTE to assess cancer risk from arsenic emissions and noncancer risks from mercury and cadmium emissions for the fisher and gardener scenarios. The final cancer risk based upon the fisher scenario and gardener scenario was less than 1-in-1 million from arsenic emissions. The final noncancer risks had a HI less than 1 for mercury (0.02) and for cadmium (0.01). Further details on the site-specific multipathway assessment can be found in Appendix 11 of the Taconite Risk Report, available in Docket ID No. EPA–HQ–OAR–2017–0664.

d. Environmental Risk Screening Results

As described in section III.C of this document, we conducted an environmental risk screening assessment for the Taconite Iron Ore Processing source category for the following pollutants: Arsenic, cadmium, D/F, HCl, HF, lead, mercury (methyl mercury and mercuric chloride), and POM.

In the Tier 1 screening analysis for PB–HAP (other than lead, which was evaluated differently), D/F and POM emissions had no exceedances of any of the ecological benchmarks evaluated. Arsenic emissions had Tier 1 exceedances for three surface soil benchmarks: Threshold level (plant communities), no-observed-adverse-effect-level (NOAEL) (avian ground insectivores—woodcock), and NOAEL (mammalian insectivores—shrew) with a maximum screening value of 4. Cadmium emissions had Tier 1 exceedances for two surface soil benchmarks: NOAEL (mammalian insectivores—shrew) and NOAEL (avian ground insectivores—woodcock) with a

maximum screening value of 4. Cadmium emissions also had Tier 1 exceedances for three fish—avian piscivores benchmarks: NOAEL (merganser), geometric-maximum-allowable-toxicant-level (GMATL) (merganser), and lowest-observed-adverse-effect-level (LOAEL) (merganser) with a maximum screening value of 3. Divalent mercury emissions had Tier 1 exceedances for the following benchmarks: Sediment threshold level, surface soil threshold level (plant communities), and surface soil threshold level (invertebrate communities) with a maximum screening value of 3. Methyl mercury had Tier 1 exceedances for the following benchmarks: fish (avian/piscivores), NOAEL (merganser), surface soil NOAEL (mammalian insectivores—shrew), and surface soil NOAEL for avian ground insectivores (woodcock) with a maximum screening value of 2.

A Tier 2 screening analysis was performed for arsenic, cadmium, divalent mercury, and methyl mercury. In the Tier 2 screening analysis, there were no exceedances of any of the ecological benchmarks evaluated for any of the pollutants.

For lead, we did not estimate any exceedances of the secondary lead NAAQS. For HCl and HF, the average modeled concentration around each facility (*i.e.,* the average concentration of all off-site data points in the modeling domain) did not exceed any ecological benchmark. In addition, each individual modeled concentration of HCl and HF (*i.e.,* each off-site data point in the modeling domain) was below the ecological benchmarks for all facilities.

Based on the results of the environmental risk screening analysis, we do not expect an adverse environmental effect as a result of HAP emissions from this source category.

e. Facility-Wide Risk Results

Six facilities have a facility-wide cancer MIR greater than or equal to 1-in-1 million. The maximum facility-wide cancer MIR is 2-in-1 million, driven by arsenic and nickel from fugitive dust and indurating emissions. The total estimated cancer incidence from the whole facility is 0.001 excess cancer cases per year, or one excess case in every 1,000 years. Approximately 40,000 people were estimated to have cancer risks above 1-in-1 million from exposure to HAP emitted from both source category and non-source category sources at six of the eight facilities in this source category. The maximum facility-wide TOSHI for the source category is estimated to be 0.2, mainly driven by emissions of manganese from fugitive dust and ore crushing emissions.

f. *What demographic groups might benefit from this regulation?*

To examine the potential for any environmental justice issues that might be associated with the source category, we performed a demographic analysis, which is an assessment of risks to individual demographic groups of the populations living within 5 km and within 50 km of the facilities. In the analysis, we evaluated the distribution of HAP-related cancer and noncancer risks from the Taconite Iron Ore Processing source category across different demographic groups within the populations living near facilities.

The results of the demographic analysis are summarized in Table 5 below. These results, for various demographic groups, are based on the estimated risks from actual emissions levels for the population living within 50 km of the facilities.

TABLE 5—TACONITE IRON ORE PROCESSING SOURCE CATEGORY DEMOGRAPHIC RISK ANALYSIS RESULTS

	Nationwide	Population with cancer risk at or above 1-in-1 million due to taconite iron ore processing	Population with chronic noncancer HI above 1 due to taconite iron ore processing
Total Population	317,746,049	38,000	0
White and Minority by Percent			
White	62	93	0
Minority	38	7	0
Minority Detail by Percent			
African American	12	1	0
Native American	0.8	2.8	0
Hispanic or Latino	18	1	0
Other and Multiracial	7	2	0
Income by Percent			
Below the Poverty Level	14	19	0
Above the Poverty Level	86	82	0
Education by Percent			
Over 25 Without High a School Diploma	14	8	0
Over 25 With a High School Diploma	86	92	0
Linguistically Isolated by Percent			
Linguistically Isolated	6	0.2	0

The results of the Taconite Iron Ore Processing source category risk assessment (described in section IV.A.1 of this preamble) indicates that actual emissions from the source category expose approximately 38,000 people to a cancer risk at or above 1-in-1 million and no one to a chronic noncancer HI greater than 1. The percent of minorities nationally (38 percent) is much higher than for the category population with cancer risk greater than or equal to 1-in-1 million (7 percent). The category population with cancer risk greater than or equal to 1-in-1 million has a greater percentage of Native American (2.8 percent) as compared to nationally (0.8 percent), but lower percentages for African American (1 percent) and Hispanic (1 percent) as compared to nationally, 12 percent and 18 percent, respectively. The category population with cancer risk greater than or equal to 1-in-1 million has about the same percentage of the population below the poverty level (18 percent) as compared to nationally (14 percent). The percentage of the population over 25 without a high school diploma and the percentage of the population that is linguistically isolated are lower for the category population (8 percent and 0.2 percent, respectively) than nationally (14 percent and 6 percent, respectively).

The methodology and the results of the demographic analysis are presented in a technical report titled *Risk and Technology Review—Analysis of Demographic Factors for Populations Living Near Taconite Iron Ore Processing Source Category Operations,* June 2019 (hereafter referred to as the *Taconite Iron Ore Processing Demographic Analysis Report*), which may be found in Docket ID No. EPA–HQ–OAR–2017–0664.

2. What are our proposed decisions regarding risk acceptability, ample margin of safety, and adverse environmental effect?

a. Risk Acceptability

As noted in section III.A of this preamble, we weigh all health risk factors in our risk acceptability determination, including the cancer MIR, the number of persons in various cancer and noncancer risk ranges, cancer incidence, the maximum noncancer TOSHI, the maximum acute noncancer HQ, the extent of noncancer risks, the distribution of cancer and noncancer risks in the exposed population, and risk estimation uncertainties (54 FR 38044, September 14, 1989).

For the Taconite Iron Ore Processing source category, the risk analysis indicates that the cancer risks to the individual most exposed could be up to 2-in-1 million due to actual emissions or up to 6-in-1 million based on allowable emissions. These risks are considerably less than 100-in-1 million, which is the presumptive upper limit of acceptable risk. The risk analysis also shows very low cancer incidence (0.001 cases per year for actual and allowable emissions), and we did not identify a potential for adverse chronic noncancer health effects. The acute noncancer risks based on actual emissions are low, with a maximum HQ of less than 1 (based on the REL) for arsenic. Therefore, we find there is little potential concern of acute noncancer health impacts from actual emissions. In addition, the risk assessment indicates no significant potential for multipathway health effects.

Considering all of the health risk information and factors discussed above, including the uncertainties discussed in section III.C.7 of this preamble, we propose to find that the risks from the Taconite Iron Ore Processing source category are acceptable.

b. Ample Margin of Safety Analysis

Although we are proposing that the risks from the Taconite Iron Ore Processing source category are acceptable, we are required to consider whether the MACT standards for the source category provide an ample margin of safety to protect public health. The risk estimates show that approximately 38,000 individuals in the exposed population have a cancer risk above 1-in-1 million based on actual emissions and 43,000 individuals have a cancer risk above 1-in-1 million based on allowable emissions. The MIR based on actual emissions is 2-in-1 million, and based on allowable emissions, the MIR is 6-in-1 million. With regard to chronic and acute noncancer risks, as described above in section IV.A.1, all HIs and HQs are below one. Under the ample margin of safety analysis, in addition to the health risks, we evaluated the cost and feasibility of available control technologies and other measures (including the controls, measures, and costs reviewed under the technology review as described in section III.B of this preamble) that could be applied to this source category to further reduce the risks (or potential risks) due to emissions of HAP identified in the risk assessment.

In this analysis, we focused on cancer risks since all the chronic and acute noncancer HIs and HQs are below one. The cancer risks are driven by metal HAP emissions (*e.g.,* arsenic, nickel, and chromium VI) from indurating furnaces and fugitive dust sources. The indurating furnaces are currently controlled via wet scrubbers. We evaluated the option of reducing emissions from indurating furnaces by installing a wet electrostatic precipitator (wet ESP) after the existing wet scrubbers. Under this scenario, we estimate that the current metal HAP emissions would be reduced by about 99.9 percent, and the MIR would be reduced from 2-in-1 million based on actual emissions and 6-in-1 based on allowable emissions to less than 1-in-1 million for both actual and allowable emissions. We estimate annual costs of about $167 million for the industry, with a cost effectiveness of about $16 million per ton of metal HAP reduced. Due to the relatively small reduction in risk and the substantial costs associated with this option, we are proposing that additional emissions controls for metal HAP from indurating furnaces are not necessary to provide an ample margin of safety to protect public health. See the technical memorandum titled *Taconite Iron Ore Processing—Ample Margin of Safety Analysis,* in Docket ID No. EPA–HQ–OAR–2017–0664 for details.

For the other affected sources that emit metal HAP (*i.e.,* ore crushing and handling operations, finished pellet handling operations, ore drying, and sources subject to the fugitive dust emission control plan), we did not identify any developments in processes, practices, or control technologies. Therefore, we are proposing that additional emissions controls for metal HAP from these affected sources are not necessary to provide an ample margin of safety to protect public health.

c. Environmental Effects

The emissions data for the Taconite Iron Ore Processing source category indicate that eight environmental HAP are emitted by sources within this source category: Arsenic, cadmium, D/F, mercury, POM, lead, HCl, and HF.

In the Tier 1 screening analysis for PB–HAP (other than lead, which was evaluated differently), D/F and POM emissions had no exceedances of any of the ecological benchmarks evaluated. Arsenic, cadmium, and mercury had Tier 1 exceedances for some of the benchmarks evaluated by a maximum screening value of 4. Therefore, a Tier 2 screening analysis was performed for arsenic, cadmium, and mercury. In the Tier 2 screening analysis, there were no exceedances of any of the ecological benchmarks evaluated for any of the pollutants.

The screening-level evaluation of the potential for adverse environmental

effects from emissions of lead indicated that the secondary NAAQS for lead would not be exceeded by any facility. The screening-level evaluation of the potential for adverse environmental effects associated with emissions of HCl and HF from the Taconite Iron Ore Processing source category indicated that each individual concentration (*i.e.,* each off-site data point in the modeling domain) was below the ecological benchmarks for all facilities. In addition, we are unaware of any adverse environmental effects caused by HAP emitted by this source category. Therefore, we do not expect there to be an adverse environmental effect as a result of HAP emissions from this source category and we are proposing that it is not necessary to set a more stringent standard to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect.

B. What are the results and proposed decisions based on our technology review?

The MACT standards for the Taconite Iron Ore Processing source category require compliance with numeric emission limits for PM, a surrogate for metal HAP, for ore crushing and handling operations, ore dryers, pellet induration furnaces, and finished pellet handling sources and for acid gases for pellet indurating furnaces. The rule requires work practice standards to reduce PM (again as a surrogate for metal HAP) emissions from fugitive dust emission sources (*i.e.,* stockpiles, material transfer points, facility roadways, tailings basins, pellet loading areas, and yard areas). Furthermore, the rule includes operation and maintenance requirements for pellet indurating furnaces to ensure good combustion to minimize emissions of formaldehyde and other organic HAP that are products of incomplete combustion.

Under the technology review we searched, reviewed, and considered several sources of information to determine whether there have been developments in practices, processes, and control technologies as required by section 112(d)(6) of the CAA. Section III.B of this preamble describes the types of information and factors we consider to determine if there have been any such ''developments.'' Our investigations included internet searches, discussions with industry representatives during site visits to taconite iron ore processing plants, a review of state permits, and a review of state air quality and regional haze implementation plans from Minnesota and Michigan, the two states where taconite iron ore processing plants are located.

Particulate matter emissions from the pellet induration furnaces are controlled by wet scrubbers or wet ESPs. Based on our review, we identified wet ESPs as a potential development in control technology for indurating furnaces, as discussed under the ample margin of safety analysis (see section IV.A.2.b of this preamble). As described in our ample margin of safety analysis, we estimate the cost for implementing this control technology would be $167 million annualized costs for the source category, with estimated cost effectiveness of $16 million per ton of metal HAP. We are proposing that it is not necessary under CAA section 112(d)(6) to require these additional controls for indurating furnaces because of the high annualized costs and because these controls are not cost effective.

With regard to the ore crushing and handling, ore drying, and finished pellet handling emissions sources as well as for fugitive dust emissions, based on our searches and reviews of the information sources described above, we did not identify any developments in practices, processes, or control technologies. For more details, refer to the document, *Technology Review for the Taconite Iron Ore Processing Source Category,* which is available in Docket ID No. EPA–HQ–OAR–2017–0664.

C. What other actions are we proposing?

In addition to the proposed determinations described above, we are proposing some revisions to the NESHAP. We are proposing revisions to the SSM provisions of the MACT rule in order to ensure that they are consistent with the Court decision in *Sierra Club* v. *EPA,* 551 F. 3d 1019 (DC Cir. 2008), which vacated two provisions that exempted sources from the requirement to comply with otherwise applicable CAA section 112(d) emission standards during periods of SSM. We are also proposing the following: (1) Facilities can reduce compliance testing duration of individual runs from 2 hours to 1 hour; (2) to remove pressure drop as a monitoring option for dynamic wet scrubbers; (3) to remove the requirements for monitoring pressure drop and conducting quarterly internal baghouse inspections whenever the baghouse is equipped with a bag leak detection system; and (4) various other changes to clarify testing, monitoring, recordkeeping, and reporting requirements and to correct typographical errors. Furthermore, we are proposing a determination that a certain compound (known as elongated mineral particulate) is not a HAP. Our analyses, proposed changes, and proposed determination related to these issues are discussed below.

1. SSM

In its 2008 decision in *Sierra Club* v. *EPA,* 551 F.3d 1019 (DC Cir. 2008), the Court vacated portions of two provisions in the EPA's CAA section 112 regulations governing the emissions of HAP during periods of SSM. Specifically, the Court vacated the SSM exemption contained in 40 CFR 63.6(f)(1) and (h)(1), holding that under section 302(k) of the CAA, emissions standards or limitations must be continuous in nature and that the SSM exemption violates the CAA's requirement that some section 112 standards apply continuously.

Consistent with *Sierra Club* v. *EPA,* we are proposing the elimination of the SSM exemption in this NESHAP and we are proposing the standards apply at all times. We are also proposing several revisions to Table 2 (the General Provisions Applicability Table) which are explained in more detail below. For example, we are proposing to eliminate the incorporation of the General Provisions' requirement that sources develop an SSM plan. We also are proposing to eliminate and revise certain recordkeeping and reporting requirements related to the SSM exemption as described below.

The EPA has attempted to ensure that the provisions we are proposing to eliminate are inappropriate, unnecessary, or redundant in the absence of the SSM exemption. We are specifically seeking comment on whether we have successfully done so.

In proposing the standards in this rule, the EPA has considered startup and shutdown periods and, for the reasons explained below, is not proposing alternative standards for those periods. The associated control devices are operational before startup and during shutdown of the affected sources at taconite iron ore processing facilities. Therefore, we expect that emissions during startup and shutdown would be no higher than emissions during normal operations. We know of no reason why the existing standards should not apply at all times.

Periods of startup, normal operations, and shutdown are all predictable and routine aspects of a source's operations. Malfunctions, in contrast, are neither predictable nor routine. Instead they are, by definition, sudden, infrequent, and not reasonably preventable failures of emissions control, process, or monitoring equipment. (40 CFR 63.2) (definition of malfunction). The EPA

interprets CAA section 112 as not requiring emissions that occur during periods of malfunction to be factored into development of CAA section 112 standards and this reading has been upheld as reasonable by the Court in *U.S. Sugar Corp.* v. *EPA,* 830 F.3d 579, 606–610 (2016). Under section 112, emissions standards for new sources must be no less stringent than the level ''achieved'' by the best controlled similar source and for existing sources generally must be no less stringent than the average emission limitation ''achieved'' by the best performing 12 percent of sources in the category. There is nothing in section 112 that directs the Agency to consider malfunctions in determining the level ''achieved'' by the best performing sources when setting emission standards. As the Court has recognized, the phrase ''average emissions limitation achieved by the best performing 12 percent of sources ''says nothing about how the performance of the best units is to be calculated.'' *Nat'l Ass'n of Clean Water Agencies* v. *EPA,* 734 F.3d 1115, 1141 (D.C. Cir. 2013). While the EPA accounts for variability in setting emissions standards, nothing in CAA section 112 requires the Agency to consider malfunctions as part of that analysis. The EPA is not required to treat a malfunction in the same manner as the type of variation in performance that occurs during routine operations of a source. A malfunction is a failure of the source to perform in a ''normal or usual manner'' and no statutory language compels the EPA to consider such events in setting CAA section 112 standards.

As the Court recognized in *U.S. Sugar Corp,* accounting for malfunctions in setting standards would be difficult, if not impossible, given the myriad different types of malfunctions that can occur across all sources in the category and given the difficulties associated with predicting or accounting for the frequency, degree, and duration of various malfunctions that might occur. *Id.* at 608 (''the EPA would have to conceive of a standard that could apply equally to the wide range of possible boiler malfunctions, ranging from an explosion to minor mechanical defects. Any possible standard is likely to be hopelessly generic to govern such a wide array of circumstances.''). As such, the performance of units that are malfunctioning is not ''reasonably'' foreseeable. See, *e.g. Sierra Club* v. *EPA,* 167 F.3d 658, 662 (D.C. Cir. 1999) (''The EPA typically has wide latitude in determining the extent of data-gathering necessary to solve a problem. We generally defer to an agency's decision to proceed on the basis of imperfect scientific information, rather than to 'invest the resources to conduct the perfect study.' ''). See also, *Weyerhaeuser* v. *Costle,* 590 F.2d 1011, 1058 (D.C. Cir. 1978) (''In the nature of things, no general limit, individual permit, or even any upset provision can anticipate all upset situations. After a certain point, the transgression of regulatory limits caused by 'uncontrollable acts of third parties,' such as strikes, sabotage, operator intoxication or insanity, and a variety of other eventualities, must be a matter for the administrative exercise of case-by-case enforcement discretion, not for specification in advance by regulation.''). In addition, emissions during a malfunction event can be significantly higher than emissions at any other time of source operation. For example, if an air pollution control device with 99-percent removal goes off-line as a result of a malfunction (as might happen if, for example, the bags in a baghouse catch fire) and the emission unit is a steady state type unit that would take days to shut down, the source would go from 99-percent control to zero control until the control device was repaired. The source's emissions during the malfunction would be 100 times higher than during normal operations. As such, the emissions over a 4-day malfunction period would exceed the annual emissions of the source during normal operations. As this example illustrates, accounting for malfunctions could lead to standards that are not reflective of (and significantly less stringent than) levels that are achieved by a well-performing non-malfunctioning source. It is reasonable to interpret CAA section 112 to avoid such a result. The EPA's approach to malfunctions is consistent with CAA section 112 and is a reasonable interpretation of the statute.

Although no statutory language compels the EPA to set standards for malfunctions, the EPA has the discretion to do so where feasible. For example, in the Petroleum Refinery Sector RTR, the EPA established a work practice standard for unique types of malfunction that result in releases from pressure relief devices (PRDs) or emergency flaring events because the EPA had information to determine that such work practices reflected the level of control that applies to the best performers. 80 FR 75178, 75211–14 (December 1, 2015). The EPA will consider whether circumstances warrant setting standards for a particular type of malfunction and, if so, whether the EPA has sufficient information to identify the relevant best performing sources and establish a standard for such malfunctions. (We also encourage commenters to provide any such information.)

Based on the EPA's knowledge of the processes and engineering judgement, malfunctions in the Taconite Iron Ore Processing source category are considered unlikely to result in a violation of the standard. Affected sources at taconite iron ore processing plants are controlled with add-on air pollution control devices which will continue to function in the event of a process upset. Also, processes in the industry are typically equipped with controls that will not allow startup of the emission source until the associated control device is operating and will automatically shut down the emission source if the associated controls malfunction. Indurating furnaces, which are the largest sources of HAP emissions, typically operate continuously for long periods of time with no significant spikes in emissions. These minimal fluctuations in emissions are controlled by the existing add-on air pollution control devices used at all plants in the industry.

In the unlikely event that a source fails to comply with the applicable CAA section 112(d) standards as a result of a malfunction event, the EPA would determine an appropriate response based on, among other things, the good faith efforts of the source to minimize emissions during malfunction periods, including preventative and corrective actions, as well as root cause analyses to ascertain and rectify excess emissions. The EPA would also consider whether the source's failure to comply with the CAA section 112(d) standard was, in fact, sudden, infrequent, not reasonably preventable, and was not instead caused, in part, by poor maintenance or careless operation. 40 CFR 63.2 (definition of malfunction).

If the EPA determines in a particular case that an enforcement action against a source for violation of an emission standard is warranted, the source can raise any and all defenses in that enforcement action and the federal district court will determine what, if any, relief is appropriate. The same is true for citizen enforcement actions. Similarly, the presiding officer in an administrative proceeding can consider any defense raised and determine whether administrative penalties are appropriate.

In summary, the EPA interpretation of the CAA and, in particular, section 112, is reasonable and encourages practices that will avoid malfunctions.

Administrative and judicial procedures for addressing exceedances of the standards fully recognize that violations may occur despite good faith efforts to comply and can accommodate those situations. *U.S. Sugar Corp.* v. *EPA,* 830 F.3d 579, 606–610 (2016).

We are proposing to revise the General Provisions Applicability Table (Table 2) entry for 40 CFR 63.6(e)(1)(i) by changing the ''yes'' in the column titled ''Applies to Subpart RRRRR'' to a ''no.'' Section 63.6(e)(1)(i) describes the general duty to minimize emissions. Some of the language in that section is no longer necessary or appropriate in light of the elimination of the SSM exemption. We are proposing instead to add general duty regulatory text at 40 CFR 63.9600(a) that reflects the general duty to minimize emissions while eliminating the reference to periods covered by an SSM exemption. The current language in 40 CFR 3.6(e)(1)(i) characterizes what the general duty entails during periods of SSM. With the elimination of the SSM exemption, there is no need to differentiate between normal operations and SSM events in describing the general duty. Therefore, the language the EPA is proposing for 40 CFR 63.9600(a) does not include that language from 40 CFR 63.6(e)(1).

We are also proposing to revise the General Provisions Applicability Table (Table 2) entry for 40 CFR 63.6(e)(1)(ii) by changing the ''yes'' in the column titled ''Applies to Subpart RRRRR'' to a ''no.'' Section 63.6(e)(1)(ii) imposes requirements that are not necessary with the elimination of the SSM exemption or are redundant with the general duty requirement being added at 40 CFR 63.9600(a).

We are proposing to revise the General Provisions Applicability Table (Table 2) entry for 40 CFR 63.6(e)(3) by changing the ''yes'' in the column titled ''Applies to Subpart RRRRR'' to a ''no.'' Generally, these paragraphs require development of an SSM plan and specify SSM recordkeeping and reporting requirements related to the SSM plan. As noted, the EPA is proposing to remove the SSM exemptions. Therefore, affected units will be subject to an emission standard during such events. The applicability of a standard during such events will ensure that sources have ample incentive to plan for and achieve compliance and, thus, the SSM plan requirements are no longer necessary.

We are proposing to revise the General Provisions Applicability Table (Table 2) entry for 40 CFR 63.6(f)(1) by changing the ''yes'' in the column titled ''Applies to Subpart RRRRR'' to a ''no.'' The current language of 40 CFR 63.6(f)(1) exempts sources from non-opacity standards during periods of SSM. As discussed above, the Court in *Sierra Club* v. *EPA* vacated the exemptions contained in this provision and held that the CAA requires that some CAA section 112 standards apply continuously. Consistent with *Sierra Club* v. *EPA,* the EPA is proposing to revise standards in this rule to apply at all times.

We are proposing to revise the General Provisions Applicability Table (Table 2) entry for 40 CFR 63.7(e)(1) by changing the ''yes'' in the column titled ''Applies to Subpart RRRRR'' to a ''no.'' Section 63.7(e)(1) describes performance testing requirements. The EPA is instead proposing to add a performance testing requirement at 40 CFR 63.9621(a). The performance testing requirements we are proposing to add differ from the General Provisions performance testing provisions in several respects. The regulatory text removes the cross-reference to 40 CFR 63.7(e)(1) and does not include the language in 40 CFR 63.7(e)(1) that restated the SSM exemption and language that precluded startup and shutdown periods from being considered ''representative'' for purposes of performance testing. The proposed performance testing provisions will not allow performance testing during malfunctions. As in 40 CFR 63.7(e)(1), performance tests conducted under this subpart should not be conducted during malfunctions because conditions during malfunctions are often not representative of normal operating conditions. The EPA is proposing to add language that requires the owner or operator to record the process information that is necessary to document operating conditions during the test and include in such record an explanation to support that such conditions represent normal operation. Section 63.7(e) requires that the owner or operator make available to the Administrator such records ''as may be necessary to determine the condition of the performance test'' available to the Administrator upon request but does not specifically require the information to be recorded. The regulatory text the EPA is proposing to add to this provision builds on that requirement and makes explicit the requirement to record the information.

We are proposing to revise the General Provisions Applicability Table (Table 2) entry for 40 CFR 63.8(c)(1)(i) and (iii) by changing the ''yes'' in the column titled ''Applies to Subpart RRRRR'' to a ''no.'' The cross-references to the general duty and SSM plan requirements in those subparagraphs are not necessary in light of other requirements of 40 CFR 63.8 that require good air pollution control practices (40 CFR 63.8(c)(1)) and that set out the requirements of a quality control program for monitoring equipment (40 CFR 63.8(d)).

We are proposing to revise the General Provisions Applicability Table (Table 2) entry for 40 CFR 63.8(d)(3) by changing the ''yes'' in the column titled ''Applies to Subpart RRRRR'' to a ''no.'' The final sentence in 40 CFR 63.8(d)(3) refers to the General Provisions' SSM plan requirement which is no longer applicable. The EPA is proposing to add to the rule at 40 CFR 63.9632(b)(5) text that is identical to 40 CFR 63.8(d)(3) except for the final sentence with the reference to SSM.

We are proposing to revise the General Provisions Applicability Table (Table 2) entry for 40 CFR 63.10(b)(2)(i) by changing the ''yes'' in the column titled ''Applies to Subpart RRRRR'' to a ''no.'' Section 63.10(b)(2)(i) describes the recordkeeping requirements during startup and shutdown. These recording provisions are no longer necessary because the EPA is proposing that recordkeeping and reporting applicable to normal operations will apply to startup and shutdown. In the absence of special provisions applicable to startup and shutdown, such as a startup and shutdown plan, there is no reason to retain additional recordkeeping for startup and shutdown periods.

We are proposing to revise the General Provisions Applicability Table (Table 2) entry for 40 CFR 63.10(b)(2)(ii) by changing the ''yes'' in the column titled ''Applies to Subpart RRRRR'' to a ''no.'' Section 63.10(b)(2)(ii) describes the recordkeeping requirements during a malfunction. The EPA is proposing to add such requirements to 40 CFR 63.9642. The regulatory text we are proposing to add differs from the General Provisions it is replacing in that the General Provisions requires the creation and retention of a record of the occurrence and duration of each malfunction of process, air pollution control, and monitoring equipment. The EPA is proposing that this requirement apply to any failure to meet an applicable standard and is requiring that the source record the date, time, and duration of the failure rather than the ''occurrence.'' The EPA is also proposing to add to 40 CFR 63.9642 a requirement that sources keep records that include a list of the affected source or equipment and actions taken to minimize emissions, an estimate of the quantity of each regulated pollutant emitted over the standard for which the source failed to meet the standard, and a description of the method used to

estimate the emissions. Examples of such methods would include product-loss calculations, mass balance calculations, measurements when available, or engineering judgment based on known process parameters. The EPA is proposing to require that sources keep records of this information to ensure that there is adequate information to allow the EPA to determine the severity of any failure to meet a standard, and to provide data that may document how the source met the general duty to minimize emissions when the source has failed to meet an applicable standard.

We are proposing to revise the General Provisions Applicability Table (Table 2) entry for 40 CFR 63.10(b)(2)(iv) by changing the ''yes'' in the column titled ''Applies to Subpart RRRRR'' to a ''no.'' When applicable, the provision requires sources to record actions taken during SSM events when actions were inconsistent with their SSM plan. The requirement is no longer appropriate because SSM plans will no longer be required. The requirement previously applicable under 40 CFR 63.10(b)(2)(iv)(B) to record actions to minimize emissions and record corrective actions is now applicable by reference to 40 CFR 63.9642.

We are proposing to revise the General Provisions Applicability Table (Table 2) entry for 40 CFR 63.10(b)(2)(v) by changing the ''yes'' in the column titled ''Applies to Subpart RRRRR'' to a ''no.'' When applicable, the provision requires sources to record actions taken during SSM events to show that actions taken were consistent with their SSM plan. The requirement is no longer appropriate because SSM plans will no longer be required.

We are proposing to revise the General Provisions Applicability Table (Table 2) entry for 40 CFR 63.10(c)(15) by changing the ''yes'' in the column titled ''Applies to Subpart RRRRR'' to a ''no.'' The EPA is proposing that 40 CFR 63.10(c)(15) no longer applies. When applicable, the provision allows an owner or operator to use the affected source's SSM plan or records kept to satisfy the recordkeeping requirements of the SSM plan, specified in 40 CFR 63.6(e), to also satisfy the requirements of 40 CFR 63.10(c)(10) through (12). The EPA is proposing to eliminate this requirement because SSM plans would no longer be required, and, therefore, 40 CFR 63.10(c)(15) no longer serves any useful purpose for affected units.

We are proposing to revise the General Provisions Applicability Table (Table 2) entry for 40 CFR 63.10(d)(5) by changing the ''yes'' in the column titled ''Applies to Subpart RRRRR'' to a ''no.'' Section 63.10(d)(5) describes the reporting requirements for startups, shutdowns, and malfunctions. To replace the General Provisions reporting requirement, the EPA is proposing to add reporting requirements to 40 CFR 63.9641. The replacement language differs from the General Provisions requirement in that it eliminates periodic SSM reports as a stand-alone report. We are proposing language that requires sources that fail to meet an applicable standard at any time to report the information concerning such events in the semi-annual compliance report already required under this rule. We are proposing that the report must contain the number, date, time, duration, and the cause of such events (including unknown cause, if applicable), a list of the affected source or equipment, an estimate of the quantity of each regulated pollutant emitted over any emission limit, and a description of the method used to estimate the emissions.

Examples of such methods would include product-loss calculations, mass balance calculations, measurements when available, or engineering judgment based on known process parameters. The EPA is proposing this requirement to ensure that there is adequate information to determine compliance, to allow the EPA to determine the severity of the failure to meet an applicable standard, and to provide data that may document how the source met the general duty to minimize emissions during a failure to meet an applicable standard.

We will no longer require owners or operators to determine whether actions taken to correct a malfunction are consistent with an SSM plan, because SSM plans would no longer be required. The proposed amendments, therefore, eliminate the cross-reference to 40 CFR 63.10(d)(5)(i) that contains the description of the previously required SSM report format and submittal schedule from this section. These specifications are no longer necessary because the events will be reported in otherwise required reports with similar format and submittal requirements.

The proposed amendments eliminate the cross-reference to 40 CFR 63.10(d)(5)(ii), which requires an immediate report for SSM when a source failed to meet an applicable standard but did not follow the SSM plan. We will no longer require owners and operators to report when actions taken during a startup, shutdown, or malfunction were not consistent with an SSM plan, because SSM plans would no longer be required.

2. Electronic Reporting

The EPA is proposing that owners and operators of taconite iron ore processing plants submit electronic copies of required performance test reports and compliance reports through EPA's Central Data Exchange (CDX) using the Compliance and Emissions Data Reporting Interface (CEDRI). A description of the electronic data submission process is provided in the memorandum, *Electronic Reporting Requirements for New Source Performance Standards (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAP) Rules,* available in Docket ID No. EPA–HQ–OAR–2017–0664. The proposed rule requires that performance test results collected using test methods that are supported by the EPA's Electronic Reporting Tool (ERT) as listed on the ERT website [21] at the time of the test be submitted in the format generated through the use of the ERT and that other performance test results be submitted in portable document format (pdf) using the attachment module of the ERT. For compliance reports, the proposed rule requires that owners and operators use the appropriate spreadsheet template to submit information to CEDRI. A draft version of the proposed template for these reports is included in the docket for this rulemaking. The EPA specifically requests comment on the content, layout, and overall design of the template.

Additionally, we have identified two broad circumstances in which electronic reporting extensions may be provided. In both circumstances, the decision to accept the claim of needing additional time to report is within the discretion of the Administrator, and reporting should occur as soon as possible. We are providing these potential extensions to protect owners and operators from noncompliance in cases where they cannot successfully submit a report by the reporting deadline for reasons outside of their control. The situation where an extension may be warranted due to outages of EPA's CDX or CEDRI which precludes an owner or operator from accessing the system and submitting required reports is addressed in 40 CFR 63.9641. The situation where an extension may be warranted due to a *force majeure* event, which is defined as an event that will be or has been caused by circumstances beyond the control of the affected facility, its contractors, or any entity controlled by

[21] *https://www.epa.gov/electronic-reporting-air-emissions/electronic-reporting-tool-ert.*

the affected facility that prevents an owner or operator from complying with the requirement to submit a report electronically as required by this rule is addressed in 40 CFR 63.9641. Examples of such events are acts of nature, acts of war or terrorism, or equipment failure or safety hazards beyond the control of the facility.

The electronic submittal of the reports addressed in this proposed rulemaking will increase the usefulness of the data contained in those reports, is in keeping with current trends in data availability and transparency, and will further assist in the protection of public health and the environment. Furthermore, it will improve compliance by facilitating the ability of regulated facilities to demonstrate compliance with requirements and by facilitating the ability of delegated state, local, tribal, and territorial air agencies and the EPA to assess and determine compliance, and will ultimately reduce burden on regulated facilities, delegated air agencies, and the EPA. Electronic reporting also eliminates paper-based, manual processes, thereby saving time and resources, simplifying data entry, eliminating redundancies, minimizing data reporting errors, and providing data quickly and accurately to the affected facilities, air agencies, the EPA, and the public. Moreover, electronic reporting is consistent with the EPA's plan [22] to implement Executive Order 13563 and is in keeping with the EPA's Agency-wide policy [23] developed in response to the White House's Digital Government Strategy.[24] For more information on the benefits of electronic reporting, see the memorandum, *Electronic Reporting Requirements for New Source Performance Standards (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAP) Rules,* available in Docket ID No. EPA–HQ–OAR–2017–0664.

3. Performance Testing

The Taconite Iron Ore Processing NESHAP performance testing requirements specify that stack tests conducted for ore crushing and handling, finished pellet handling, ore drying, and indurating furnace affected sources must consist of three separate runs of a minimum of 2 hours for each run. Industry representatives have stated that 2-hour test runs are unnecessary because an adequate sample volume can be obtained when conducting a 1-hour test. Industry representatives also pointed out that Minnesota state rules for performance testing only require that test runs be 1 hour in duration. They claim longer run time increases the cost of testing without any improvement in the data collected. With the time needed for test contractors to set up and break down their sampling equipment, perform the necessary QA/QC checks, and conduct a minimum of 6 hours of testing for a three-run test on a single stack, testing can take 9 to 10 hours to complete.

The EPA has previously concluded that the representative method detection limit for EPA Method 5 of 40 CFR part 60, appendix A–3, is 2 milligrams for a sample volume of 1 dry standard cubic meter.[25] This is the approximate sample volume for a 1-hour test run. This detection limit is equivalent to 0.0026 gr/dscf, which is well below the emission limits in this rule. Additionally, we reviewed a number of test reports submitted during the development of this action. After examining those PM test results, we did not find any of the test results to be below the method detection limit, even when the test run was only 1 hour long.

Based upon our review of available information, we agree that a test run time of 1 hour should provide an adequate sample volume to determine compliance with the emission limits if good testing practices are followed. Therefore, we are proposing to revise the minimum time for test runs for performance tests conducted on ore crushing and handling, finished pellet handling, ore drying, and indurating furnace affected sources from a minimum of 2 hours for each test run to a minimum of 1 hour for each test run. While we agree that this change should not cause an issue with determining compliance, as the number of samples below the method detection limit should not increase as long as good testing practices are followed, we are also proposing that if the measurement result is reported as below the method detection limit, the method detection limit will be used for that value when calculating the average particulate concentration.

Performance testing of indurating furnaces is required no less frequently than twice per 5-year permit term. Industry has requested that the EPA revise the frequency to once every 5 years if the performance test results are less than 80 percent of the emissions limit. We currently do not have sufficient justification or data to support this change. Therefore, we are not proposing this change. However, we solicit comments, data, and information as to whether this change would be appropriate or if other possible alternatives to the current requirement should be considered that would provide the industry more flexibility while ensuring that emissions would remain below the PM limits. In particular, we are interested in emissions data or other information that would support a margin of 80 percent, or some other margin, as sufficient to ensure that emissions would not exceed the emission limits for the 5-year period.

4. Baghouse Monitoring

Under the current rule, baghouses that are used on affected sources to comply with the emission limits for PM are required to be equipped with a bag leak detection system in order to monitor the relative change in PM loadings. The current rule contains installation, operation, and maintenance requirements that apply to bag leak detection systems to ensure their proper performance. The Taconite Iron Ore Processing NESHAP also requires that the owner or operator monitor the daily pressure drop across each baghouse in addition to conducting physical inspections of several baghouse components on a daily, weekly, or monthly basis depending on the baghouse component. Then, the interior of the baghouse must be inspected on a quarterly basis to determine if there are air leaks. In view of the requirement for baghouses to be equipped with a bag leak detection system, the requirements to monitor baghouse pressure drop and to conduct baghouse inspections are redundant and, therefore unnecessary. Therefore, we are proposing to remove the requirements for conducting quarterly internal baghouse inspections whenever the baghouse is equipped with a bag leak detection system that is installed, operated, and maintained in compliance with the requirements in the Taconite Iron Ore Processing NESHAP. The use of bag leak detection systems is superior to older methods of monitoring baghouse performance (such as visual inspections) and is more consistent with monitoring

[22] EPA's *Final Plan for Periodic Retrospective Reviews,* August 2011. Available at: *https://www.regulations.gov/document?D=EPA-HQ-OA-2011-0156-0154.*

[23] *E-Reporting Policy Statement for EPA Regulations,* September 2013. Available at: *https://www.epa.gov/sites/production/files/2016-03/documents/epa-ereporting-policy-statement-2013-09-30.pdf.*

[24] *Digital Government: Building a 21st Century Platform to Better Serve the American People,* May 2012. Available at: *https://obamawhitehouse.archives.gov/sites/default/files/omb/egov/digital-government/digital-government.html.*

[25] U.S. EPA. Memorandum from Conniesue Oldham to Bob Schell. *Revision of Estimated Method 5 Detection Limit.* June 15, 2012.

requirements for baghouses required in other EPA regulations.

Industry has also requested that the EPA revise the requirement at 40 CFR 63.9600(b)(2) to initiate corrective action to determine the cause of a bag leak detection system alarm within 1 hour of its occurrence. We currently do not have sufficient justification or data to support this change. Therefore, we are not proposing this change. However, we solicit comments, data, and information as to whether a longer time frame within which industry is required to initiate corrective action would be appropriate, or if other possible alternatives to the current requirement should be considered that would provide the industry more flexibility while ensuring that emissions would remain below the PM limits.

5. Dynamic Wet Scrubbers

The current rule requires that where dynamic wet scrubbers, also known as low energy scrubbers, are used to comply with PM emission limits, the owner or operator must establish site-specific operating limits for scrubber water flow rate and either fan amperage or pressure drop during the PM performance testing for each dynamic wet scrubber. Compliance with the operating limits is determined by monitoring the daily average scrubber water flow rate and either the daily average fan amperage or the daily average pressure drop. Since the MACT rule was promulgated, we have determined that pressure drop is not adequate for monitoring dynamic scrubbers as the pressure drop for these scrubbers is very low and does not vary greatly. Furthermore, the operator is not able to adjust or control the differential pressure in order to remain in compliance. Therefore, we are proposing to remove pressure drop as a monitoring option for dynamic wet scrubbers. Under the proposed amendments, dynamic wet scrubbers used to comply with the Taconite Iron Ore Processing NESHAP emission limits for PM would be required to establish and monitor the scrubber water flow rate and fan amperage. While we maintain that scrubber water flow is an appropriate operating parameter for these scrubbers, we request comment on whether an operating parameter other than fan amperage or pressure drop would be as effective or more appropriate to monitor in conjunction with scrubber water flow to ensure the continued removal efficiency of the scrubber.

6. Performance Testing of Similar Sources

Under the current rule, the owner/operator may elect to group up to six similar ore crushing and handling operations and finished pellet handling operations sources and conduct a compliance test on a single representative unit. The rule establishes the criteria that emission units must meet to be considered similar. This provision has the benefit of reducing testing costs for those facilities that can take advantage of it. Industry representatives requested that the EPA modify the rule language to allow up to 10 emission units in a group of similar sources. However, we currently do not have sufficient justification or data to support this change. Therefore, we are not proposing revisions to this requirement at this time. However, we request comments and information from companies and other stakeholders on the positive and/or negative aspects of increasing the number of similar sources that can be grouped for testing purposes, including the potential economic benefits for companies and potential environmental impacts, and whether the EPA should allow such an increase in the number of units in a group of similar sources for testing, and if so, why.

7. Elongated Mineral Particulate

In 2004, after promulgation of the original Taconite Iron Ore Processing NESHAP, the National Wildlife Federation filed a petition for review of that rule with the Court (Case No. 03–1458). In that petition, the National Wildlife Federation alleged that the EPA had failed to set standards for what they believed to be emissions of asbestos, or asbestos-like fibers, from taconite iron ore processing plants. We are referring to these compounds as amphibole ''elongated mineral particulate (EMP).'' The EPA subsequently requested, and was granted, a partial voluntary remand to further investigate this issue and consider possible options to address the issue, as appropriate. As part of the development of this RTR proposed rulemaking, we gathered and reviewed available information on the amphibole EMP. Based on available information, amphibole EMP emissions only occur from the operations at one of the taconite iron ore processing plants, due to the effects of the Duluth Gabbro Complex on the associated taconite iron ore mine—specifically, the Peter Mitchell Mine associated with the Northshore Mining Company processing plant located in Silver Bay, Minnesota.

After reviewing and evaluating available information, we have determined that the EMP do not meet the definition of ''asbestos'' found in current EPA regulations and technical documents. This is because asbestos is always defined as the asbestiform varieties of certain minerals (see 40 CFR 61.141, 763.83, and 763.163), whereas the EMP in question developed in the non-asbestiform geologic form. Also, a study by Ross *et al.* (*The search for asbestos within the Peter Mitchell Taconite iron ore mine, near Babbitt, Minnesota,* which is available in the docket, Docket ID No. EPA–HQ–OAR–2017–0664) found no asbestos in the Peter Mitchell Mine. Ross *et al.* analyzed 53 samples from 30 sites within the mine where fibrous minerals were thought to potentially occur. Samples were analyzed using transmission electron microscopes and other state-of-the-art equipment. No asbestos of any type was found in the mine pit samples. In another study by Wilson *et al.,* ambient air samples from monitors at the taconite mill and in a nearby town were analyzed. It was found that the fibers collected by the ambient air monitors were non-asbestiform ferroactinolite and grunerite, not asbestos. (*Risk assessment due to environmental exposures to fibrous particulates associated with taconite ore,* which is available in the docket, Docket ID No. EPA–HQ–OAR–2017–0664.)

We also evaluated the EMP to determine if they might meet the definition of ''fine mineral fibers'' (the other HAP listed in CAA section 112(b) which we initially thought might be interpreted to include EMP). Footnote 3 after the list of HAP found in CAA section 112(b)(1) explains that ''[f]ine mineral fibers includes mineral fiber emissions from facilities manufacturing or processing glass, rock or slag fibers (or other mineral derived fibers) of average diameter 1 micrometer or less.'' The *EPA Health Effects Notebook* (available at *https://www.epa.gov/haps/health-effects-notebook-hazardous-air-pollutants*) further explains that the term ''fine mineral fibers'' was intended to apply to the synthetic vitreous fibers glasswool, rockwool, slagwool, glass filaments, and refractory ceramic fibers. Based on the CAA definition, and further interpretation provided in the *EPA Health Effects Notebook,* we conclude that EMP do not meet the definition of ''fine mineral fibers'' because the taconite iron ore processing facilities are not manufacturing or processing synthetic vitreous fibers such as rockwool, glasswool, slagwool, glass filaments, and refractory ceramic fibers.

Since the EMP do not meet the definition of HAP pursuant to CAA

section 112(b), the EPA did not review the EMP for regulation under CAA section 112. Nevertheless, we note that the EMP are a component of PM which are subject to control by the NESHAP as a surrogate for metal HAP and acid gases. We also note that the Minnesota Pollution Control Agency requires this facility to monitor the EMP and ensure ambient levels of EMP near the facility are no higher than levels found in a non-affected location (*i.e.,* St. Paul, Minnesota). Also, EMP are the subject of an exposure study being conducted in taconite communities in Minnesota by the EPA's Office of Research and Development (ORD) and the EPA's Region 5 office. More information on the EPA's review of the EMP and EPA's proposed determination is available in the memorandum, *EPA's Analysis of Elongated Mineral Particulate,* which is available in Docket ID No. EPA–HQ–OAR–2017–0664.

E. What compliance dates are we proposing?

We are proposing that existing facilities must comply with all changes proposed in this action 180 days after promulgation of the final rule. All new or reconstructed facilities must comply with all requirements in the final rule upon startup. Our experience with similar industries that are required to convert reporting mechanisms, install necessary hardware and software, become familiar with the process of submitting performance test results electronically through the EPA's CEDRI, test these new electronic submission capabilities, reliably employ electronic reporting, and convert logistics of reporting processes to different time-reporting parameters, shows that a time period of a minimum of 90 days, and more typically, 180 days, is generally necessary to successfully complete these changes. Our experience with similar industries further shows that this sort of regulated facility generally requires a time period of 180 days to read and understand the amended rule requirements; evaluate their operations to ensure that they can meet the standards during periods of startup and shutdown as defined in the rule and make any necessary adjustments; adjust parameter monitoring and recording systems to accommodate revisions; and update their operations to reflect the revised requirements. The EPA recognizes the confusion that multiple different compliance dates for individual requirements would create and the additional burden such an assortment of dates would impose. From our assessment of the time frame needed for compliance with the entirety of the revised requirements, the EPA considers a period of 180 days to be the most expeditious compliance period practicable, and, thus, is proposing that existing affected sources be in compliance with all of this regulation's revised requirements within 180 days of the regulation's effective date.

V. Summary of Cost, Environmental, and Economic Impacts

A. What are the affected sources?

The Taconite Iron Ore Processing source category consists of eight facilities. One facility (Empire Mine) that is currently in a state of indefinite idle, is expected to resume operations once market conditions become more favorable. Also, a new facility is under construction near Nashwauk, Minnesota. The date that this new facility will begin operations is unknown, but not expected until after completion of this rulemaking. The affected sources at a taconite iron ore processing plant include ore crushing and handling operations, ore dryers, indurating furnaces, and finished pellet handling operations. The owner/operator of a taconite iron ore processing plant must also prepare and operate according to a fugitive dust emissions control plan to minimize emissions from sources of fugitive emissions (*e.g.,* stockpiles, tailings basins, roadways, pellet loading areas, material transfer points, and yard areas).

B. What are the air quality impacts?

In this action, we are proposing no new emission limits and no additional controls; therefore, no air quality impacts are expected as a result of the proposed amendments.

C. What are the cost impacts?

The proposed amendments include no changes to emission standards or add-on controls. As described in section IV.C.3 of this preamble, the proposed amendments would reduce emissions performance test run times from 2 hours to 1 hour and remove the unnecessary requirement to conduct quarterly internal visual inspections of baghouses that are equipped with a bag leak detection system. The proposed amendments would replace the current reporting requirements with electronic reporting. Electronic reporting eliminates paper-based, manual processes, thereby saving time and resources, simplifying data entry, eliminating redundancies, and minimizing data reporting errors, ultimately reducing the burden on regulated facilities. Therefore, the proposed amendments impose no additional costs. In fact, the amendments and clarifications to rule language are expected to result in a reduction of current costs because compliance will be more straightforward. As described in the cost memorandum, we estimate the proposed amendments will result in an overall cost savings of $190,000 per year mainly due to the reduced testing duration and elimination of need for internal visual baghouse inspections.

D. What are the economic impacts?

Economic impact analyses focus on changes in market prices and output levels. If changes in market prices and output levels in the primary markets are significant enough, impacts on other markets may also be examined. Both the magnitude of costs associated with the proposed requirements and the distribution of these costs among affected facilities can have a role in determining how the market will change in response to a proposed rule. Because the overall costs and savings associated with the proposed revisions are relatively small, no significant economic impacts from the proposed amendments are anticipated.

E. What are the benefits?

While the proposed amendments would not result in reductions in emissions of HAP, this action, if finalized, would result in improved monitoring, compliance, and implementation of the rule. Also, the electronic reporting requirements will enhance transparency by making performance test results and compliance reports more readily available to the public.

VI. Request for Comments

We solicit comments on this proposed action. In addition to general comments on this proposed action, we are also interested in additional data that may improve the risk assessments and other analyses. We are specifically interested in receiving any improvements to the data used in the site-specific emissions profiles used for risk modeling. Such data should include supporting documentation in sufficient detail to allow characterization of the quality and representativeness of the data or information. Section VII of this preamble provides more information on submitting data.

VII. Submitting Data Corrections

The site-specific emissions profiles used in the source category risk and demographic analyses and instructions are available for download on the RTR website at *https://www.epa.gov/*

stationary-sources-air-pollution/taconite-iron-ore-processing-national-emission-standards-hazardous. The data files include detailed information for each HAP emissions release point for the facilities in the source category.

If you believe that the data are not representative or are inaccurate, please identify the data in question, provide your reason for concern, and provide any ''improved'' data that you have, if available. When you submit data, we request that you provide documentation of the basis for the revised values to support your suggested changes. To submit comments on the data downloaded from the RTR website, complete the following steps:

1. Within this downloaded file, enter suggested revisions to the data fields appropriate for that information.

2. Fill in the commenter information fields for each suggested revision (*i.e.,* commenter name, commenter organization, commenter email address, commenter phone number, and revision comments).

3. Gather documentation for any suggested emissions revisions (*e.g.,* performance test reports, material balance calculations).

4. Send the entire downloaded file with suggested revisions in Microsoft® Access format and all accompanying documentation to Docket ID No. EPA–HQ–OAR–2017–0664 (through the method described in the **ADDRESSES** section of this preamble).

5. If you are providing comments on a single facility or multiple facilities, you need only submit one file for all facilities. The file should contain all suggested changes for all sources at that facility (or facilities). We request that all data revision comments be submitted in the form of updated Microsoft® Excel files that are generated by the Microsoft® Access file. These files are provided on the RTR website at *https://www.epa.gov/stationary-sources-air-pollution/taconite-iron-ore-processing-national-emission-standards-hazardous.*

VIII. Statutory and Executive Order Reviews

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

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

This action is not a significant regulatory action and was, therefore, not submitted to OMB for review.

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is not expected to be an Executive Order 13771 regulatory action because this action is not significant under Executive Order 12866.

C. Paperwork Reduction Act (PRA)

The information collection activities in this proposed rule have been submitted for approval to OMB under the PRA. The information collection request (ICR) document that the EPA prepared has been assigned EPA ICR number 2050.08. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here.

We are proposing amendments that require electronic reporting, remove the malfunction exemption, and impose other revisions that affect reporting and recordkeeping for taconite iron ore processing facilities. This information would be collected to assure compliance with 40 CFR part 63, subpart RRRRR.

Respondents/affected entities: Owners or operators of taconite iron ore processing facilities.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart LLLLL).

Estimated number of respondents: Eight (total).

Frequency of response: Initial, semiannual, and annual.

Total estimated burden: The annual recordkeeping and reporting burden for facilities to comply with all of the requirements in the NESHAP is estimated to be 1,000 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: The annual recordkeeping and reporting burden for facilities to comply with all of the requirements in the NESHAP is estimated to be $550,000 (per year). The only costs associated with the information collection activity is labor cost. There are no capital/startup or operation and maintenance costs for this ICR.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9.

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden to the EPA using the docket identified at the beginning of this rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs via email to *OIRA_submission@omb.eop.gov,* Attention: Desk Officer for the EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt, OMB must receive comments no later than October 25, 2019. The EPA will respond to any ICR-related comments in the final rule.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities. Based on the Small Business Administration size category for this source category, no small entities are subject to this action.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local, or tribal governments or the private sector.

F. Executive Order 13132: Federalism

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

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

This action does not have tribal implications as specified in Executive Order 13175. No tribal governments own facilities subject to this proposed action. Thus, Executive Order 13175 does not apply to this action. However, since tribal officials expressed significant interest in this rulemaking, consistent with the EPA Policy on Consultation and Coordination with Indian Tribes, a tribal consultation is planned for this rulemaking.

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

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because the EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. This action, if finalized, would result in improved monitoring,

compliance, and implementation of the rule, which could lower the risk to all people affected by emissions from these facilities, including children. This action's health and risk assessments are contained in section IV of this preamble and in the Taconite Risk Report, which is available in the docket.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

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

J. National Technology Transfer and Advancement Act (NTTAA)

This action involves technical standards. The EPA proposes to use ANSI/ASME PTC 19.10–1981 Part 10 (2010), ''Flue and Exhaust Gas Analyses,'' manual portion only, as an alternative to EPA Method 3B and incorporates the alternative method by reference. The ANSI/ASME PTC 19.10–1981 Part 10 (2010) method incorporates both manual and instrumental methodologies for the determination of oxygen content of the exhaust gas. The manual method segment of the oxygen determination is performed through the absorption of oxygen. The method is acceptable as an alternative to EPA Method 3B and is available from the American Society of Mechanical Engineers (ASME) at *http://www.asme.org;* by mail at Three Park Avenue, New York, NY 10016–5990; or by telephone at (800) 843–2763.

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

The EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations, and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). To the extent that this action, if finalized, would result in improved monitoring, compliance, and implementation of the rule, we believe that it could decrease the risks posed by taconite iron ore processing facilities for these populations. This action's health and risk assessments are contained in section IV of this action. The documentation for this decision is contained in section IV.A.1 of this preamble and in the Taconite Risk Report, which is available in Docket ID No. EPA–HQ–OAR–2017–0664.

List of Subjects in 40 CFR Part 63

Environmental protection, Air pollution control, Hazardous substances, Incorporation by reference, Reporting and recordkeeping requirements.

Dated: August 28, 2019.

Andrew R. Wheeler,

Administrator.

For the reasons set forth in the preamble, the EPA proposes to amend 40 CFR part 63 as follows:

PART 63—NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR SOURCE CATEGORIES

■ 1. The authority citation for part 63 continues to read as follows:

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

■ 2. Section 63.14 is amended by revising paragraphs (e)(1) and (n)(3) to read as follows:

§ 63.14 Incorporations by reference.

* * * * *

(e) * * *

(1) ANSI/ASME PTC 19.10–1981, Flue and Exhaust Gas Analyses [Part 10, Instruments and Apparatus], issued August 31, 1981, IBR approved for §§ 63.309(k), 63.457(k), 63.772(e) and (h), 63.865(b), 63.1282(d) and (g), 63.1625(b), 63.3166(a), 63.3360(e), 63.3545(a), 63.3555(a), 63.4166(a), 63.4362(a), 63.4766(a), 63.4965(a), 63.5160(d), table 4 to subpart UUUU, 63.9307(c), 63.9323(a), 63.9621(b) and (c), 63.11148(e), 63.11155(e), 63.11162(f), 63.11163(g), 63.11410(j), 63.11551(a), 63.11646(a), and 63.11945, table 5 to subpart DDDDD, table 4 to subpart JJJJJ, table 4 to subpart KKKKK, tables 4 and 5 of subpart UUUUU, table 1 to subpart ZZZZZ, and table 4 to subpart JJJJJJ.

* * * * *

(n) * * *

(3) EPA–454/R–98–015, Office of Air Quality Planning and Standards (OAQPS), Fabric Filter Bag Leak Detection Guidance, September 1997, *https://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=2000D5T6.PDF,* IBR approved for §§ 63.548(e), 63.864(e), 63.7525(j), 63.8450(e), 63.8600(e), 63.9632(a)(5), and 63.11224(f).

* * * * *

Subpart RRRRR—National Emission Standards for Hazardous Air Pollutants for the Taconite Iron Ore Processing

■ 3. Section 63.9583 is revised to read as follows:

§ 63.9583 When do I have to comply with this subpart?

(a) If you have an affected source the construction or reconstruction of which is commenced before December 18, 2002, you must comply with each emission limitation, work practice standard, and operation and maintenance requirement in this subpart that applies to you no later than October 30, 2006, except as provided in paragraphs (f)(1) and (2) of this section.

(b) If you have an affected source the construction or reconstruction of which is commenced on or after December 18, 2002, and its initial startup date is on or before October 30, 2003, you must comply with each emission limitation, work practice standard, and operation and maintenance requirement in this subpart that applies to you by October 30, 2003, except as noted in paragraphs (f)(1) and (2) of this section.

(c) If you have an affected source and its initial startup date is after October 30, 2003, you must comply with each emission limitation, work practice standard, and operation and maintenance requirement in this subpart that applies to you upon initial startup, except as noted in paragraphs (f)(1) and (2) of this section.

(d) If your taconite iron ore processing plant is an area source that becomes a major source of HAP, the compliance dates in paragraphs (d)(1) and (2) of this section apply to you.

(1) Any portion of the taconite iron ore processing plant that is a new affected source or a new reconstructed source must be in compliance with this subpart upon startup, except as noted in paragraphs (f)(1) and (2) of this section.

(2) All other parts of the taconite iron ore processing plant must be in compliance with this subpart no later than 3 years after the plant becomes a major source, except as noted in paragraphs (f)(1) and (2) of this section.

(e) You must meet the notification and schedule requirements in § 63.9640. Several of these notifications must be submitted before the compliance date for your affected source.

(f)(1) If you have an affected source the construction or reconstruction of which is commenced before September 25, 2019, you must comply with the following requirements of this subpart by [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**]: § 63.9590(b)(2); § 63.9600(a); § 63.9610(a) introductory text; § 63.9621(a); § 63.9622(b) introductory text, (b)(1) and (2) and (d)(2); § 63.9623(b)(2); § 63.9631(c); § 63.9632(a)(3); § 63.9634(b)(3), (f) introductory text, and (f)(1), (3), and (4);

§ 63.9637; § 63.9641(b)(7)(ii), (b)(8)(ii) and (iv), (c), (e), (g), (h), (i), and (j); § 63.9642(a)(4), (5), and (6) and (b)(3); § 63.9643(d); Table 2 to this subpart.

(2) If you have an affected source the construction or reconstruction of which is commenced on or after September 25, 2019, you must comply with all the requirements of this subpart by [DATE OF PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**] or the date of startup, whichever is later.

■ 4. Section 63.9590 is amended by revising paragraph (b)(2) to read as follows:

§ 63.9590 What emission limitations must I meet?

* * * * *

(b) * * *

(2) For each dynamic wet scrubber applied to meet any particulate matter emission limit in Table 1 to this subpart, you must maintain the daily average scrubber water flow rate and the daily average fan amperage (a surrogate for fan speed as revolutions per minute) at or above the minimum levels established during the initial performance test.

* * * * *

■ 5. Section 63.9600 is amended by revising paragraphs (a) and (b)(2) introductory text to read as follows:

§ 63.9600 What are my operation and maintenance requirements?

(a) You must always operate and maintain any affected source, including associated air pollution control equipment and monitoring equipment, in a manner consistent with safety and good air pollution control practices for minimizing emissions. The general duty to minimize emissions does not require the owner or operator to make any further efforts to reduce emissions if levels required by the applicable standard have been achieved. Determination of whether such operation and maintenance procedures are being used will be based on information available to the Administrator which may include, but is not limited to, monitoring results, review of operation and maintenance procedures, review of operation and maintenance records, and inspection of the source.

(b) * * *

(2) Corrective action procedures for bag leak detection systems. In the event a bag leak detection system alarm is triggered, you must initiate corrective action to determine the cause of the alarm within 1 hour of the alarm, initiate corrective action to correct the cause of the problem within 24 hours of the alarm, and complete the corrective action as soon as practicable. If the alarm sounds more than 5 percent of the operating time during a 6-month period as determined according to § 63.9634(d)(3), it is considered an operating parameter deviation. Corrective actions may include, but are not limited to, the actions listed in paragraphs (b)(2)(i) through (vi) of this section.

* * * * *

■ 6. Section 63.9610 is amended by revising paragraph (a) introductory text and removing and reserving paragraph (c) to read as follows:

§ 63.9610 What are my general requirements for complying with this subpart?

(a) You must be in compliance with the requirements in paragraphs (a)(1) through (6) of this section at all times.

* * * * *

■ 7. Section 63.9620 is amended by revising paragraph (f) introductory text and removing paragraph (f)(3) to read as follows:

§ 63.9620 On which units and by what date must I conduct performance tests or other initial compliance demonstrations?

* * * * *

(f) If you elect to test representative emission units as provided in paragraph (e) of this section, the units that are grouped together as similar units must meet the criteria in paragraphs (f)(1) and (2) of this section.

* * * * *

■ 8. Section 63.9621 is amended by revising paragraphs (a), (b)(1) and (2), and (c)(1) and (2) to read as follows:

§ 63.9621 What test methods and other procedures must I use to demonstrate initial compliance with the emission limits for particulate matter?

(a) You must conduct each performance test that applies to your affected source under normal maximum operating conditions of the affected source. The owner or operator may not conduct performance tests during periods of malfunction. The owner or operator must record the process information that is necessary to document operating conditions during the test and include in such record an explanation to support that such conditions represent normal operation. Upon request, the owner or operator shall make available to the Administrator such records as may be necessary to determine the conditions of performance tests. You must also conduct each performance test that applies to your affected source according to the requirements in paragraphs (b) and (c) of this section.

(b) * * *

(1) Except as provided in § 63.9620(e), determine the concentration of particulate matter in the stack gas for each emission unit according to the test methods listed in paragraphs (b)(1)(i) through (v) of this section.

(i) Method 1 or 1A in appendix A–1 to part 60 of this chapter to select sampling port locations and the number of traverse points. Sampling ports must be located at the outlet of the control device and prior to any releases to the atmosphere.

(ii) Method 2, 2A, 2C, 2D, or 2F in appendix A–1 to part 60 of this chapter or Method 2G in appendix A–2 to part 60 of this chapter, as applicable, to determine the volumetric flow rate of the stack gas.

(iii) Method 3A or 3B in appendix A–2 to part 60 of this chapter to determine the dry molecular weight of the stack gas. The voluntary consensus standard ANSI/ASME PTC 19.10–1981—Part 10 (incorporated by reference—see § 63.14) may be used as an alternative to the manual procedures (but not instrumental procedures) in Method 3B.

(iv) Method 4 in appendix A–3 to part 60 of this chapter to determine the moisture content of the stack gas.

(v) Method 5 or 5D in appendix A–3 to part 60 of this chapter or Method 17 in appendix A–6 to part 60 of this chapter to determine the concentration of particulate matter.

(2) Each Method 5, 5D, or 17 performance test must consist of three separate runs. Each run must be conducted for a minimum of 1 hour. If any measurement result is reported as below the method detection limit, use the method detection limit for that value when calculating the average particulate matter concentration. The average particulate matter concentration from the three runs will be used to determine compliance, as shown in Equation 1 of this section.

$$C_i = \frac{C_1 + C_2 + C_3}{3} \quad (Eq.\ 1)$$

Where:

C_i = Average particulate matter concentration for emission unit, grains per dry standard cubic foot, (gr/dscf);

C_1 = Particulate matter concentration for run 1 corresponding to emission unit, gr/dscf;

C_2 = Particulate matter concentration for run 2 corresponding to emission unit, gr/dscf; and

C_3 = Particulate matter concentration for run 3 corresponding to emission unit, gr/dscf.

* * * * *

(c) * * *

(1) Determine the concentration of particulate matter for each stack according to the test methods listed in paragraphs (c)(1)(i) through (v) of this section.

(i) Method 1 or 1A in appendix A–1 to part 60 of this chapter to select sampling port locations and the number of traverse points. Sampling ports must be located at the outlet of the control device and prior to any releases to the atmosphere.

(ii) Method 2, 2A, 2C, 2D, or 2F in appendix A–1 to part 60 of this chapter or Method 2G in appendix A–2 to part 60 of this chapter, as applicable, to determine the volumetric flow rate of the stack gas.

(iii) Method 3A or 3B in appendix A–2 to part 60 of this chapter to determine the dry molecular weight of the stack gas. The voluntary consensus standard ANSI/ASME PTC 19.10–1981—Part 10 (incorporated by reference—see § 63.14) may be used as an alternative to the manual procedures (but not instrumental procedures) in Method 3B.

(iv) Method 4 in appendix A–3 to part 60 of this chapter to determine the moisture content of the stack gas.

(v) Method 5 or 5D in appendix A–3 to part 60 of this chapter to determine the concentration of particulate matter.

(2) Each Method 5 or 5D performance test must consist of three separate runs. Each run must be conducted for a minimum of 1 hour. If any measurement result is reported as below the method detection limit, use the method detection limit for that value when calculating the average particulate matter concentration. The average particulate matter concentration from the three runs will be used to determine compliance, as shown in Equation 1 of this section.

* * * * *

■ 9. Section 63.9622 is amended by revising paragraphs (b) and (d)(2) to read as follows:

§ 63.9622 What test methods and other procedures must I use to establish and demonstrate initial compliance with the operating limits?

* * * * *

(b) For dynamic wet scrubbers subject to performance testing in § 63.9620 and operating limits for scrubber water flow rate and fan amperage in § 63.9590(b)(2), you must establish site-specific operating limits according to the procedures in paragraphs (b)(1) and (2) of this section.

(1) Using the CPMS required in § 63.9631(b), measure and record the scrubber water flow rate and the fan amperage every 15 minutes during each run of the particulate matter performance test.

(2) Calculate and record the average scrubber water flow rate and the average fan amperage for each individual test run. Your operating limits are established as the lowest average scrubber water flow rate and the lowest average fan amperage value corresponding to any of the three test runs.

* * * * *

(d) * * *

(2) For each individual test run, calculate and record the average value for each operating parameter in paragraphs (d)(1)(i) through (iii) of this section for each wet electrostatic precipitator field. Your operating limits are established as the lowest average value for each operating parameter of secondary voltage and water flow rate corresponding to any of the three test runs, and the highest average value for each stack outlet temperature corresponding to any of the three test runs.

* * * * *

■ 10. Section 63.9623 is amended by revising paragraph (b)(2) to read as follows:

§ 63.9623 How do I demonstrate initial compliance with the emission limitations that apply to me?

* * * * *

(b) * * *

(2) For each dynamic wet scrubber subject to performance testing in § 63.9620 and operating limits for scrubber water flow rate and fan amperage in § 63.9590(b)(2), you have established appropriate site-specific operating limits and have a record of the scrubber water flow rate and the fan amperage value, measured during the performance test in accordance with § 63.9622(b).

* * * * *

■ 11. Section 63.9625 is amended by revising the introductory text to read as follows:

§ 63.9625 How do I demonstrate initial compliance with the operation and maintenance requirements that apply to me?

For each air pollution control device subject to operating limits in § 63.9590(b), you have demonstrated initial compliance with the operation and maintenance requirements if you meet all of the requirements in paragraphs (a) through (d) of this section.

* * * * *

■ 12. Section 63.9631 is amended by revising paragraphs (a) introductory text and (c) to read as follows:

§ 63.9631 What are my monitoring requirements?

(a) For each baghouse applied to meet any particulate matter emission limit in Table 1 to this subpart, you must install, operate, and maintain a bag leak detection system to monitor the relative change in particulate matter loadings according to the requirements in § 63.9632(a), and conduct inspections at their specified frequencies according to the requirements in paragraphs (a)(1) through (6) and (8) of this section. For each baghouse applied to meet any particulate matter emission limit in Table 1 to this subpart that is not required by § 63.9632(a) to be equipped with a bag leak detection system, you must conduct inspections at their specified frequencies according to the requirements in paragraphs (a)(1) through (8) of this section.

* * * * *

(c) For each dynamic wet scrubber subject to the scrubber water flow rate and the fan amperage operating limits in § 63.9590(b)(2), you must install, operate, and maintain a CPMS according to the requirements in § 63.9632(b) through (e) and monitor the daily average scrubber water flow rate and the daily average fan amperage according to the requirements in § 63.9633.

* * * * *

■ 13. Section 63.9632 is amended by:

■ a. Revising paragraphs (a) introductory text and (a)(1).

■ b. Redesignating paragraphs (a)(3) through (8) as paragraphs (a)(4) through (9).

■ c. Adding new paragraph (a)(3).

■ d. Revising newly redesignated paragraphs (a)(4), (a)(5) introductory text, (a)(7) introductory text, and (a)(7)(i).

■ e. Revising paragraphs (b)(3) through (6) and (f)(2) and (4).

The revisions and addition read as follows:

§ 63.9632 What are the installation, operation, and maintenance requirements for my monitoring equipment?

(a) For each negative pressure baghouse or positive pressure baghouse equipped with a stack, applied to meet any particulate emission limit in Table 1 to this subpart, you must install, operate, and maintain a bag leak detection system for each exhaust stack according to the requirements in paragraphs (a)(1) through (9) of this section.

(1) A bag leak detection system installed before September 25, 2019, must be certified by the manufacturer to be capable of detecting emissions of particulate matter at concentrations of 10 milligrams per actual cubic meter (0.0044 grains per actual cubic foot) or less. A bag leak detection system installed after September 25, 2019, must be certified by the manufacturer to be capable of detecting emissions of particulate matter at concentrations of 1 milligram per actual cubic meter (0.00044 grains per actual cubic foot) or less.

* * * * *

(3) The bag leak detection system must be equipped with a device to continuously record the output signal from the sensor.

(4) The system must be equipped with an alarm that will sound when an increase in relative particulate loadings is detected over the alarm level set point established according to paragraph (a)(5) of this section. The alarm must be located such that it can be heard by the appropriate plant personnel.

(5) For each bag leak detection system, you must develop and submit to the Administrator for approval, a site-specific monitoring plan that addresses the items identified in paragraphs (a)(5)(i) through (v) of this section. The monitoring plan shall be consistent with the manufacturer's specifications and recommendations contained in the U.S. Environmental Protection Agency (U.S. EPA) guidance document, ''Fabric Filter Bag Leak Detection Guidance'' (EPA–454/R–98–015) (incorporated by reference—see § 63.14). You must operate and maintain the bag leak detection system according to the site-specific monitoring plan at all times. The plan shall describe all of the items in paragraphs (a)(5)(i) through (v) of this section.

* * * * *

(7) Following initial adjustment, do not adjust sensitivity or range, averaging period, alarm set point, or alarm delay time, without approval from the Administrator except as provided for in paragraph (a)(7)(i) of this section. In no event may the sensitivity be increased more than 100 percent or decreased by more than 50 percent over a 365-day period unless such adjustment follows a complete baghouse inspection that demonstrates the baghouse is in good operating condition.

(i) Once per quarter, you may adjust the sensitivity or range of the bag leak detection system to account for seasonal effects, including temperature and humidity, according to the procedures identified in the site-specific monitoring plan required under paragraph (a)(5) of this section.

* * * * *

(b) * * *

(3) Performance evaluation procedures, a schedule for performing such procedures, and acceptance criteria (*e.g.,* calibrations), as well as corrective action to be taken if a performance evaluation does not meet the acceptance criteria. If a CPMS calibration fails, the CPMS is considered to be inoperative until you take corrective action and the system passes calibration.

(4) Ongoing operation and maintenance procedures and a schedule for preventative maintenance procedures, in a manner consistent with good air pollution control practices and in accordance with the general requirements of § 63.8(c)(1)(ii), (c)(3), (c)(4)(ii), and (c)(7) and (8).

(5) Ongoing data quality assurance procedures in accordance with the general requirements of § 63.8(d)(1) and (2). The owner or operator shall keep these written procedures on record for the life of the affected source or until the affected source is no longer subject to the provisions of this part, to be made available for inspection, upon request, by the Administrator. If the performance evaluation plan is revised, the owner or operator shall keep previous (*i.e.,* superseded) versions of the performance evaluation plan on record to be made available for inspection, upon request, by the Administrator, for a period of 5 years after each revision to the plan.

(6) Ongoing recordkeeping and reporting procedures in accordance with the general requirements of § 63.10(c)(1) through (14), (e)(1), and (e)(2)(i).

* * * * *

(f) * * *

(2) You must develop and implement a quality control program for operating and maintaining each COMS according to § 63.8(a) and (b), (c)(1)(ii), (c)(2) through (8), (d)(1) and (2), and (e) through (g) and Procedure 3 in appendix F to 40 CFR part 60. At a minimum, the quality control program must include a daily calibration drift assessment, quarterly performance audit, and annual zero alignment of each COMS.

* * * * *

(4) You must determine and record the 6-minute average opacity for periods during which the COMS is not out of control. All COMS must complete a minimum of one cycle of sampling and analyzing for each successive 10-second period and one cycle of data recording for each successive 6-minute period.

■ 14. Section 63.9633 is amended by revising paragraphs (a) and (b) to read as follows:

§ 63.9633 How do I monitor and collect data to demonstrate continuous compliance?

(a) Except for monitoring malfunctions, out of control periods, associated repairs, and required quality assurance or control activities (including as applicable, calibration checks and required zero and span adjustments), you must monitor continuously (or collect data at all required intervals) at all times an affected source is operating.

(b) You may not use data recorded during monitoring malfunctions, out of control periods, associated repairs, and required quality assurance or control activities in data averages and calculations used to report emission or operating levels, or to fulfill a minimum data availability requirement. You must use all the data collected during all other periods in assessing compliance.

* * * * *

■ 15. Section 63.9634 is amended by:

■ a. Revising paragraphs (b)(3), (d) introductory text, and (d)(2).

■ b. Adding paragraph (d)(3).

■ c. Revising paragraphs (f) introductory text, (f)(1), (3), and (4), (h)(1), and (j)(1) and (2).

The revisions and addition read as follows:

§ 63.9634 How do I demonstrate continuous compliance with the emission limitations that apply to me?

* * * * *

(b) * * *

(3) For ore crushing and handling and finished pellet handling emission units not selected for initial performance testing and defined within a group of similar emission units in accordance with § 63.9620(e), the site-specific operating limits established for the emission unit selected as representative of a group of similar emission units will be used as the operating limit for each emission unit within the group. The operating limit established for the representative unit must be met by each emission unit within the group.

* * * * *

(d) For each baghouse applied to meet any particulate emission limit in Table 1 to this subpart, you must demonstrate continuous compliance by completing the requirements in paragraphs (d)(1) through (3) of this section.

* * * * *

(2) Inspecting and maintaining each baghouse according to the requirements in § 63.9631(a) and recording all information needed to document conformance with the requirements in § 63.9631(a). If you increase or decrease the sensitivity of the bag leak detection system beyond the limits specified in your site-specific monitoring plan, you must include a copy of the required written certification by a responsible official in the next semiannual compliance report.

(3) Each bag leak detection system must be operated and maintained such that the alarm does not sound more than 5 percent of the operating time during a 6-month period. Calculate the alarm time as specified in paragraphs (d)(3)(i) through (iii) of this section.

(i) If inspection of the fabric filter demonstrates that no corrective action is required, no alarm time is counted.

(ii) If corrective action is required, each alarm time (*i.e.,* time that the alarm sounds) is counted as a minimum of 1 hour.

(iii) If it takes longer than 1 hour to initiate corrective action, each alarm time is counted as the actual amount of time taken to initiate corrective action.

* * * * *

(f) For each dynamic wet scrubber subject to the operating limits for scrubber water flow rate and the fan amperage in § 63.9590(b)(2), you must demonstrate continuous compliance by completing the requirements of paragraphs (f)(1) through (4) of this section.

(1) Maintaining the daily average scrubber water flow rate and the daily average fan amperage at or above the minimum levels established during the initial or subsequent performance test.

* * * * *

(3) Collecting and reducing monitoring data for scrubber water flow rate and fan amperage according to § 63.9632(c) and recording all information needed to document conformance with the requirements in § 63.9632(c).

(4) If the daily average scrubber water flow rate or daily average fan amperage, is below the operating limits established for a corresponding emission unit or group of similar emission units, you must then follow the corrective action procedures in paragraph (j) of this section.

* * * * *

(h) * * *

(1) Maintaining the daily average secondary voltage and daily average scrubber water flow rate for each field at or above the minimum levels established during the initial or subsequent performance test. Maintaining the daily average stack outlet temperature at or below the maximum levels established during the initial or subsequent performance test.

* * * * *

(j) * * *

(1) You must initiate and complete initial corrective action within 10 calendar days and demonstrate that the initial corrective action was successful. During any period of corrective action, you must continue to monitor and record all required operating parameters for equipment that remains in operation. After the initial corrective action, if the daily average operating parameter value for the emission unit or group of similar emission units meets the operating limit established for the corresponding unit or group, then the corrective action was successful and the emission unit or group of similar emission units is in compliance with the established operating limits.

(2) If the initial corrective action required in paragraph (j)(1) of this section was not successful, then you must complete additional corrective action within 10 calendar days and demonstrate that the subsequent corrective action was successful. During any period of corrective action, you must continue to monitor and record all required operating parameters for equipment that remains in operation. If the daily average operating parameter value for the emission unit or group of similar emission units meets the operating limit established for the corresponding unit or group, then the corrective action was successful and the emission unit or group of similar emission units is in compliance with the established operating limits.

* * * * *

■ 16. Section 63.9637 is revised to read as follows:

§ 63.9637 What other requirements must I meet to demonstrate continuous compliance?

(a) *Deviations.* You must report each instance in which you did not meet each emission limitation in Table 1 to this subpart that applies to you. You also must report each instance in which you did not meet the work practice standards in § 63.9591 and each instance in which you did not meet each operation and maintenance requirement in § 63.9600 that applies to you. These instances are deviations from the emission limitations, work practice standards, and operation and maintenance requirements in this subpart. These deviations must be reported in accordance with the requirements in § 63.9641.

(b) [Reserved]

■ 17. Section 63.9640 is amended by revising paragraph (e)(2) to read as follows:

§ 63.9640 What notifications must I submit and when?

* * * * *

(e) * * *

(2) For each initial compliance demonstration that does include a performance test, you must submit the notification of compliance status, including the performance test results, before the close of business on the 60th calendar day following the completion of the performance test according to § 63.10(d)(2). If the performance test results have been submitted electronically in accordance with § 63.9641(f), the process unit(s) tested, the pollutant(s) tested, and the date that such performance test was conducted may be submitted in the notification of compliance status report in lieu of the performance test results. The performance test results must be submitted to the Compliance and Emissions Data Reporting Interface (CEDRI) by the date the notification of compliance status report is submitted.

■ 18. Section 63.9641 is amended by:

■ a. Revising paragraphs (a)(2) and (4), (b) introductory text, and (b)(2) and (3).

■ b. Removing and reserving paragraph (b)(4).

■ c. Revising paragraphs (b)(7), (b)(8) introductory text, (b)(8)(ii) through (vii) and (b)(8)(ix), and (c).

■ d. Adding paragraphs (f), (g), and (h).

The revisions and additions read as follows:

§ 63.9641 What reports must I submit and when?

(a) * * *

(2) The first compliance report must be electronically submitted, postmarked or delivered no later than July 31 or January 31, whichever date comes first after your first compliance report is due.

* * * * *

(4) Each subsequent compliance report must be electronically submitted, postmarked or delivered no later than July 31 or January 31, whichever date comes first after the end of the semiannual reporting period.

* * * * *

(b) *Compliance report contents.* Each compliance report must include the information in paragraphs (b)(1) through (8) of this section, as applicable.

* * * * *

(2) Statement by a responsible official, with the official's name, title, and signature, certifying the truth, accuracy, and completeness of the content of the report. If your report is submitted via CEDRI, the certifier's electronic signature during the submission process replaces the requirement in this paragraph (b)(2).

(3) Date of report and beginning and ending dates of the reporting period. You are no longer required to provide the date of report when the report is submitted via CEDRI.

* * * * *

(7) For each deviation from an emission limitation in Table 1 to this subpart that occurs at an affected source where you are not using a continuous monitoring system (including a CPMS or COMS) to comply with an emission limitation in this subpart, the compliance report must contain the information in paragraphs (b)(7)(i) and (ii) of this section.

(i) The total operating time in hours of each affected source during the reporting period.

(ii) Information on the affected sources or equipment, the emission limited deviation from, the start date, start time, duration in hours, and cause of each deviation (including unknown cause) as applicable, an estimate of the quantity in pounds of each regulated pollutant emitted over an emission limit and a description of the method used to estimate the emissions, and the corrective action taken.

(8) For each deviation from an emission limitation occurring at an affected source where you are using a continuous monitoring system (including a CPMS or COMS) to comply with the emission limitation in this subpart, you must include the information in paragraphs (b)(1) through (4) of this section and the information in paragraphs (b)(8)(i) through (xi) of this section.

* * * * *

(ii) The start date, start time, and duration in hours (or minutes for COMS) that each continuous monitoring system was inoperative, except for zero (low-level) and high-level checks.

(iii) The start date, start time, and duration in hours (or minutes for COMS) that each continuous monitoring system was out-of-control, including the information in § 63.8(c)(8).

(iv) For each affected source or equipment, the date, the time that each deviation started and stopped, the cause of the deviation, and whether each deviation occurred during a period of malfunction or during another period.

(v) The total duration in hours (or minutes for COMS) of all deviations for each CMS during the reporting period, the total operating time in hours of the affected source during the reporting period, and the total duration as a percent of the total source operating time during that reporting period.

(vi) A breakdown of the total duration in hours (or minutes for COMS) of the deviations during the reporting period including those that are due to control equipment problems, process problems, other known causes, and other unknown causes.

(vii) The total duration in hours (or minutes for COMS) of continuous monitoring system downtime for each continuous monitoring system during the reporting period, the total operating time in hours of the affected source during the reporting period, and the total duration of continuous monitoring system downtime as a percent of the total source operating time during the reporting period.

* * * * *

(ix) The monitoring equipment manufacturer and model number and the pollutant or parameter monitored.

* * * * *

(c) *Submitting compliance reports electronically.* Beginning on [DATE 180 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], submit all subsequent compliance reports to the EPA via CEDRI, which can be accessed through the EPA's Central Data Exchange (CDX) (*https://cdx.epa.gov/*). You must use the appropriate electronic report template on the CEDRI website (*https://www.epa.gov/electronic-reporting-air-emissions/compliance-and-emissions-data-reporting-interface-cedri*) for this subpart. The report must be submitted by the deadline specified in this subpart, regardless of the method in which the report is submitted. If you claim some of the information required to be submitted via CEDRI is confidential business information (CBI), submit a complete report, including information claimed to be CBI, to the EPA. The report must be generated using the appropriate form on the CEDRI website. Submit the file on a compact disc, flash drive, or other commonly used electronic storage medium and clearly mark the medium as CBI. Mail the electronic medium to U.S. EPA/OAQPS/SPPD/CORE CBI Office, Attention: Taconite Iron Ore Processing Sector Lead, MD C404–02, 4930 Old Page Rd., Durham, NC 27703. The same file with the CBI omitted must be submitted to the EPA via the EPA's CDX as described earlier in this paragraph (c).

* * * * *

(f) *Performance tests.* Within 60 days after the date of completing each performance test required by this subpart, you must submit the results of the performance test following the procedures specified in paragraphs (f)(1) through (3) of this section.

(1) *Data collected using test methods supported by the EPA's Electronic Reporting Tool (ERT) as listed on the EPA's ERT website (https://www.epa.gov/electronic-reporting-air-emissions/electronic-reporting-tool-ert) at the time of the test.* Submit the results of the performance test to the EPA via CEDRI, which can be accessed through the EPA's CDX (*https://cdx.epa.gov/*). The data must be submitted in a file format generated through the use of the EPA's ERT. Alternatively, you may submit an electronic file consistent with the extensible markup language (XML) schema listed on the EPA's ERT website.

(2) *Data collected using test methods that are not supported by the EPA's ERT as listed on the EPA's ERT website at the time of the test.* The results of the performance test must be included as an attachment in the ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT website. Submit the ERT generated package or alternative file to the EPA via CEDRI.

(3) *Confidential business information (CBI).* If you claim some of the information submitted under paragraph (f)(1) or (2) of this section is CBI, you must submit a complete file, including information claimed to be CBI, to the EPA. The file must be generated through the use of the EPA's ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT website. Submit the file on a compact disc, flash drive, or other commonly used electronic storage medium and clearly mark the medium as CBI. Mail the electronic medium to U.S. EPA/OAQPS/CORE CBI Office, Attention: Group Leader, Measurement Policy Group, MD C404–02, 4930 Old Page Rd., Durham, NC 27703. The same file with the CBI omitted must be submitted to the EPA via the EPA's CDX as described in paragraphs (f)(1) and (2) of this section.

(g) *Claims of EPA system outage.* If you are required to electronically submit a report through CEDRI in the EPA's CDX, you may assert a claim of

EPA system outage for failure to timely comply with the reporting requirement. To assert a claim of EPA system outage, you must meet the requirements outlined in paragraphs (g)(1) through (7) of this section.

(1) You must have been or will be precluded from accessing CEDRI and submitting a required report within the time prescribed due to an outage of either the EPA's CEDRI or CDX systems.

(2) The outage must have occurred within the period of time beginning five business days prior to the date that the submission is due.

(3) The outage may be planned or unplanned.

(4) You must submit notification to the Administrator in writing as soon as possible following the date you first knew, or through due diligence should have known, that the event may cause or has caused a delay in reporting.

(5) You must provide to the Administrator a written description identifying:

(i) The date(s) and time(s) when CDX or CEDRI was accessed and the system was unavailable;

(ii) A rationale for attributing the delay in reporting beyond the regulatory deadline to EPA system outage;

(iii) Measures taken or to be taken to minimize the delay in reporting; and

(iv) The date by which you propose to report, or if you have already met the reporting requirement at the time of the notification, the date you reported.

(6) The decision to accept the claim of EPA system outage and allow an extension to the reporting deadline is solely within the discretion of the Administrator.

(7) In any circumstance, the report must be submitted electronically as soon as possible after the outage is resolved.

(h) *Claims of force majeure.* If you are required to electronically submit a report through CEDRI in the EPA's CDX, you may assert a claim of force majeure for failure to timely comply with the reporting requirement. To assert a claim of force majeure, you must meet the requirements outlined in paragraphs (h)(1) through (5) of this section.

(1) You may submit a claim if a force majeure event is about to occur, occurs, or has occurred or there are lingering effects from such an event within the period of time beginning five business days prior to the date the submission is due. For the purposes of this section, a force majeure event is defined as an event that will be or has been caused by circumstances beyond the control of the affected facility, its contractors, or any entity controlled by the affected facility that prevents you from complying with the requirement to submit a report electronically within the time period prescribed. Examples of such events are acts of nature (*e.g.,* hurricanes, earthquakes, or floods), acts of war or terrorism, or equipment failure or safety hazard beyond the control of the affected facility (*e.g.,* large scale power outage).

(2) You must submit notification to the Administrator in writing as soon as possible following the date you first knew, or through due diligence should have known, that the event may cause or has caused a delay in reporting.

(3) You must provide to the Administrator:

(i) A written description of the force majeure event;

(ii) A rationale for attributing the delay in reporting beyond the regulatory deadline to the force majeure event;

(iii) Measures taken or to be taken to minimize the delay in reporting; and

(iv) The date by which you propose to report, or if you have already met the reporting requirement at the time of the notification, the date you reported.

(4) The decision to accept the claim of force majeure and allow an extension to the reporting deadline is solely within the discretion of the Administrator.

(5) In any circumstance, the reporting must occur as soon as possible after the force majeure event occurs.

■ 19. Section 63.9642 is amended by:

■ a. Revising paragraph (a) introductory text.

■ b. Removing and reserving paragraph (a)(2).

■ c. Adding paragraphs (a)(4) through (6).

■ d. Revising paragraph (b)(3).

The revisions and additions read as follows:

§ 63.9642 What records must I keep?

(a) You must keep the records listed in paragraphs (a)(1) through (6) of this section.

* * * * *

(4) In the event that an affected unit fails to meet an applicable standard, record the number of failures. For each failure record the date, time, the cause and duration of each failure.

(5) For each failure to meet an applicable standard, record and retain a list of the affected sources or equipment, an estimate of the quantity of each regulated pollutant emitted over any emission limit and a description of the method used to estimate the emissions.

(6) Record actions taken in accordance with the general duty requirements to minimize emissions in § 63.9600(a) and any corrective actions taken to return the affected unit to its normal or usual manner of operation.

(b) * * *

(3) Previous (that is, superseded) versions of the performance evaluation plan as required in § 63.9632(b)(5), with the program of corrective action included in the plan required under § 63.8(d)(2).

* * * * *

■ 20. Section 63.9650 is revised to read as follows:

§ 63.9650 What parts of the General Provisions apply to me?

Table 2 to this subpart shows which parts of the General Provisions in §§ 63.1 through 63.16 apply to you.

■ 21. Section 63.9651 is amended by revising paragraph (c) introductory text and adding paragraph (c)(5) to read as follows:

§ 63.9651 Who implements and enforces this subpart?

* * * * *

(c) The authorities that will not be delegated to State, local, or tribal agencies are specified in paragraphs (c)(1) through (5) of this section.

* * * * *

(5) Approval of an alternative to any electronic reporting to the EPA required by this subpart.

■ 22. Section 63.9652 is amended by:

■ a. Removing the definition of ''Conveyor belt transfer point''.

■ b. Revising the definition of ''Deviation''.

■ c. Removing the definition of ''Wet grinding and milling''.

■ d. Adding the definition of ''Wet scrubber''.

The revision and addition read as follows:

§ 63.9652 What definitions apply to this subpart?

* * * * *

Deviation means any instance in which an affected source subject to this subpart, or an owner or operator of such a source:

(1) Fails to meet any requirement or obligation established by this subpart, including but not limited to any emission limitation (including operating limits) or operation and maintenance requirement; or

(2) Fails to meet any term or condition that is adopted to implement an applicable requirement in this subpart and that is included in the operating permit for any affected source required to obtain such a permit.

* * * * *

Wet scrubber means an air pollution control device that removes particulate matter and acid gases from the waste gas stream of stationary sources. The pollutants are removed primarily

through the impaction, diffusion, interception and/or absorption of the pollutant onto droplets of liquid. Wet scrubbers include venturi scrubbers, marble bed scrubbers, or impingement scrubbers. For purposes of this subpart, wet scrubbers do not include dynamic wet scrubbers.

■ 23. Table 2 to subpart RRRRR of part 63 is revised to read as follows:

As required in § 63.9650, you must comply with the requirements of the NESHAP General Provisions (40 CFR part 63, subpart A) shown in the following table:

TABLE 2 TO SUBPART RRRRR OF PART 63—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART RRRRR OF PART 63

Citation	Subject	Applies to subpart RRRRR	Explanation
§ 63.1(a)(1)–(4)	Applicability	Yes.	
§ 63.1(a)(5)	[Reserved]	No.	
§ 63.1(a)(6)	Applicability	Yes.	
§ 63.1(a)(7)–(9)	[Reserved]	No.	
§ 63.1(a)(10)–(12)	Applicability	Yes.	
§ 63.1(b)(1)	Initial Applicability Determination	Yes.	
§ 63.1(b)(2)	[Reserved]	No.	
§ 63.1(b)(3)	Initial Applicability Determination	Yes.	
§ 63.1(c)(1)–(2)	Applicability After Standard Established, Permit Requirements.	Yes.	
§ 63.1(c)(3)–(4)	[Reserved]	No.	
§ 63.1(c)(5)	Area Source Becomes Major	Yes.	
§ 63.1(d)	[Reserved]	No.	
§ 63.1(e)	Equivalency of Permit Limits	Yes.	
§ 63.2	Definitions	Yes.	
§ 63.3(a)–(c)	Units and Abbreviations	Yes.	
§ 63.4(a)(1)–(2)	Prohibited Activities	Yes.	
§ 63.4(a)(3)–(5)	[Reserved]	No.	
§ 63.4(b)–(c)	Circumvention, Fragmentation	Yes.	
§ 63.5(a)(1)–(2)	Construction/Reconstruction, Applicability.	Yes.	
§ 63.5(b)(1)	Construction/Reconstruction, Applicability.	Yes.	
§ 63.5(b)(2)	[Reserved]	No.	
§ 63.5(b)(3)–(4)	Construction/Reconstruction, Applicability.	Yes.	
§ 63.5(b)(5)	[Reserved]	No.	
§ 63.5(b)(6)	Applicability	Yes.	
§ 63.5(c)	[Reserved]	No.	
§ 63.5(d)(1)–(4)	Application for Approval of Construction or Reconstruction.	Yes.	
§ 63.5(e)	Approval of Construction or Reconstruction.	Yes.	
§ 63.5(f)	Approval Based on State Review	Yes.	
§ 63.6(a)	Compliance with Standards and Maintenance Requirements.	Yes.	
§ 63.6(b)(1)–(5)	Compliance Dates for New/Reconstructed Sources.	Yes.	
§ 63.6(b)(6)	[Reserved]	No.	
§ 63.6(b)(7)	Compliance Dates for New/Reconstructed Sources.	Yes.	
§ 63.6(c)(1)–(2)	Compliance Dates for Existing Sources.	Yes.	
§ 63.6(c)(3)–(4)	[Reserved]	No.	
§ 63.6(c)(5)	Compliance Dates for Existing Sources.	Yes.	
§ 63.6(d)	[Reserved]	No.	
§ 63.6(e)(1)(i)	Operation and Maintenance Requirements—General Duty to Minimize Emissions.	No	See § 63.9600(a) for general duty requirement.
§ 63.6(e)(1)(ii)	Operation and Maintenance Requirements—Requirement to Correct Malfunction as Soon as Possible.	No.	
§ 63.6(e)(1)(iii)	Operation and Maintenance Requirements—Enforceability.	Yes.	
§ 63.6(e)(2)	[Reserved]	No.	
§ 63.6(e)(3)	Startup, Shutdown, Malfunction (SSM) Plan.	No.	
§ 63.6(f)(1)	SSM Exemption	No.	
§ 63.6(f)(2)–(3)	Methods for Determining Compliance	Yes.	
§ 63.6(g)(1)–(3)	Alternative Nonopacity Standard	Yes.	
§ 63.6(h)	Compliance with Opacity and Visible Emission (VE) Standards.	No	Opacity limits in subpart RRRRR are established as part of performance testing in order to set operating limits for ESPs.
§ 63.6(i)(1)–(14)	Extension of Compliance	Yes.	

TABLE 2 TO SUBPART RRRRR OF PART 63—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART RRRRR OF PART 63—Continued

Citation	Subject	Applies to subpart RRRRR	Explanation
§ 63.6(i)(15)	[Reserved]	No.	
§ 63.6(i)(16)	Extension of Compliance	Yes.	
§ 63.6(j)	Presidential Compliance Exemption	Yes.	
§ 63.7(a)(1)–(2)	Applicability and Performance Test Dates.	No	Subpart RRRRR specifies performance test applicability and dates.
§ 63.7(a)(3)–(4)	Performance Testing Requirements	Yes.	
§ 63.7(b)	Notification	Yes.	
§ 63.7(c)	Quality Assurance/Test Plan	Yes.	
§ 63.7(d)	Testing Facilities	Yes.	
§ 63.7(e)(1)	Conduct of Performance Tests	No	See § 63.9621.
§ 63.7(e)(2)–(4)	Conduct of Performance Tests	Yes.	
§ 63.7(f)	Alternative Test Method	Yes.	
§ 63.7(g)	Data Analysis	Yes	Except this subpart specifies how and when the performance test results are reported.
§ 63.7(h)	Waiver of Tests	Yes.	
§ 63.8(a)(1)–(2)	Monitoring Requirements	Yes.	
§ 63.8(a)(3)	[Reserved]	No.	
§ 63.8(a)(4)	Additional Monitoring Requirements for Control Devices in § 63.11.	No	Subpart RRRRR does not require flares.
§ 63.8(b)(1)–(3)	Conduct of Monitoring	Yes.	
§ 63.8(c)(1)(i)	Operation and Maintenance of CMS	No	See § 63.9632 for operation and maintenance requirements for monitoring. See § 63.9600(a) for general duty requirement.
§ 63.8(c)(1)(ii)	Spare parts for CMS Equipment	Yes.	
§ 63.8(c)(1)(iii)	SSM Plan for CMS	No.	
§ 63.8(c)(2)–(3)	CMS Operation/Maintenance	Yes.	
§ 63.8(c)(4)	Frequency of Operation for CMS	No	Subpart RRRRR specifies requirements for operation of CMS.
§ 63.8(c)(5)–(8)	CMS Requirements	Yes	CMS requirements in § 63.8(c)(5) and (6) apply only to COMS for dry electrostatic precipitators.
§ 63.8(d)(1)–(2)	Monitoring Quality Control	Yes.	
§ 63.8(d)(3)	Monitoring Quality Control	No	See § 63.9632(b)(5).
§ 63.8(e)	Performance Evaluation of CMS	Yes.	
§ 63.8(f)(1)–(5)	Alternative Monitoring Method	Yes.	
§ 63.8(f)(6)	Relative Accuracy Test Alternative (RATA).	No	Subpart RRRRR does not require continuous emission monitoring systems.
§ 63.8(g)(1)–(4)	Data Reduction	Yes.	
§ 63.8(g)(5)	Data That Cannot Be Used	No	Subpart RRRRR specifies data reduction requirements.
§ 63.9	Notification Requirements	Yes	Additional notifications for CMS in § 63.9(g) apply to COMS for dry electrostatic precipitators.
§ 63.10(a)	Recordkeeping and Reporting, Applicability and General Information.	Yes.	
§ 63.10(b)(1)	General Recordkeeping Requirements.	Yes.	
§ 63.10(b)(2)(i)	Records of SSM	No	See § 63.9642 for recordkeeping when there is a deviation from a standard.
§ 63.10(b)(2)(ii)	Recordkeeping of Failures to Meet Standard.	No	See § 63.9642 for recordkeeping of (1) date, time and duration; (2) listing of affected source or equipment, and an estimate of the quantity of each regulated pollutant emitted over the standard; and (3) actions to minimize emissions and correct the failure.
§ 63.10(b)(2)(iii)	Maintenance Records	Yes.	
§ 63.10(b)(2)(iv)	Actions Taken to Minimize Emissions During SSM.	No.	
§ 63.10(b)(2)(v)	Actions Taken to Minimize Emissions During SSM.	No.	
§ 63.10(b)(2)(vi)	Recordkeeping for CMS Malfunctions	Yes.	
§ 63.10(b)(2)(vii)–(xii)	Recordkeeping for CMS	Yes.	
§ 63.10(b)(2)(xiii)	Records for Relative Accuracy Test	No	Subpart RRRRR does not require continuous emission monitoring systems.
§ 63.10(b)(2)(xiv)	Records for Notification	Yes.	
§ 63.10(b)(3)	Applicability Determinations	Yes.	
§ 63.10(c)(1)–(6)	Additional Recordkeeping Requirements for Sources with CMS.	Yes.	
§ 63.10(c)(7)–(8)	Records of Excess Emissions and Parameter Monitoring Exceedances for CMS.	No	Subpart RRRRR specifies recordkeeping requirements.
§ 63.10(c)(9)	[Reserved]	No.	

TABLE 2 TO SUBPART RRRRR OF PART 63—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART RRRRR OF PART 63—Continued

Citation	Subject	Applies to subpart RRRRR	Explanation
§ 63.10(c)(10)–(14)	CMS Recordkeeping	Yes	
§ 63.10(c)(15)	Use of SSM Plan	No.	
§ 63.10(d)(1)–(2)	General Reporting Requirements	Yes	Except this subpart specifies how and when the performance test results are reported.
§ 63.10(d)(3)	Reporting opacity or VE observations	No	Subpart RRRRR does not have opacity and VE standards that require the use of Method 9 of appendix A–4 to 40 CFR part 60 or Method 22 of appendix A–7 to 40 CFR part 60.
§ 63.10(d)(5)	SSM Reports	No. See 63.9641 for malfunction reporting requirements.	
§ 63.10(e)	Additional Reporting Requirements	Yes.	
§ 63.10(f)	Waiver of Recordkeeping or Reporting Requirements.	Yes.	
§ 63.11	Control Device and Work Practice Requirements.	No	Subpart RRRRR does not require flares.
§ 63.12(a)–(c)	State Authority and Delegations	Yes.	
§ 63.13(a)–(c)	State/Regional Addresses	Yes.	
§ 63.14(a)–(t)	Incorporations by Reference	Yes.	
§ 63.15(a)–(b)	Availability of Information and Confidentiality.	Yes.	
§ 63.16	Performance Track Provisions	Yes.	

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Part IV

Department of Agriculture

Forest Service

36 CFR Part 251

Land Uses; Special Uses; Procedures for Operating Plans and Agreements for Vegetation Management Within and Along Powerline Rights-of-Way; Proposed Rule

DEPARTMENT OF AGRICULTURE

Forest Service

36 CFR Part 251

RIN 0596–AD36

Land Uses; Special Uses; Procedures for Operating Plans and Agreements for Vegetation Management Within and Along Powerline Rights-of-Way

AGENCY: Forest Service, USDA.

ACTION: Proposed rule.

SUMMARY: The U.S. Department of Agriculture, Forest Service (Agency) is proposing to amend its existing regulations, for the Agency's special uses to implement Section 512 of the Federal Land Policy and Management Act, as added by section 211 of division O, Consolidated Appropriations Act, 2018 (hereinafter ''Section 512''). This section governs the development and approval of operating plans and agreements for vegetation and facility management on National Forest System (NFS) lands within rights-of-way for electric transmission and distribution facilities (powerlines) and on their abutting lands.

DATES: Comments must be received in writing by November 25, 2019.

ADDRESSES: Submit comments electronically by following the instructions at the Federal eRulemaking portal at *http://www.regulations.gov.* Comments also may be submitted by mail to the USDA Forest Service, Lands and Realty Staff, 201 14th Street SW, Mailstop 1124, Washington, DC 20250–1125. If comments are sent electronically, duplicate comments should not be sent by mail. Comments should be confined to issues pertinent to the proposed rule, and the reasons for any recommended changes should be explained. The specific section and wording being addressed should be referenced, where possible. All comments, including names and addresses when provided, will be placed in the record and will be available for public inspection and copying. The public may inspect comments received on this proposed rule in the Lands and Realty Management Staff, 1st Floor Southwest, 201 14th Street SW, Washington, DC 20250–1125, on business days between 8:30 a.m. and 4:00 p.m. Those wishing to inspect comments are encouraged to call ahead at 202–205–1196 to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Reggie Woodruff, Energy Program Manager, Lands and Realty Management staff, (202) 205–1196.

SUPPLEMENTARY INFORMATION:

Background and Need for the Proposed Rule

The proposed rule is being promulgated pursuant to Section 512 (43 U.S.C. 1772), which is an amendment to Title V of FLPMA (43 U.S.C. 1761–1772). Section 501(a)(5) of FLPMA (43 U.S.C. 1761(a)(5)) authorizes the Forest Service to issue or reissue right-of-way authorizations for powerlines on NFS lands. Section 501(b)(1) of FLPMA (43 U.S.C. 1761(b)(1)) provides that prior to issuing or reissuing a special use authorization for a right-of-way, the Forest Service must require that the applicant submit any plans, contracts, or other information related to the proposed or existing use of the right-of-way that the Agency deems necessary to determine, in accordance with FLPMA, whether to issue or reissue the authorization and the terms and conditions that should be included in the authorization.

Section 503(c) of FLPMA (43 U.S.C. 1763(c)) provides that right-of-way authorizations must be issued or reissued pursuant to Title V of FLMPA and its implementing regulations and must also be subject to such terms and conditions as the Forest Service may prescribe regarding extent, duration, survey, location, construction, maintenance, transfer or assignment, and termination. Section 505 of FLPMA (43 U.S.C. 1765) gives the Forest Service broad discretion to establish terms and conditions in right-of-way authorizations, including terms and conditions that will effectuate the purposes of FLPMA and its implementing regulations and minimize damage to scenic and aesthetic values and fish and wildlife habitat and otherwise protect the environment (43 U.S.C. 1765(a)(i)–(ii)). In addition, Section 505(b) (43 U.S.C. 1765(b)) requires the Forest Service to include terms and conditions in right-of-way authorizations that the Agency deems necessary to protect federal property and economic interests; efficiently manage the lands which are subject or adjacent to the right-of-way; protect lives and property; protect the interests of individuals living in the general area traversed by the right-of-way who rely on the fish, wildlife, and other biotic resources of the area for subsistence purposes; require location of the right-of-way along a route that will cause least damage to the environment, taking into consideration feasibility and other relevant factors; and otherwise protect the public interest in the lands traversed by or adjacent to the right-of-way.

Consistent with this statutory authority, the Forest Service regulates the occupancy and use of NFS lands for powerline rights-of-way through issuance of a special use authorization under 36 CFR part 251, subpart B. The Forest Service must include in special use authorizations terms and conditions the Agency deems necessary to effectuate the purposes of FLPMA and its implementing regulations (36 CFR 251.56(a)(1)(i)(A)); minimize damage to scenic and esthetic values and fish and wildlife habitat and otherwise protect the environment (36 CFR 251.56(a)(1)(i)(B)); protect federal property and economic interests (36 CFR 251.56(a)(1)(ii)(A)); efficiently manage the lands subject and adjacent to the authorized use (36 CFR 251.56(a)(1)(ii)(B)); protect lives and property (36 CFR 251.56(a)(1)(ii)(D)); protect the interests of individuals living in the general area of the authorized use who rely on resources of the area (36 CFR 251.56(a)(1)(ii)(E)); and otherwise protect the public interest (36 CFR 251.56(a)(1)(ii)(G)).

Based on these statutory and regulatory requirements, the Forest Service issues special use authorizations for powerline rights-of-way that require the holder, in consultation with the Forest Service, to prepare an operating plan that includes provisions governing vegetation and facility management on NFS lands within and abutting the right-of-way. Right-of-way authorizations for powerlines on NFS lands also require Forest Service approval of the operating plan before it is implemented.

In 2018, Congress amended FLPMA to add Section 512, which establishes requirements for the development and approval of operating plans and agreements for vegetation and facility management on NFS lands within powerline rights-of-way and on their abutting lands. Consistent with the definitions in Section 512(a), the Forest Service is proposing to amend its regulations at 36 CFR 251.51 to add definitions for ''hazard tree,'' ''operating plan or agreement for an electric transmission or distribution line,'' and ''owner or operator.'' The proposed rule would define an operating plan or agreement for a powerline on NFS lands as a plan or agreement that provides for long-term, cost-effective, efficient, and timely inspection, operation, maintenance and vegetation management of the powerline within the right-of-way and on abutting NFS lands, including management of hazard trees, to enhance electric reliability, promote public safety, and avoid fire hazards.

In addition, the Forest Service is proposing to revise 36 CFR 251.56, which governs terms and conditions in special use authorizations, to add a new paragraph (h), entitled *Operating plans and agreements for electric transmission and distribution facilities.* Consistent with Section 512(c), this new paragraph would include requirements for operating plans and agreements for powerlines. Per Section 512(c)(1) and (c)(4)(A), paragraph (h) of the proposed rule would provide for the operating plan or agreement to be prepared by the owner or operator of the powerline, approved by the authorized officer, and incorporated by reference into the corresponding special use authorization. Consistent with Section 512(d), paragraphs (h)(1) and (h)(2) of the proposed rule would specify when an agreement instead of an operating plan may be used. Consistent with Section 512(k), paragraph (h)(3) would provide that an existing operating plan must, at the holder's initiative, be revised consistent with Section 512 and submitted to the Forest Service for approval. Paragraph (h)(4), per Section 512(c)(1), would provide that an operating plan or agreement may be prepared by the owner or operator alone or in consultation with the Forest Service.

Per Section 512(c)(3) and (c)(4), (e), and (f), paragraph (h)(5) of the proposed rule would address the contents of an operating plan or agreement for a powerline, including:

- Coordination between the owner or operator and the Forest Service;
- Compliance with applicable law; applicable reliability and safety standards; the applicable land management plan; environmental compliance; resource protection; fire control; routine, non-routine, and emergency maintenance of the powerline; and road and trail construction, reconstruction, and maintenance in support of the powerline;
- Best management practices for vegetation management, procedures for marking timber, and road and trail standards and best management practices;
- Types of activities that require prior written approval from the Forest Service, including construction, reconstruction, and non-routine maintenance of the powerline; non-emergency vegetation management; and road and trail construction and reconstruction in support of the powerline; and
- Timeframes for:
  - The owner or operator to notify the Forest Service of routine, non-routine, and emergency maintenance of the powerline and non-emergency and emergency vegetation management for the powerline;
  - The owner or operator to request approval from the Forest Service of non-routine maintenance of and non-emergency vegetation management for the powerline; and
  - The authorized officer to respond to a request by the owner or operator for approval of non-routine maintenance of and non-emergency vegetation management for the powerline.
- Procedures for prior Forest Service approval of non-emergency vegetation management and emergency vegetation management of the powerline without prior Forest Service approval; and
- Procedures for modification of an approved operating plan or agreement.

Per Section 512(c)(4)(A), paragraph (h)(6) of the proposed rule would require proposed operating plans and agreements to be reviewed and approved in accordance with procedures developed jointly by the Forest Service and the United States Department of the Interior, Bureau of Land Management. Paragraph (h)(6), consistent with Section 512(c)(4), would require these procedures to specify timeframes for:

- Submission of agency comments on a proposed operating plan or agreement;
- Approval of a proposed operating plan or agreement, to the maximum extent practicable, within 120 days from the date the proposed operating plan or agreement was submitted; and
- Approval of any necessary modifications to an approved operating plan or agreement.

Per Section 512(c)(1) and (c)(4)(A), proposed paragraph (h)(7) would provide that when an approved operating plan or agreement expires before termination of the corresponding special use authorization, the owner or operator must prepare a new proposed operating plan or agreement, either solely or in consultation with the authorized officer, and submit it to the authorized officer for review and approval in accordance with the procedures described in proposed paragraph (h)(6).

Consistent with Section 512(h)(1), proposed paragraph (h)(8) would require the Forest Service to report annually on its website requests for approval of activities to be conducted under operating plans and agreements and the response to those requests.

Proposed paragraph (h)(9)(i), per Section 512(g)(1), would provide that strict liability in tort may not be imposed on an owner or operator for injury or damages resulting from the Forest Service's unreasonably withholding or delaying approval of an operating plan or agreement or unreasonably failing to adhere to an applicable schedule in an approved operating plan or agreement. Consistent with Section 512(g)(2), proposed paragraph (h)(9)(ii) would provide that for 10 years from the effective date of Section 512, strict liability in tort for injury or damages resulting from activities conducted by an owner or operator under an approved agreement may not exceed $500,000 per incident.

Consistent with Section 512(b), proposed paragraph (h)(10) would require the Forest Service to issue and periodically update guidance to ensure that operating plans and agreements for powerline authorizations are appropriately developed, approved, and implemented. Proposed paragaph (h)(10) would require that the guidance:

- Be developed in consultation with owners of powerlines;
- Be compatible with mandatory reliability standards established by the Electric Reliability Organization;
- Consider all applicable law, including fire safety and electrical system reliability requirements, such as reliability standards established by the Electric Reliability Organization;
- Consider the 2016 Memorandum of Understanding on Vegetation Management for Powerline Rights-of-Way Among the Edison Electric Institute, Utility Arborist Association, the National Park Service, the United States Fish and Wildlife Service, the Bureau of Land Management, the Forest Service, and the United States Environmental Protection Agency, and any successor memorandum of understanding;
- Seek to minimize the need for case-by-case approvals for non-emergency vegetation management (including hazard tree removal), facility inspection, and operation and maintenance of powerlines; and
- Provide for prompt and timely review of requests to conduct non-emergency vegetation management of powerlines.

Per Section 512(c)(5), the Forest Service's current regulations implementing the National Environmental Policy Act (NEPA) at 36 CFR 220.6(d)(10) and (e)(2) exclude categories of actions covered by an operating plan or agreement for a powerline authorization from documentation in an environmental assessment (EA) or an environmental impact statement (EIS). Section 220.6(d)(10) establishes a categorical exclusion from documentation in an EA or EIS (CE) for reissuance of an existing

special use authorization that involves only administrative changes and does not involve changes in the authorized facilities or increase in the scope or intensity of authorized activities, or extension to the term of the authorization, when the holder is in full compliance with the terms and conditions of the existing authorization. Section 220.6(e)(2) establishes a CE for additional construction or reconstruction of existing powerlines in a designated corridor, including reconstructing a powerline by replacing poles and wires.

Proposed revisions to the Forest Service's NEPA regulations at 36 CFR 220.5 (84 FR 27544) would enhance the Agency's ability to rely on a CE in approving activities covered by an operating plan or agreement for a powerline authorization. Proposed § 220.5(d)(11) would establish a new CE that does not require a project or case file and decision memo for reissuance of special use authorizations to reduce the backlog of expired and expiring authorizations. One of the examples for this CE would be issuance of a new authorization to replace a powerline authorization that is at the end of its term. In addition, the proposed revisions to the Agency's NEPA regulations would expand the current CE for special use authorizations at § 220.5(e)(3) from 5 to 20 acres and would remove the qualifier ''minor.'' One of the examples for this CE would be approval of up to a 40-foot-wide, 4-mile-long utility corridor on NFS lands.

As provided by Section 512(j)(2), the Forest Service will publish a final rule by March 31, 2020. The Agency anticipates that implementation of the rule would promote the reliability of the United States' electrical grid and would reduce the threat of damage to powerlines, natural resources, and nearby communities by streamlining approval for routine and emergency vegetation management within and abutting powerline rights-of-way on NFS lands.

Regulatory Certifications

Executive Order 12866

Executive Order (E.O.) 12866 provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget will review all significant rules. OIRA has determined that this proposed rule is not significant.

Executive Order 13771

The proposed rule has been reviewed in accordance with E.O. 13771 on reducing regulation and controlling regulatory costs and has been designated as an ''other action'' for purposes of the E.O.

Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), OIRA has designated this rule as not a major rule, as defined by 5 U.S.C. 804(2).

National Environmental Policy Act

This proposed rule would establish procedures for the development and approval of operating plans and agreements for vegetation and facility management within and abutting powerline rights-of-way on NFS lands. Agency regulations at 36 CFR 220.6(d)(2) (73 FR 43093) exclude from documentation in an environmental assessment or environmental impact statement rules, regulations, or policies to establish Service-wide administrative procedures, program processes, or instructions. The Agency has concluded that this proposed rule falls within this category of actions and that no extraordinary circumstances exist which would require preparation of an environment assessment or environmental impact statement.

Regulatory Flexibility Act Analysis

This proposed rule has been considered in light of the Regulatory Flexibility Act (5 U.S.C. 602 *et seq.*). This proposed rule would not have any direct effect on small entities as defined by the Regulatory Flexibility Act. The proposed rule would not impose recordkeeping requirements on small entities; would not affect their competitive position in relation to large entities; and would not affect their cash flow, liquidity, or ability to remain in the market. Therefore, the Forest Service has determined that this proposed rule would not have a significant economic impact on a substantial number of small entities pursuant to the Regulatory Flexibility Act.

Federalism

The Agency has considered this proposed rule under the requirements of E.O. 13132, *Federalism* and has determined that the proposed rule conforms with the Federalism principles set out in the E.O.; would not impose any compliance costs on the states; and would not have substantial direct effects on the states, the relationship between the federal government and the states, or the distribution of power and responsibilities among the various levels of government. Therefore, the Agency has determined that no further assessment of Federalism implications is necessary.

Consultation and Coordination With Indian Tribal Governments

The Agency has determined that national tribal consultation is not necessary for this proposed rule. This proposed rule, which would implement statutory requirements governing operating plans and agreements for powerline rights-of-way on NFS lands, is programmatic and would not have any direct effects on tribes. Tribal consultation will occur as appropriate in connection with specific applications for powerline rights-of-way on NFS lands.

No Takings Implications

This proposed rule has been analyzed in accordance with the principles and criteria contained in E.O. 12630, *Governmental Actions and Interference with Constitutionally Protect Property Rights.* The Agency has determined that the proposed rule would not pose the risk of a taking of private property.

Controlling Paperwork Burdens on the Public

This proposed rule does not contain any recordkeeping or reporting requirements or other information collection requirements as defined in 5 U.S.C. 1320 that are not already required by law or not already approved for use. Accordingly, the review provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) and its implementing regulations at 5 CFR part 1320 do not apply.

Energy Effects

This proposed rule has been reviewed under E.O. 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.* The Agency has determined that this proposed rule does not constitute a significant energy action as defined in the E.O.

Civil Justice Reform

This proposed rule has been reviewed under E.O. 12988, *Civil Justice Reform.* If the proposed rule were adopted, (1) all state and local laws and regulations that conflict with the proposed rule or that would impede its full implementation would be preempted; (2) no retroactive effect would be given to the proposed rule; and (3) it would not require administrative proceedings before parties may file suit in court challenging its provisions.

Unfunded Mandates

Pursuant to Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538), the Agency has assessed the effects of this proposed rule on state, local, and tribal governments and the private sector. This proposed rule would not compel the expenditure of $100 million or more by any state, local, or tribal government or anyone in the private sector. Therefore, a statement under section 202 of the act is not required.

List of Subjects in 36 CFR Part 251

Electric power, Mineral resources, National Forests, Rights-of-way, and Water resources.

Therefore, for the reasons set out in the preamble, the Forest Service proposes to amend part 251, subpart B, of title 36 of the Code of Federal Regulations as follows:

PART 251—LAND USES

Subpart B—Special Uses

■ 1. Revise the authority citation for part 251, subpart B, to read as follows:

Authority: 16 U.S.C. 460*l*–6a, 460*l*–6d, 472, 497b, 497c, 551, 580d, 1134, 3210; 30 U.S.C. 185; 43 U.S.C. 1740, 1761–1772.

■ 2. In § 251.51, add definitions for ''hazard tree,'' ''operating plan or agreement for an electric transmission or distribution facility,'' and ''owner or operator,'' in alphabetical order, to read as follows:

§ 251.51 Definitions.

* * * * *

Hazard tree—for purposes of vegetation management for an electric transmission or distribution line, any tree or part thereof (whether located inside or outside a right-of-way) that has been designated, prior to tree failure, by a certified or licensed arborist or forester under the supervision of the Forest Service or the owner or operator (a) to be dead, likely to die within the routine vegetation management cycle, or likely to fail within the routine vegetation management cycle; and (b) if the tree or part of the tree failed, likely to cause substantial damage or disruption of a transmission or distribution facility or come within 10 feet of an electric power line.

* * * * *

Operating plan or agreement for an electric transmission or distribution facility—a plan or an agreement prepared by the owner or operator of an electric transmission or distribution facility, approved by the authorized officer, and incorporated by reference into the corresponding special use authorization that provides for long-term, cost-effective, efficient, and timely inspection, operation, maintenance, and vegetation management of the electric transmission and distribution facility within the right-of-way and on abutting National Forest System lands, including management of hazard trees, to enhance electric reliability, promote public safety, and avoid fire hazards.

* * * * *

Owner or operator—for purposes of an electric transmission or distribution facility, the owner or operator of the facility or a contractor or other agent engaged by the owner or operator of the facility.

* * * * *

■ 3. In § 251.56, add paragraph (h), to read as follows:

§ 251.56 Terms and conditions.

* * * * *

(h) *Operating plans and agreements for electric transmission and distribution facilities (hereinafter, and for purposes of this paragraph only, ''operating plans'' and ''agreements'').* An operating plan or agreement consistent with 36 CFR 251.56(h) is required for new and reauthorized electric transmission and distribution facilities on National Forest System lands. Operating plans and agreements must have prior written approval from the authorized officer.

(1) *Use of operating plans.* Operating plans, rather than agreements, are required for electric transmission and distribution facilities that are subject to the mandatory reliability standards established by the Electric Reliability Organization and that sold more than 1,000,000 megawatt hours of electric energy for purposes other than resale during each of the 3 calendar years immediately preceding March 23, 2018.

(2) *Use of agreements.* Electric transmission and distribution facilities that are not subject to the mandatory reliability standards established by the Electric Reliability Organization or that sold less than or equal to 1,000,000 megawatt hours of electric energy for purposes other than resale during each of the 3 calendar years immediately preceding March 23, 2018, may be subject to an agreement, instead of an operating plan.

(3) *Existing operating plans.* Existing operating plans shall be modified at the owner's or operator's initiative as necessary to be consistent with 36 CFR 251.56(h) and submitted to the authorized officer for approval. Existing operating plans that are consistent with 36 CFR 251.56(h) do not have to be submitted for re-approval by the authorized officer.

(4) *Development of proposed operating plans and agreements.* Owners and operators may develop a proposed operating plan or agreement on their own or in consultation with the authorized officer.

(5) *Content of operating plans and agreements.* At a minimum, operating plans and agreements shall:

(i) Identify the electric transmission or distribution facility covered by the operating plan or agreement (hereinafter ''covered line'');

(ii) Consider preexisting operating plans and agreements for the covered line;

(iii) Address coordination between the owner or operator and the Forest Service and specify their points of contact;

(iv) Address compliance with applicable law; applicable reliability and safety standards (owners and operators subject to mandatory reliability standards established by the Electric Reliability Organization or superseding standards may use those standards as part of their operating plan); the applicable land management plan; environmental compliance; resource protection; fire control; routine, non-routine, and emergency maintenance of the covered line; and road and trail construction, reconstruction, and maintenance in support of the covered line;

(v) Identify best management practices for vegetation management, procedures for marking timber, and road and trail standards and best management practices;

(vi) Address the types of activities conducted under the operating plan or agreement that require prior written approval from the authorized officer under 36 CFR 251.61, including construction, reconstruction, and non-routine maintenance of the covered line; non-emergency vegetation management; and road and trail construction and reconstruction in support of the covered line;

(vii) Specify timeframes for:

(A) The owner or operator to notify the authorized officer of routine, non-routine, and emergency maintenance of the covered line and non-emergency and emergency vegetation management for the covered line;

(B) The owner or operator to request approval from the authorized officer of non-routine maintenance of and non-emergency vegetation management for the covered line; and

(C) The authorized officer to respond to a request by the owner or operator for approval of non-routine maintenance of

and non-emergency vegetation management for the covered line;

(viii) Include the following procedures with regard to authorized officer approval of vegetation management:

(A) *Non-emergency vegetation management.* Non-emergency vegetation management must have prior written approval from the authorized officer, unless all 3 of the following conditions are met:

(*1*) The owner or operator has submitted a request for approval to the authorized officer in accordance with the specified timeframe in the approved operating plan or agreement;

(*2*) The proposed vegetation management is in accordance with the approved operating plan or agreement; and

(*3*) The authorized officer has failed to respond to the request in accordance with the specified timeframe in the approved operating plan or agreement.

(B) *Emergency vegetation management.* If vegetation or hazard trees have contacted or, as specified in the operating plan or agreement, present an imminent danger of contacting the covered line from within or adjacent to the right-of-way for the covered line, the owner or operator may, without prior written approval from the authorized officer, prune or remove the vegetation or hazard trees to avoid the disruption of electric service and eliminate immediate fire and safety hazards. The owner or operator shall notify the authorized officer in writing of the location and quantity of the pruning or removal within 24 hours of the pruning or removal;

(ix) Include the following procedures for modification of an approved operating plan or agreement:

(A) The authorized officer shall give the owner or operator of the covered line prior notice of any changed conditions that warrant a modification of the approved operating plan or agreement;

(B) The authorized officer shall give the owner or operator an opportunity to submit a proposed modification of the approved operating plan or agreement, consistent with the procedures described in paragraph (h)(6) of this section, to address the changed conditions;

(C) The authorized officer shall consider the proposed modification consistent with the procedures described in paragraph (h)(6) of this section; and

(D) The owner or operator may continue to implement the approved operating plan or agreement to the extent it does not directly and adversely affect the conditions prompting the modification; and

(x) For agreements only, reflect the relative financial resources of the owner or operator of the covered line compared to other owners or operators of an electric transmission or distribution facility.

(6) *Review and approval of proposed operating plans and agreements.* Proposed operating plans and agreements shall be submitted to the authorized officer for review and approval in writing before they are implemented. Proposed operating plans and agreements shall be reviewed and approved in accordance with procedures developed jointly by the Forest Service and the United States Department of the Interior, Bureau of Land Management. These procedures shall be consistent with applicable law and shall specify timeframes for:

(i) Submission of applicable agency comments on a proposed operating plan or agreement;

(ii) Approval of a proposed operating plan or agreement that, to the maximum extent practicable, is within 120 days from the date the proposed operating plan or agreement was submitted; and

(iii) Approval of any necessary modifications to an approved operating plan or agreement.

(7) *Expiration of approved operating plans and agreements before termination of the corresponding special use authorization.* Upon expiration of an approved operating plan or agreement before termination of the corresponding special use authorization, the owner or operator must prepare a new proposed operating plan or agreement, either solely or in consultation with the authorized officer, and submit it to the authorized officer for review and approval in accordance with the procedures described in paragraph (h)(6) of this section.

(8) *Reporting of requests and responses to requests for non-emergency vegetation management.* The Forest Service shall annually report on its website requests for approval of non-emergency vegetation management pursuant to paragraph (h)(5)(viii)(A) of this section and responses to those requests.

(9) *Strict Liability.* (i) Notwithstanding paragraph (d)(2) of this section, strict liability in tort may not be imposed on an owner or operator for injury or damages resulting from the authorized officer's unreasonably withholding or delaying approval of an operating plan or agreement or unreasonably failing to adhere to an applicable schedule in an approved operating plan or agreement.

(ii) Notwithstanding paragraph (d)(2) of this section, for 10 years from March 23, 2018, strict liability in tort for injury or damages resulting from activities conducted by an owner or operator under an approved agreement may not exceed $500,000 per incident.

(10) *Guidance.* To enhance the reliability of the electric grid and to reduce the threat of wildfire damage to, and wildfire caused by vegetation-related conditions within, electric transmission and distribution rights-of-way and abutting NFS lands, including hazard trees, the Forest Service shall issue and periodically update guidance to ensure that provisions are appropriately developed and implemented for utility vegetation management, facility inspection, and operation and maintenance of rights-of-way. The guidance shall:

(i) Be developed in consultation with owners;

(ii) Be compatible with mandatory reliability standards established by the Electric Reliability Organization;

(iii) Consider all applicable law, including fire safety and electrical system reliability requirements, such as reliability standards established by the Electric Reliability Organization;

(iv) Consider the 2016 Memorandum of Understanding on Vegetation Management for Powerline Rights-of-Way Among the Edison Electric Institute, Utility Arborist Association, the National Park Service, the U.S. Fish and Wildlife Service, the Bureau of Land Management, the Forest Service, and the U.S. Environmental Protection Agency, and any successor memorandum of understanding;

(v) Seek to minimize the need for case-by-case approvals for non-emergency vegetation management (including hazard tree removal), facility inspection, and operation and maintenance of electric transmission and distribution facilities; and

(vi) Provide for prompt and timely review of requests to conduct non-emergency vegetation management.

Dated: September 5, 2019.

Daniel James Jiron,

Acting Deputy Under Secretary, Natural Resources and Environment.

[FR Doc. 2019–20741 Filed 9–24–19; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

36 CFR Part 251

RIN 0596–AD38

Land Uses; Special Uses; Streamlining Processing of Communications Use Applications

AGENCY: Forest Service, USDA.

ACTION: Proposed rule.

SUMMARY: The U.S. Department of Agriculture, Forest Service (Agency), is proposing to amend its existing regulations to implement part of Title VIII, Subtitle G, Section 8705, of the Agriculture Improvement Act of 2018, which requires regulations that streamline the Agency's procedures for evaluating applications to locate or modify communications facilities on National Forest System (NFS) lands.

DATES: Comments must be received in writing by November 25, 2019.

ADDRESSES: You may send comments, identified by RIN 0596–AD38, via one of the following methods:

1. *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for sending comments.
2. *Email: SM.FS.WO_LandStaff@usda.gov.*
3. *Mail:* Director, Lands Staff, 201 14th Street SW, Washington, DC 20250–1124.
4. *Hand Delivery/Courier:* Director, Lands Staff, 1st Floor Southeast, 201 14th Street SW, Washington, DC 20250–1124.

All comments, including names and addresses when provided, will be placed in the record and will be available for public inspection and copying. The public may inspect comments received at the Office of the Director, Lands, 1st Floor Southeast, Sidney R. Yates Federal Building, 201 14th Street SW, Washington, DC, during normal business hours. Visitors are encouraged to call ahead at 202–205–3563 to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Joey Perry, Lands Staff, 530–252–6699, *joey.perry@usda.gov.* Individuals who use telecommunication devices for the deaf may call the Federal Relay Service at 800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION:

Background

The Forest Service is responsible for managing Federal lands that are adjacent to rural and urban areas. The Forest Service authorizes the occupancy and use of NFS lands for communications facilities (buildings, towers and ancillary improvements) and fiber optic lines, which provide critical communications services, including television, radio, cellular, emergency services and broadband, to these areas. The Forest Service administers over 3,700 special use authorizations for communications uses at 1,530 communications sites and more than 400 communications use authorizations for fiber optic lines on NFS lands.

The Secretary of Agriculture's Rural Prosperity Task Force Report of 2017 identified connecting rural communities across the United States as a strategic priority for USDA because ''[i]n today's information-driven global economy, e-connectivity is not simply an amenity—it has become essential.''

On January 8, 2018, the President signed Executive Order 13821, *Streamlining and Expediting Requests to Locate Broadband Facilities in Rural America,* which states that ''Americans need access to reliable, affordable broadband internet service to succeed in today's information-driven, global economy'' (83 FR 1507). The Executive Order directs Federal agencies ''to use all viable tools to accelerate the deployment and adoption of affordable, reliable, modern high-speed broadband connectivity to rural America. . . .'' *Id.* Agencies are encouraged to reduce barriers to capital investments, remove obstacles to broadband services, and more efficiently employ Government resources. *Id.*

Section 6409 of the Middle Class Tax Relief and Job Creation Act of 2012, as amended by section 606(a), division P, Consolidated Appropriations Act, 2018, also known as the Making Opportunities for Broadband Investment and Limiting Excessive and Needless Obstacles to Wireless Act (MOBILE NOW Act), requires the Forest Service within 270 days of receipt of an application for a communications facility or a communications use to grant or deny the application and to notify the applicant of the grant or denial.

Need for Proposed Rule

The President signed the Agriculture Improvement Act of 2018 (the Farm Bill) into law on December 20, 2018. Title VIII, Subtitle G, Section 8705, of the Farm Bill requires the Forest Service to issue regulations that streamline the process for evaluating applications for communications facilities on NFS lands and that require charging a programmatic administrative fee for communications use authorizations to cover the cost of the Forest Service's communications site program. Specifically, Section 8705(b) and (c) requires the Forest Service to issue regulations that:

(1) Streamline the process for evaluating applications to locate or modify communications facilities on NFS lands;

(2) Ensure, to the maximum extent practicable, that the process is uniform and standardized across the Forest Service;

(3) Require that the applications for communications uses on NFS lands be evaluated and granted on a competitively neutral, technologically neutral, and non-discriminatory basis;

(4) Include procedures for tracking applications for communications uses;

(5) Include a minimum term of 15 years for communications use authorizations;

(6) Require that a processing fee be charged for an application for a communications use;

(7) Provide for prioritizing or streamlining evaluation of applications for communications uses on previously disturbed NFS lands; and

(8) Require that a programmatic administrative fee be charged for communications use authorizations to cover the costs of administering the Forest Service's communications site program. The Forest Service will publish a subsequent document in the **Federal Register** for a proposed rule to implement the programmatic administrative fee. The programmatic administrative fee is not going to be collected pursuant to the currently enacted authority at this time.

In addition, Section 8705(d) of the Farm Bill requires that in promulgating the regulations, the Forest Service consider how multiple communications facility applications can be considered simultaneously and how to eliminate overlapping requirements among organizational units in authorizing communications facilities on NFS lands.

Current Forest Service regulations at 36 CFR part 251, subpart B, govern the processing of special use applications and issuance of special use authorizations for uses of NFS lands, including communications uses. Forest Service Handbook (FSH) 2709.11, Chapter 10, provides direction for processing special use applications and issuing special use authorizations. FSH 2709.11, Chapter 90, provides direction for communications site management, including processing of communications use applications and administration of communications use authorizations.

A description of proposed regulatory revisions and compliance with the statutory requirements follows.

Proposed Revisions to Existing Regulations

Section 251.54 of the current regulations sets forth the procedures by which the Agency reviews proposals and processes applications for special use authorizations. As required by Section 8705(b)(1) through (b)(3) of the Farm Bill, existing § 251.54(g) contains numerous requirements for evaluating and granting special use applications, including applications for communications uses, in a uniform, standardized manner that is competitively and technologically neutral and non-discriminatory. Specifically, existing § 251.54(g)(2)(i) through (g)(2)(iii) requires all special use applications to be evaluated in accordance with applicable law, including the National Environmental Policy Act (NEPA), and requires the Forest Service to defer to relevant findings of another Federal agency. Existing § 251.54(g)(4) requires the Forest Service to evaluate all special use applications based on the information provided by the applicant and other relevant information such as environmental findings. These requirements are reinforced by Forest Service directives in FSH 2709.11, Chapter 10, section 11.14, paragraph 1, which prohibits discrimination against a proponent because of race, color, religion, sex, age, disability, marital status, or national origin; sections 11.25, 12.51, and 12.52, which address compliance with applicable environmental law; and section 11.3, paragraph 1a, which encourages use of the standard special use application form, Standard Form 299.

In addition, as required by Section 8705(c)(4) of the Farm Bill, existing regulations at 36 CFR 251.54(g)(4) provide for streamlining evaluation of applications for communications uses on previously disturbed NFS lands. In particular, § 251.54(g)(4) provides that a group of applications for similar uses having minor environmental impacts may be evaluated with one analysis and approved in one decision. This provision allows for evaluation of applications for similar communications uses with minor environmental impacts, which may often be the case for proposed uses on previously disturbed NFS lands, to be streamlined in one analysis and one decision. Existing § 251.54(g)(4) is also consistent with the requirement in Section 8705(d) of the Farm Bill that in promulgating the regulations, the Forest Service consider how multiple communications facility applications can be considered simultaneously and how to eliminate overlapping requirements among organizational units in authorizing communications facilities on NFS lands.

Proposed revisions to the Forest Service's NEPA regulations at 36 CFR part 220 (84 FR 27544) would further streamline evaluation of communications use applications by facilitating reliance on a categorical exclusion from documentation in an environmental assessment or environmental impact statement (CE). The proposed revisions to the Agency's NEPA regulations would expand the current CE for special use authorizations at § 220.5(e)(3) from 5 to 20 acres and would remove the qualifier ''minor'' to cover placement of additional communications facilities like towers and generators. The proposed NEPA rule would also establish a new CE at § 220.5(d)(11) that does not require a project or case file and decision memo for reissuance of special use authorizations, which would reduce the backlog of expired and expiring authorizations.

Consistent with the MOBILE NOW Act, existing directives at FSH 2709.11, Chapter 90, section 90.3, paragraph 5, provide that within 270 days of acceptance of a proposal as an application for a new communications facility or co-location of a new communications use in or on a facility managed by the Forest Service, or within 270 days of receipt of an application for modification of an existing communications facility or co-located communications use on a facility managed by the Forest Service, the authorized officer must grant or deny the application and notify the applicant in writing of the grant or denial.

The Forest Service proposes to reinforce existing regulatory requirements implementing Section 8705 of the Farm Bill and the MOBILE NOW Act by adding two subparagraphs to § 251.54(g)(4), which governs evaluation of special use applications. The first new subparagraph would implement the streamlining provisions for communications use applications by incorporating the requirement for the Agency to grant or deny an application for a communications use within 270 days of receipt and to notify the applicant in writing of the grant or denial. The second new subparagraph would provide for establishment of a process in the Forest Service's directive system for tracking applications for communications uses that provides for (a) identifying the number of applications received, approved, and denied; (b) for applications that are denied, describing the reasons for denial; and (c) describing the amount of time between receipt of an application and grant or denial of the application.

The Forest Service proposes to further implement Section 8705 of the Farm Bill by adding two subparagraphs to § 251.54(g)(5), which governs issuance of special use authorizations. Existing regulations do not address the term for communications use authorizations. Consistent with Section 8705(c)(2) of the Farm Bill, new paragraph (g)(5)(ii) would establish a term for communications use authorizations of 30 years, unless case-specific circumstances warrant a shorter term.

As noted, the Forest Service will publish a subsequent document in the **Federal Register** for a proposed rule to implement Section 8705(c)(3)(B) of the Farm Bill, which requires regulations to implement a new programmatic administrative fee for communications use authorizations to cover the costs of administering the Forest Service's communications site program. The programmatic administrative fee is not going to be collected pursuant to the currently enacted authority at this time.

Proposed Revisions to Forest Service Directives

FSH 2709.11, Chapter 90

The Forest Service is proposing revisions to its directives at FSH 2709.11, Chapter 90, concurrently with this rulemaking. Consistent with Section 8705(b) and (c)(1) of the Farm Bill and the proposed revisions to the Agency's regulations, the proposed directives would amend Chapter 90, section 90.4, to establish responsibility for the tracking system for communications use applications; section 92 to provide for a 30-day review period by communications use authorizations holders of new or modified communications site management plans; section 94.1 to implement procedures that would expedite requests to co-locate communications uses in or on existing communications facilities; and section 94.3 to establish procedures for inputting data needed to track communications use applications.

A separate document will be published in the **Federal Register** announcing the availability of the proposed directives and list information on how to comment on the proposed directives. When the document is published, the proposed directives and a copy of the **Federal Register** document

will be posted at *https://www.fs.fed.us/specialuses/special_comm.shtml.*

Other Streamlining Efforts Implementing Section 8705 of the Farm Bill

The Forest Service is developing an online mapping tool of communications sites on NFS lands. This mapping tool will provide basic information concerning the communications sites, such as their geographical location, site designation, and local contact information. This information will enable the public and stakeholders to locate communications sites on NFS lands and complete an initial feasibility assessment prior to submitting a proposal and application for use and occupancy of NFS lands. Once implemented, the online mapping tool will reinforce existing and proposed regulatory and directive requirements implementing the streamlining provisions in Section 8705(b)(1) of the Farm Bill. Implementation of the online mapping tool is not subject to public notice and comment under applicable law.

Regulatory Certifications

Executive Order 12866

Executive Order (E.O.) 12866 provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget will review all significant rules. OIRA has determined that this proposed rule is not significant.

Executive Order 13771

This proposed rule has been reviewed in accordance with E.O. 13771 on reducing regulation and controlling regulatory costs and has been designated as an ''other action'' for purposes of the E.O.

Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), OIRA has designated this proposed rule as not a major rule as defined by 5 U.S.C. 804(2).

National Environmental Policy Act

The proposed rule would establish procedures for streamlining the Forest Service's evaluation of applications to locate or modify communications facilities on NFS lands. Agency regulations at 36 CFR 220.6(d)(2) (73 FR 43093) exclude from documentation in an environmental assessment or environmental impact statement rules, regulations, or policies to establish Service-wide administrative procedures, program processes, or instructions. The Agency has concluded that the proposed rule falls within this category of actions and that no extraordinary circumstances exist which would require preparation of an environmental assessment or environmental impact statement.

Regulatory Flexibility Act Analysis

The Agency has considered the proposed rule under the requirements of the Regulatory Flexibility Act (5 U.S.C. 602 *et seq.*). This proposed rule would not have any direct effect on small entities as defined by the Regulatory Flexibility Act. The proposed rule would not impose recordkeeping requirements on small entities; would not affect their competitive position in relation to large entities; and would not affect their cash flow, liquidity, or ability to remain in the market. Therefore, the Forest Service has determined that this proposed rule would not have a significant economic impact on a substantial number of small entities pursuant to the Regulatory Flexibility Act.

Federalism

The Agency has considered the proposed rule under the requirements of E.O. 13132, *Federalism.* The Agency has determined that the proposed rule conforms with the federalism principles set out in this executive order; would not impose any compliance costs on the states; and would not have substantial direct effects 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. Therefore, the Agency has concluded that the proposed rule does not have Federalism implications.

Consultation With Tribal Governments

The Agency has determined that national tribal consultation is not necessary for the proposed rule. The proposed rule, which would update the Forest Service's administrative procedures for reviewing applications and issuing authorizations for communications uses, is programmatic and would not have any direct effects on tribes. Tribal consultation will occur as appropriate in connection with specific applications for communications facilities on NFS lands.

No Takings Implications

The Agency has analyzed the proposed rule in accordance with the principles and criteria in E.O. 12630, *Governmental Actions and Interference with Constitutionally Protect Property Rights.* The Agency has determined that the proposed rule would not pose the risk of a taking of private property.

Energy Effects

The Agency has reviewed the proposed rule under E.O. 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.* The Agency has determined that the proposed rule would not constitute a significant energy action as defined in E.O. 13211.

Civil Justice Reform

The Forest Service has analyzed the proposed rule in accordance with the principles and criteria in E.O. 12988, *Civil Justice Reform.* After adoption of the proposed rule, (1) all state and local laws and regulations that conflict with the proposed rule or that impede its full implementation would be preempted; (2) no retroactive effect would be given to the proposed rule; and (3) it would not require administrative proceedings before parties may file suit in court challenging its provisions.

Unfunded Mandates

Pursuant to Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538), signed into law on March 22, 1995, the Agency has assessed the effects of the proposed rule on state, local, and tribal governments and the private sector. The proposed rule would not compel the expenditure of $100 million or more by any state, local, or tribal government or anyone in the private sector. Therefore, a statement under section 202 of the Act is not required.

Controlling Paperwork Burdens on the Public

The proposed rule does not contain any recordkeeping or reporting requirements or other information collection requirements as defined in 5 CFR part 1320 that are not already required by law or not already approved for use. Accordingly, the review provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) and its implementing regulations at 5 CFR part 1320 do not apply.

List of Subjects in 36 CFR Part 251

Electric power, Mineral resources, National forests, Rights-of-way, and Water resources.

Therefore, for the reasons set forth in the preamble, the Forest Service proposes to amend part 251, subpart B, of title 36 of the Code of Federal Regulations as follows:

PART 251—LAND USES

Subpart B—Special Uses

■ 1. The authority citation for part 251, subpart B, continues to read as follows:

Authority: 16 U.S.C. 460*l*–6a, 460*l*–6d, 472, 497b, 497c, 551, 580d, 1134, 3210; 30 U.S.C. 185; 43 U.S.C. 1740, 1761–1771.

■ 2. In § 251.54, revise paragraphs (g)(4) and (g)(5) to read as follows:

§ 251.54 Proposal and application requirements and procedures.

* * * * *

(g) * * *

(4) *Response to all other applications*—(i) *General.* Based on evaluation of the information provided by the applicant and other relevant information such as environmental findings, the authorized officer shall decide whether to approve the proposed use, approve the proposed use with modifications, or deny the proposed use. A group of applications for similar uses having minor environmental impacts may be evaluated with one analysis and approved in one decision.

(ii) *Communications use applications.* Within 270 days of acceptance of a proposal as an application for a new communications facility or co-location of a new communications use in or on a facility managed by the Forest Service, or within 270 days of receipt of an application for modification of an existing communications facility or co-located communications use on a facility managed by the Forest Service, the authorized officer shall grant or deny the application and notify the applicant in writing of the grant or denial.

(iii) *Tracking of communications use applications.* The Forest Service shall establish a process in its directive system (36 CFR 200.4) for tracking applications for communications uses that provides for:

(A) Identifying the number of applications received, approved, and denied;

(B) For applications that are denied, describing the reasons for denial; and

(C) Describing the amount of time between receipt of an application and grant or denial of the application.

(5) *Authorization of a special use*—(i) *General.* Upon a decision to approve a special use or a group of similar uses, the authorized officer may issue one or more special use authorizations as defined in § 251.51 of this subpart.

(ii) *Minimum term for communications use authorizations.* The term for a communications use authorization shall be 30 years, unless case-specific circumstances warrant a shorter term.

Dated: September 6, 2019.

Daniel James Jiron,

Acting Deputy Under Secretary, Natural Resources and Environment.

[FR Doc. 2019–20742 Filed 9–24–19; 8:45 am]

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FEDERAL REGISTER

Vol. 84 Wednesday,

No. 186 September 25, 2019

Part V

The President

Proclamation 9930—National POW/MIA Recognition Day, 2019

Federal Register
Vol. 84, No. 186
Wednesday, September 25, 2019

Presidential Documents

Title 3—

The President

Proclamation 9930 of September 19, 2019

National POW/MIA Recognition Day, 2019

By the President of the United States of America

A Proclamation

Our American story is filled with countless examples of patriots who have gone beyond the call of duty to defend our precious liberties and cherished freedoms. National POW/MIA Recognition Day is an opportunity for our Nation to honor the intrepid spirit and admirable bravery of all former American prisoners of war, while also reaffirming our promise never to relent in our quest to locate the Soldiers, Sailors, Marines, Airmen, Coast Guardsmen, Merchant Marines, and civilians who remain missing in action.

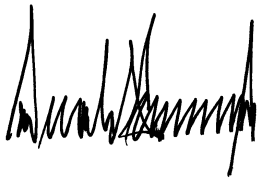
Seventy-five years ago, more than 150,000 American and Allied troops took part in the D-Day invasion on the beaches of Normandy. Among the stalwart heroes who helped alter history for the betterment of humankind on the morning of June 6, 1944, are 261 American service members missing in action. Their immeasurable sacrifice will forever be preserved in the hearts of those who continue to enjoy the hard-earned blessings of peace and prosperity.

As Americans, it is our sacred duty to pay tribute to the brave men and women of our Armed Forces for their service and sacrifice, especially those who endured unimaginable physical and emotional trauma as prisoners of war and those who never returned to American soil. It is also our solemn obligation never to leave a service member behind. My Administration is dedicated to locating and identifying the more than 81,000 American service members unaccounted for—many of whom were former prisoners of war—to help alleviate the grieving and prolonged uncertainty of their families. We vow to pursue the fullest possible accounting of these gallant patriots.

On September 20, 2019, the black and white flag symbolizing America's Missing in Action and Prisoners of War will be flown over the White House; the United States Capitol; the Departments of State, Defense, and Veterans Affairs; the Selective Service System Headquarters; the World War II Memorial; the Korean War Veterans Memorial; the Vietnam Veterans Memorial; United States post offices; national cemeteries; and other locations across our country. Our Nation salutes our former prisoners of war, and we show reverence to the service members who remain missing in action and to their waiting families. America will always preserve their legacy.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim September 20, 2019, as National POW/MIA Recognition Day. I call upon the people of the United States to join me in saluting all American POWs and those missing in action who valiantly served our country. I call upon Federal, State, and local government officials and private organizations to observe this day with appropriate ceremonies and activities.

IN WITNESS WHEREOF, I have hereunto set my hand this nineteenth day of September, in the year of our Lord two thousand nineteen, and of the Independence of the United States of America the two hundred and forty-fourth.



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Federal Register/Code of Federal Regulations	
General Information, indexes and other finding aids	**202–741–6000**
Laws	**741–6000**
Presidential Documents	
Executive orders and proclamations	**741–6000**
The United States Government Manual	**741–6000**
Other Services	
Electronic and on-line services (voice)	**741–6020**
Privacy Act Compilation	**741–6050**

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FEDERAL REGISTER PAGES AND DATE, SEPTEMBER

45873–46418 3
46419–46652 4
46653–46874 5
46875–47114 6
47115–47404 9
47405–47874 10
47875–48040 11
48041–48228 12
48229–48546 13
48547–48782 16
48783–49004 17
49005–49190 18
49191–49434 19
49435–49634 20
49635–49934 23
49935–50286 24
50287–50710 25

CFR PARTS AFFECTED DURING SEPTEMBER

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

2 CFR

1800 49191

3 CFR

Proclamations:
9917 46865
9918 46867
9919 46869
9920 46871
9921 47873
9922 48223
9923 48225
9924 48541
9925 48547
9926 49003
9927 49185
9928 49187
9929 49629
9930 50709

Executive Orders:
13885 46873
13886 48041
13887 49935

Administrative Orders:
Memorandums:
Memorandum of January 13, 2017 (Revoked by Memorandum of September 6, 2019) 48227
Memorandum of September 6, 2019 .....48227, 48549
Notices:
Notice of September 10, 2019 48039
Notice of September 12, 2019 48545
Notice of September 19, 2019 49633
Presidential Determinations:
No. 2019–23 of September 13, 2019 49189

5 CFR

532 49941
843 49635
1650 46419
1651 46419

Proposed Rules:
315 48794
432 48794
532 49483
752 48794

6 CFR

37 .....46423, 48045

7 CFR

Subtitle A 47405
Subtitle B 47405
54 .....48551, 49637
56 49637
70 49637
210 50287
220 50287
226 50287
253 45873
319 49191
460 48518
718 45877
760 48518
810 50293
1146 46653
1208 49942
1217 50294
1412 45877
1416 48518
1970 49644

Proposed Rules:
Subtitle A 47443
Subtitle B 47443
301 49680
319 49680
923 49682
993 49963
3565 45927

8 CFR

Proposed Rules:
103 46040
208 47148

9 CFR

Ch. I 47405
Ch. II 47405
Ch. III 47405

Proposed Rules:
Ch. I 47443
Ch. II 47443
Ch. III 47443

10 CFR

430 46661

Proposed Rules:
26 48750
30 47443
40 47443
50 47443
52 47443
60 47443
61 .....47443, 48309
63 47443
70 47443
71 47443
72 47443
430 .....46469, 46830, 49965
431 48006

12 CFR

Ch. X 48229, 48246, 48260

Proposed Rules:
337 46470

611 49684
615 ....49069, 49684
620 49684
621 49684
628 49684
630 49684

13 CFR

Proposed Rules:
120 48807

14 CFR

23 49648
39 ....45895, 46426, 46429, 46432, 46434, 46875, 47406, 47407, 47410, 47875, 47877, 48045, 48047, 48050, 48563, 48783, 49005, 49944, 50301
71 ....46438, 46877, 47413, 47415, 48052, 49008, 49010, 49011, 49012, 50304
95 48054
97 ....47115, 47116, 47118, 47120

Proposed Rules:
39 ....46496, 46896, 46898, 46900, 46903, 47170, 47173, 47445, 47906, 48083, 48310, 48569, 49484, 49487, 50336, 50339
71 ....46905, 47909, 48085, 48086, 48572, 50341, 50344, 50346, 50347
121 50349

15 CFR

Proposed Rules:
922 45929

16 CFR

1130 49947
1215 49435
1229 46878

17 CFR

241 47416
271 47420
276 47420

Proposed Rules:
3 49071
13 49490
39 ....49071, 49072
140 ....49071, 49072

18 CFR

385 46438

Proposed Rules:
806 48312

19 CFR

12 46676
24 ....46678, 49650
141 46676

20 CFR

401 45900
404 49950
655 49439

21 CFR

Proposed Rules:
15 47911
101 48809
130 48809
216 46688
1100 50566
1107 50566
1114 50566
1308 48815
1310 48314

24 CFR

Proposed Rules:
5 48820
92 48820
93 48820
232 48321
574 48820
960 48820
966 48820
982 48820

26 CFR

1 ....49651, 50108
301 ....46440, 46681

Proposed Rules:
1 ....47175, 47191, 47447, 47455, 50152

28 CFR

Proposed Rules:
16 49073

29 CFR

4022 48272
4044 48272

Proposed Rules:
103 49691

30 CFR

906 46184

Proposed Rules:
935 46703

31 CFR

515 47121
582 46440

Proposed Rules:
50 46907
800 50174
802 50214

32 CFR

88 48274
111 49457
117 47879
312 47880
318 46681
505 46681
806b 46882

33 CFR

100 ....45901, 46682, 48059, 48274, 48276, 49015, 49193
165 ....45903, 45905, 46882, 46883, 46885, 47123, 47427, 47429, 47431, 47880, 48059, 48062, 48064, 48066, 48278, 48281, 48786, 48788, 49017, 49020, 49022, 49194, 49460

Proposed Rules:
165 46498
167 46501
334 48090

34 CFR

Ch. III 47433
668 49788
682 49788
685 49788

36 CFR

Proposed Rules:
251 ....50698, 50703

37 CFR

1 45907

Proposed Rules:
210 49966

39 CFR

Proposed Rules:
3050 50353

40 CFR

9 ....49025, 49040
51 47882
52 ....45910, 45918, 46877, 46889, 46892, 47437, 47884, 47885, 47887, 47889, 47893, 47895, 47897, 48068, 48789, 49057, 49062, 49462, 49465, 49467, 49659, 49661, 49663, 49667, 49670, 49671, 50305
60 ....47882, 49470
61 47882
62 47899
63 47882
70 50307
80 49470
81 ....47895, 47897, 48286, 49467
151 46100
180 ....47125, 47130, 47136, 48071, 49195, 49475
300 ....46684, 48077, 48565, 49479, 49480, 49481, 49675, 49951, 49952, 49953, 50307
721 ....49025, 49040

Proposed Rules:
52 ....45930, 45931, 47211, 47213, 47216, 47914, 49202, 49492, 49699, 50354, 50363
60 ....49497, 50244
63 ....46138, 46610, 47074, 47346, 48708, 49382, 50660
80 46909
81 ....47216, 49492
191 50367
194 50367
228 49075
281 48573
282 78573
721 47923
1042 46909

42 CFR

88 49954
405 47494
424 47494
447 50308
455 47494
457 47494
498 47494

44 CFR

64 ....46685, 49676

Proposed Rules:
62 45933

46 CFR

10 47141

Proposed Rules:
11 48842
502 ....45934, 48578
515 ....45934, 48578
545 ....48850, 50369

47 CFR

25 47146
73 ....46920, 49677

Proposed Rules:
73 49205
74 49205

48 CFR

Ch. I 47860, 47868
1 47861
2 47862
4 47861
9 47865
13 ....47861, 47865
15 47865
19 47862
22 47866
25 ....47865, 47866
39 47861
42 47865
52 ....47861, 47862, 47866
Ch. II 48508, 48210
App. F 48510
204 48510
209 48507
212 ....48507, 48510
213 48507
216 48510
217 48510
218 48504
237 ....48504, 48510
239 ....48496, 48498
247 48506
252 ....48496, 48498, 48499, 48500, 48501, 48503, 48504, 48506, 48507, 48510
801 46448
815 46448
816 46448
837 46448
849 46448
852 46448
871 46448

Proposed Rules:
1 49498
9 49974
12 ....49498, 49502, 49974
13 49974
25 49498
29 ....49498, 49502
43 49974
52 ....49498, 49502, 49974
227 48513
229 48512
252 ....48512, 48513
1502 48856
1512 48856
1513 48856
1516 48856
1532 48856
1539 48856
1552 48856

49 CFR

395 48077

Proposed Rules:
382 46923
383 ....45938, 46923
384 ....45938, 46923
395 ....45940, 49212
571 48866
585 48866
1002 48872
1011 48882

1111.....48872, 48882
1114.....48872
1115.....48872

50 CFR

17.....48290
21.....45921
26.....47640
32.....47640
36.....47640
71.....47640
219.....46788
402.....50333
622 .....45924, 47902, 50333, 50334
635 .....47440, 48566, 48791
648.....48081
660.....49960
679 .....45295, 46457, 46458, 46686, 47904, 49066, 49678

Proposed Rules:

17 .....46927, 47231, 48090
218.....48388
226.....49214
622.....48890
635.....45941, 49236
648.....48899
660.....48094

LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws**.

Last List August 28, 2019

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