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

The Code of Federal Regulations is sold by the Superintendent of Documents.

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 211

RIN 3206–AN47

Veterans' Preference

AGENCY: Office of Personnel Management.

ACTION: Final rule.

SUMMARY: The U.S. Office of Personnel Management (OPM) is issuing a final rule to implement a statutory change pertaining to veterans' preference. This change is made in response to the Gold Star Fathers Act of 2015. The Act broadens the category of individuals eligible for veterans' preference to provide that fathers of certain permanently disabled or deceased veterans shall be included with mothers of such veterans as preference eligibles for treatment in the civil service.

DATES: This rule will be effective January 7, 2019.

FOR FURTHER INFORMATION CONTACT: Roseanna Ciarlante by telephone on (267) 932–8640, by fax at (202) 606–4430, by TTY at (202) 418–3134, or by email at *Roseanna.Ciarlante@opm.gov.*

SUPPLEMENTARY INFORMATION: On October 7, 2015, the Gold Star Fathers Act of 2015 (the ''Act'') was enacted as Public Law 114–62. The Act provides an amendment to the eligibility criteria for veterans' preference purposes by amending subparagraphs (F) and (G) to 5 U.S.C. 2108(3). The amendment provides that fathers of certain permanently disabled or deceased veterans shall be included with mothers of such veterans as preference eligibles for treatment in the civil service. The Act also changes the requirements for parents of such veterans to qualify for this preference.

The Act replaces 5 U.S.C. 2108(3)(F) to state that the parent of an individual who lost his or her life under honorable conditions while serving in the armed forces during a war, in a campaign or expedition for which a campaign badge has been authorized, or during the period beginning April 28, 1952, and ending July 1, 1955, is eligible for preference if the spouse of that parent is totally and permanently disabled; or that parent, when preference is claimed, is unmarried or, if married, legally separated from his or her spouse.

The Act also replaces 5 U.S.C. 2108(3)(G) to state that the parent of a service-connected permanently and totally disabled veteran is eligible for preference if the spouse of that parent is totally and permanently disabled; or that parent, when preference is claimed, is unmarried or, if married, legally separated from his or her spouse.

On December 27, 2016, OPM issued an interim rule at 81 FR 94909, amending 5 CFR 211.102(d) to state that a ''preference eligible'' is ''a veteran, disabled veteran, sole survivor veteran, spouse, widow, widower, or parent who meets the definition of 'preference eligible' in 5 U.S.C. 2108.'' The amendment replaced the word ''mother'' with the word ''parent'' to conform to the statutory definition.

Discussion of Comments

During the 60-day comment period between December 27, 2016 and February 27, 2017, OPM received one comment from an individual. The individual expressed concern that absent oversight, agencies will use this change to (1) replace their older career employees with a non-career workforce, and (2) circumvent unspecified special hiring authorities. The commenter did not articulate how giving the fathers of certain permanently-disabled or deceased veterans the same rights as mothers would have these effects. Because the commenter's concern is unclear and speculative, OPM cannot address it.

OPM acknowledges that oversight of veterans' preference is critical. OPM conducts regular reviews of veterans hiring across the Government to ensure that veterans are receiving the entitlements they have earned in the Federal hiring process. We have identified no systemic abuses or issues with veterans' preference or veterans hiring practices.

Regulatory Impact Analysis

OPM has examined the impact of this rule as required by Executive Order 12866 and Executive Order 13563, which directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public, health, and safety effects, distributive impacts, and equity). A regulatory impact analysis must be prepared for major rules with economically significant effects of $100 million or more in any one year. This rule was not designated as a ''significant regulatory action,'' under Executive Order 12866 and was not reviewed by the Office of Management and Budget.

Reducing Regulation and Controlling Regulatory Costs

This final rule is not an E.O. 13771 regulatory action because this rule is not significant under E.O. 12866.

Regulatory Flexibility Act

The Office of Personnel Management certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Act of 1995

This rule will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any year and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

This action pertains to agency management, personnel, and organization and does not substantially affect the rights or obligations of nonagency parties and, accordingly, is not a ''rule'' as that term is used by the Congressional Review Act (Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA)). Therefore, the reporting requirement of 5 U.S.C. 801 does not apply.

Paperwork Reduction Act of 1995

Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork

Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number.

This rule involves a collection of information subject to the PRA—Standard Form (SF) 15, *Application for 10-Point Veteran Preference,* OMB No. 3206–0001. OPM is currently reinstating this expired collection with changes to include an expanded population. The systems of record notice for this collection is: OPM GOVT–1 (*https://www.opm.gov/information-management/privacy-policy/sorn/opm-sorn-govt-1-general-personnel-records.pdf*).

List of Subjects in 5 CFR Part 211

Government employees, Veterans.

U.S. Office of Personnel Management

Alexys Stanley,

Regulatory Affairs Analyst.

Accordingly, OPM amends part 211 of title 5, Code of Federal Regulations, as follows:

PART 211—VETERAN PREFERENCE

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

Authority: 5 U.S.C. 1302, 2108, 2108a.

■ 2. In § 211.102, revise paragraph (d) introductory text to read as follows:

§ 211.102 Definitions.

* * * * *

(d) *Preference eligible* means a veteran, disabled veteran, sole survivor veteran, spouse, widow, widower, or parent who meets the definition of ''preference eligible'' in 5 U.S.C. 2108.

* * * * *

[FR Doc. 2018–26265 Filed 12–6–18; 8:45 am]

BILLING CODE 6325–39–P

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 531

RIN 3206–AN64

General Schedule Locality Pay Areas

AGENCY: Office of Personnel Management.

ACTION: Final rule.

SUMMARY: On behalf of the President's Pay Agent, the Office of Personnel Management (OPM) is issuing final regulations to establish six new General Schedule locality pay areas, make certain changes to the definitions of existing locality pay areas, and make minor clarifying changes to the names of two locality pay areas. Those changes in locality pay area definitions are applicable on the first day of the first pay period beginning on or after January 1, 2019. Locality pay rates for the six new locality pay areas will be set by the President.

DATES: The regulations are effective January 5, 2019, and are applicable on the first day of the first pay period beginning on or after January 1, 2019.

FOR FURTHER INFORMATION CONTACT: Joe Ratcliffe by email at *pay-leave-policy@opm.gov* or by telephone at (202) 606–2838.

SUPPLEMENTARY INFORMATION: Section 5304 of title 5, United States Code (U.S.C.), authorizes locality pay for General Schedule (GS) employees with duty stations in the United States and its territories and possessions. Section 5304(f) authorizes the President's Pay Agent (the Secretary of Labor, the Director of the Office of Management and Budget (OMB), and the Director of the Office of Personnel Management (OPM)) to determine locality pay areas. The boundaries of locality pay areas must be based on appropriate factors, which may include local labor market patterns, commuting patterns, and the practices of other employers. The Pay Agent must give thorough consideration to the views and recommendations of the Federal Salary Council, a body composed of experts in the fields of labor relations and pay policy and representatives of Federal employee organizations. The President appoints the members of the Federal Salary Council, which submits annual recommendations on the locality pay program to the Pay Agent. The establishment or modification of locality pay area boundaries must conform to the notice and comment provisions of the Administrative Procedure Act (5 U.S.C. 553).

On July 9, 2018, OPM published a proposed rule in the **Federal Register** on behalf of the Pay Agent. (See 83 FR 31694.) The proposed rule proposed linking locality pay area definitions to metropolitan statistical areas (MSAs) and combined statistical areas (CSAs) defined by OMB in OMB Bulletin No. 18–03, and proposed establishing four new locality pay areas: Birmingham-Hoover-Talladega, AL; Burlington-South Burlington, VT; San Antonio-New Braunfels-Pearsall, TX; and Virginia Beach-Norfolk, VA-NC. The proposed rule also proposed adding two ''Rest of U.S.'' locations to the geographic definitions of two existing locality pay areas and making minor, clarifying changes to the names of two locality pay areas. The proposed rule did not propose modifying the standard commuting and GS employment criteria used in the locality pay program to evaluate, as possible areas of application, locations adjacent to the metropolitan area comprising the basic locality pay area. (A basic locality pay area is an OMB-defined MSA or CSA on which the definition of a locality pay area is based, and an area of application is a location that is not part of a basic locality pay area but is included in the locality pay area. Criteria used to establish areas of application were explained in the proposed rule.)

The proposed rule provided a 30-day comment period. Accordingly, the Pay Agent reviewed comments received through August 8, 2018. After considering those comments, the Pay Agent has decided to implement the locality pay area definitions in the proposed rule, with two additional changes based on recommendations received from the Federal Salary Council on July 10, 2018. Those changes are the establishment of a new Corpus Christi-Kingsville-Alice, TX, locality pay area and establishment of a new Omaha-Council Bluffs-Fremont, NE-IA, locality pay area.

On July 10, 2018—the day after the proposed rule was published—the Pay Agent received the Federal Salary Council's recommendations for locality pay for January 2019, which included a recommendation to establish a Corpus Christi-Kingsville-Alice, TX, locality pay area and an Omaha-Council Bluffs-Fremont, NE-IA, locality pay area. (The Council's recommendations for locality pay for January 2019 are posted at *https://www.opm.gov/policy-data-oversight/pay-leave/pay-systems/general-schedule/federal-salary-council/recommedation17.pdf.*) Because the Council based that recommendation on the same criteria as used for the four new locality pay areas included in the proposed rule, we have approved the Council's recommendation regarding the two additional locality pay areas. In addition, a number of commenters on the proposed rule supported the establishment of these two additional locality pay areas. Accordingly, these final regulations establish a Corpus Christi-Kingsville-Alice, TX, locality pay area and an Omaha-Council Bluffs-Fremont, NE-IA, locality pay area. As with the four new locality pay areas included in the proposed rule, locality pay rates for the two additional new locality pay areas will be set by the President at a later date after they are established by these final regulations.

Impact and Implementation

Establishing 6 new locality pay areas will impact about 70,000 GS employees. Locality pay rates now applicable in those areas will not change automatically because locality pay percentages are established by Executive order under the President's authority in 5 U.S.C. 5304 or 5304a, and the President decides each year whether to adjust locality pay percentages. When locality pay percentages are adjusted, past practice has been to allocate a percent of the total GS payroll for locality pay raises and to have the overall dollar cost for such pay raises be the same, regardless of the number of locality pay areas. If a percent of the total GS payroll is allocated for locality pay increases, the addition of new areas results in a somewhat smaller amount to allocate for locality pay increases in existing areas. Implementing higher locality pay rates in the six new locality pay areas could thus result in relatively lower pay increases for employees in existing locality pay areas than they would otherwise receive.

Establishing McKinley County, NM, as an area of application to the Albuquerque-Santa Fe-Las Vegas, NM, locality pay area will impact about 1,600 GS employees. Establishing San Luis Obispo County, CA, as an area of application to the Los Angeles-Long Beach, CA, locality pay area will impact about 100 GS employees.

Using the definitions of MSAs and CSAs in OMB Bulletin No. 18–03 as the basis for locality pay area boundaries will impact about 153 GS employees in the new San Antonio-New Braunfels-Pearsall, TX, locality pay area. However, those GS employees are included in the impact statement above regarding establishment of the six new locality pay areas. No other locality pay areas are impacted by using MSAs and CSAs in OMB Bulletin No. 18–03 as the basis for locality pay area boundaries.

The changes in the names of the Boston-Worcester-Providence, MA-RI-NH-CT-ME and Albany-Schenectady, NY, locality pay areas will have no impact on GS employees because the geographic boundaries of the two locality pay areas affected will remain the same.

Comments on the Proposed Rule

OPM received 184 comments on the proposed rule. Most commenters supported the proposed changes in the definitions of locality pay areas.

A number of comments reflected misunderstanding of the proposed rule's definitions of locality pay areas, with some comments indicating a belief that certain counties actually included in a proposed locality pay area were excluded. As explained in the proposed rule, locality pay areas consist of (1) the MSA or CSA comprising the basic locality pay area and, where criteria recommended by the Federal Salary Council and approved by the Pay Agent are met, (2) areas of application. Regarding the MSAs and CSAs comprising basic locality pay areas, these final regulations define MSA as the geographic scope of an MSA as defined in OMB Bulletin No. 18–03 and define CSA as the geographic scope of a CSA as defined in OMB Bulletin No. 18–03. (OMB Bulletin No. 18–03 is posted at *https://www.whitehouse.gov/wp-content/uploads/2018/04/OMB-BULLETIN-NO.-18-03-Final.pdf.*) Where a locality pay area defined in these regulations lists one or more locations in addition to the MSA or CSA comprising the basic locality pay area, those additional locations are areas of application that meet criteria recommended by the Federal Salary Council and approved by the President's Pay Agent. OPM plans to post the definitions of locality pay areas on its website soon after these final regulations are issued.

Some commenters objected that certain locations were to remain in the ''Rest of U.S.'' locality pay area under the proposed rule. Some of these commenters were concerned about locations in MSAs or CSAs in the ''Rest of U.S.'' locality pay area for which the Federal Salary Council has studied disparities between non-Federal pay and Federal pay over several years of data. For such locations that will remain in the ''Rest of U.S.'' locality pay area, the Council found that the pay disparities do not significantly exceed the pay disparity for the ''Rest of U.S.'' locality pay area over the same period. Some commenters were concerned about locations that will remain in the ''Rest of U.S.'' locality pay area because those locations do not meet the criteria for areas of application. Some commenters were concerned about rural locations that do not qualify as areas of application and for which the locality pay program's current salary survey methodology cannot produce reliable estimates due to data insufficiency with respect to non-Federal salaries. For example, some comments expressed concern about Accomack and Northampton Counties, VA, not being included in the proposed Virginia Beach-Norfolk, VA-NC, locality pay area. These two counties comprise an area known as the Eastern Shore of Virginia and do not meet the Pay Agent's criteria to be part of the Virginia Beach-Norfolk, VA-NC, locality pay area. In some cases, comments expressed concern regarding possible recruitment and retention difficulties the commenters believe agencies may have in certain locations that will remain in the ''Rest of U.S.'' locality pay area when these final regulations are put into effect. The Pay Agent has no evidence that the changes these final regulations will make in locality pay area definitions will create recruitment and retention challenges for Federal employers. However, should recruitment and retention challenges exist in a location, Federal agencies have considerable administrative authority to address those challenges through the use of current pay flexibilities. Information on these flexibilities is posted on the OPM website at *http://www.opm.gov/policy-data-oversight/pay-leave/pay-and-leave-flexibilities-for-recruitment-and-retention.*

A number of commenters expressed their views on pay levels in locality pay areas. Some commenters suggested specific locality pay percentages to apply to new or existing locality pay areas, and some commenters offered opinions on the extent to which pay increases are needed in some locality pay areas compared to others. Some commenters expressed concern that existing locality pay areas' future pay levels could be set lower than they otherwise would, due to establishment of new locality pay areas. Such comments as these are outside of the scope of these final regulations. The purpose of these final regulations is to define the boundaries of locality pay areas. The role of the Pay Agent with regard to locality pay percentages is to report annually to the President what locality pay percentages would go into effect under the Federal Employees Pay Comparability Act of 1990 (FEPCA). The President establishes a base General Schedule and sets locality pay percentages each year by Executive order.

Some commenters expressed the belief that various indicators of living costs should be considered in defining locality pay areas or in setting locality pay. Living costs are not directly considered in the locality pay program. Locality pay is not designed to equalize living standards for GS employees across the country. Under 5 U.S.C. 5304, locality pay rates are based on comparisons of GS pay and non-Federal pay at the same work levels in a locality pay area. Relative living costs may indirectly affect non-Federal pay levels, but living costs are just one of many

factors that affect the supply of and demand for labor, and therefore labor costs, in a locality pay area.

Some commenters objected that, as a consequence of the definitions of current locality pay areas, adjacent counties are included in two different locality pay areas while receiving different locality payments. These commenters were concerned that the adjacent California Counties of Sacramento and San Joaquin receive different locality payments, with Sacramento County receiving Sacramento-Roseville, CA-NV, locality pay and San Joaquin County receiving higher San Jose-San Francisco-Oakland, CA, locality pay. Sacramento County is located in the Sacramento-Roseville, CA, CSA, which is the basis for the geographic definition of the Sacramento-Roseville, CA-NV, locality pay area. San Joaquin County is located in the San Jose-San Francisco-Oakland, CA, CSA, which is the basis for the geographic definition of the San Jose-San Francisco-Oakland, CA, locality pay area. Locality pay percentages are based on comparisons in each locality pay area between GS and non-Federal pay for the entire locality pay area. The results of such pay comparisons differ between the Sacramento-Roseville, CA-NV, and San Jose-San Francisco-Oakland, CA, locality pay areas. Consequently, those two locality pay areas and the locations comprising them receive different locality payments.

One commenter suggested a change in the criteria for evaluating Federal facilities that cross locality pay area boundaries. This commenter suggested that the term ''facility'' in those criteria be replaced with the term ''Federal administrative boundary.'' The commenter stated that most GS employees with duty stations within the Tahoe National Forest are in the Sacramento-Roseville, CA-NV, locality pay area, while Sierra County, CA, remains in the ''Rest of U.S.'' locality pay area. The commenter reported that the U.S. Forest Service is having difficulty recruiting and retaining employees for its duty stations in Sierra County. The Pay Agent's criteria for evaluating Federal facilities that cross locality pay area boundaries is intended to cover single Federal facilities rather than large geographic areas such as National Forests. As stated above, Federal agencies have considerable administrative authority to address significant recruitment and retention challenges through the use of current pay flexibilities.

Some commenters expressed concern that certain Federal pay systems outside of the General Schedule would not benefit from the changes planned for definitions of GS locality pay areas. The purpose of these final regulations is to define locality pay areas for Federal employees who receive locality pay under 5 U.S.C. 5304, not to set pay levels for Federal employees who do not receive locality pay under 5 U.S.C. 5304.

One commenter suggested that all GS employees should receive the same locality pay rates regardless of location. The purpose of locality pay is to reduce pay disparities, which vary by locality pay area. Therefore, it is appropriate that locality rates differ between locations.

Expected Impact of the Final Rule

Establishing new locality pay areas could have the long-term effect of increasing pay for Federal employees in affected locations if the President establishes higher locality pay percentages for those new pay areas. In addition, studies do suggest that increasing wages can raise the wages of other workers when employers need to compete for personnel. However, when locality pay percentages are adjusted, the practice has been to allocate a percent of the total GS payroll for locality pay raises and to have the overall cost for such pay raises be the same, regardless of the number of locality pay areas.

OPM expects this final rule to impact approximately 71,700 GS employees. Of the changes this final rule implements, the most significant change in terms of employment results from establishment of the Virginia Beach-Norfolk, VA-NC locality pay area, in which approximately 30,400 GS employees would be affected. Considering the relatively small number of employees affected, OPM does not anticipate this rule will substantially impact local economies or have a large impact in local labor markets. In addition, OPM did not receive any comments expressing concern regarding such impact.

As future locality pay rulemakings may impact higher volumes of employees in geographical areas and could rise to the level of impacting markets, OPM will continue to study the implications of such impacts in E.O. 13771 designations for future rules as needed.

Regulatory Procedures

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

Executive Orders 13563 and 12866 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, distribute impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule has been designated a ''significant regulatory action,'' although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget (OMB).

Reducing Regulation and Controlling Regulatory Costs

This rule is not an Executive Order 13771 regulatory action because this rule is related to agency organization, management, or personnel.

Regulatory Flexibility Act

OPM certifies that this rule will not have a significant economic impact on a substantial number of small entities as this rule only applies to Federal agencies and employees.

Federalism

OPM has examined this rule in accordance with Executive Order 13132, Federalism, and has determined that this rule will not have any negative impact on the rights, roles and responsibilities of State, local, or tribal governments.

Civil Justice Reform

This regulation meets the applicable standard set forth in Executive Order 12988.

Unfunded Mandates Act of 1995

This rule will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any year and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

This action pertains to agency management, personnel, and

organization and does not substantially affect the rights or obligations of nonagency parties and, accordingly, is not a ''rule'' as that term is used by the Congressional Review Act (Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA)). Therefore, the reporting requirement of 5 U.S.C. 801 does not apply.

Paperwork Reduction Act

This rule does not impose any new reporting or record-keeping requirements subject to the Paperwork Reduction Act.

List of Subjects in 5 CFR Part 531

Government employees, Law enforcement officers, Wages.

Office of Personnel Management.

Alexys Stanley,

Regulatory Affairs Analyst.

Accordingly, OPM is amending 5 CFR part 531 as follows:

PART 531—PAY UNDER THE GENERAL SCHEDULE

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

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

Subpart F—Locality-Based Comparability Payments

■ 2. In § 531.602, the definitions of ''CSA'' and ''MSA'' are revised to read as follows:

§ 531.602 Definitions.

* * * * *

CSA means the geographic scope of a Combined Statistical Area, as defined by the Office of Management and Budget (OMB) in OMB Bulletin No. 18–03.

* * * * *

MSA means the geographic scope of a Metropolitan Statistical Area, as defined by the Office of Management and Budget (OMB) in OMB Bulletin No. 18–03.

* * * * *

■ 3. In § 531.603, paragraph (b) is revised to read as follows:

§ 531.603 Locality pay areas.

* * * * *

(b) The following are locality pay areas for the purposes of this subpart:

(1) Alaska—consisting of the State of Alaska;

(2) Albany-Schenectady, NY-MA—consisting of the Albany-Schenectady, NY CSA and also including Berkshire County, MA;

(3) Albuquerque-Santa Fe-Las Vegas, NM—consisting of the Albuquerque-Santa Fe-Las Vegas, NM CSA and also including McKinley County, NM;

(4) Atlanta—Athens-Clarke County—Sandy Springs, GA-AL—consisting of the Atlanta—Athens-Clarke County—Sandy Springs, GA CSA and also including Chambers County, AL;

(5) Austin-Round Rock, TX—consisting of the Austin-Round Rock, TX MSA;

(6) Birmingham-Hoover-Talladega, AL—consisting of the Birmingham-Hoover-Talladega, AL CSA and also including Calhoun County, AL;

(7) Boston-Worcester-Providence, MA-RI-NH-ME—consisting of the Boston-Worcester-Providence, MA-RI-NH-CT CSA, except for Windham County, CT, and also including Androscoggin County, ME, Cumberland County, ME, Sagadahoc County, ME, and York County, ME;

(8) Buffalo-Cheektowaga, NY—consisting of the Buffalo-Cheektowaga, NY CSA;

(9) Burlington-South Burlington, VT—consisting of the Burlington-South Burlington, VT MSA;

(10) Charlotte-Concord, NC-SC—consisting of the Charlotte-Concord, NC-SC CSA;

(11) Chicago-Naperville, IL-IN-WI—consisting of the Chicago-Naperville, IL-IN-WI CSA;

(12) Cincinnati-Wilmington-Maysville, OH-KY-IN—consisting of the Cincinnati-Wilmington-Maysville, OH-KY-IN CSA and also including Franklin County, IN;

(13) Cleveland-Akron-Canton, OH—consisting of the Cleveland-Akron-Canton, OH CSA and also including Harrison County, OH;

(14) Colorado Springs, CO—consisting of the Colorado Springs, CO MSA and also including Fremont County, CO, and Pueblo County, CO;

(15) Columbus-Marion-Zanesville, OH—consisting of the Columbus-Marion-Zanesville, OH CSA;

(16) Corpus Christi-Kingsville-Alice, TX—consisting of the Corpus Christi-Kingsville-Alice, TX CSA;

(17) Dallas-Fort Worth, TX-OK—consisting of the Dallas-Fort Worth, TX-OK CSA and also including Delta County, TX;

(18) Davenport-Moline, IA-IL—consisting of the Davenport-Moline, IA-IL CSA;

(19) Dayton-Springfield-Sidney, OH—consisting of the Dayton-Springfield-Sidney, OH CSA and also including Preble County, OH;

(20) Denver-Aurora, CO—consisting of the Denver-Aurora, CO CSA and also including Larimer County, CO;

(21) Detroit-Warren-Ann Arbor, MI—consisting of the Detroit-Warren-Ann Arbor, MI CSA;

(22) Harrisburg-Lebanon, PA—consisting of the Harrisburg-York-Lebanon, PA CSA, except for Adams County, PA, and York County, PA, and also including Lancaster County, PA;

(23) Hartford-West Hartford, CT-MA—consisting of the Hartford-West Hartford, CT CSA and also including Windham County, CT, Franklin County, MA, Hampden County, MA, and Hampshire County, MA;

(24) Hawaii—consisting of the State of Hawaii;

(25) Houston-The Woodlands, TX—consisting of the Houston-The Woodlands, TX CSA and also including San Jacinto County, TX;

(26) Huntsville-Decatur-Albertville, AL—consisting of the Huntsville-Decatur-Albertville, AL CSA;

(27) Indianapolis-Carmel-Muncie, IN—consisting of the Indianapolis-Carmel-Muncie, IN CSA and also including Grant County, IN;

(28) Kansas City-Overland Park-Kansas City, MO-KS—consisting of the Kansas City-Overland Park-Kansas City, MO-KS CSA and also including Jackson County, KS, Jefferson County, KS, Osage County, KS, Shawnee County, KS, and Wabaunsee County, KS;

(29) Laredo, TX—consisting of the Laredo, TX MSA;

(30) Las Vegas-Henderson, NV-AZ—consisting of the Las Vegas-Henderson, NV-AZ CSA;

(31) Los Angeles-Long Beach, CA—consisting of the Los Angeles-Long Beach, CA CSA and also including Kern County, CA, San Luis Obispo County, CA, and Santa Barbara County, CA;

(32) Miami-Fort Lauderdale-Port St. Lucie, FL—consisting of the Miami-Fort Lauderdale-Port St. Lucie, FL CSA and also including Monroe County, FL;

(33) Milwaukee-Racine-Waukesha, WI—consisting of the Milwaukee-Racine-Waukesha, WI CSA;

(34) Minneapolis-St. Paul, MN-WI—consisting of the Minneapolis-St. Paul, MN-WI CSA;

(35) New York-Newark, NY-NJ-CT-PA—consisting of the New York-Newark, NY-NJ-CT-PA CSA and also including all of Joint Base McGuire-Dix-Lakehurst;

(36) Omaha-Council Bluffs-Fremont, NE-IA—consisting of the Omaha-Council Bluffs-Fremont, NE-IA CSA;

(37) Palm Bay-Melbourne-Titusville, FL—consisting of the Palm Bay-Melbourne-Titusville, FL MSA;

(38) Philadelphia-Reading-Camden, PA-NJ-DE-MD—consisting of the Philadelphia-Reading-Camden, PA-NJ-DE-MD CSA, except for Joint Base McGuire-Dix-Lakehurst;

(39) Phoenix-Mesa-Scottsdale, AZ—consisting of the Phoenix-Mesa-Scottsdale, AZ MSA;

(40) Pittsburgh-New Castle-Weirton, PA-OH-WV—consisting of the Pittsburgh-New Castle-Weirton, PA-OH-WV CSA;

(41) Portland-Vancouver-Salem, OR-WA—consisting of the Portland-Vancouver-Salem, OR-WA CSA;

(42) Raleigh-Durham-Chapel Hill, NC—consisting of the Raleigh-Durham-Chapel Hill, NC CSA and also including Cumberland County, NC, Hoke County, NC, Robeson County, NC, Scotland County, NC, and Wayne County, NC;

(43) Richmond, VA—consisting of the Richmond, VA MSA and also including Cumberland County, VA, King and Queen County, VA, and Louisa County, VA;

(44) Sacramento-Roseville, CA-NV—consisting of the Sacramento-Roseville, CA CSA and also including Carson City, NV, and Douglas County, NV;

(45) San Antonio-New Braunfels-Pearsall, TX—consisting of the San Antonio-New Braunfels-Pearsall, TX CSA;

(46) San Diego-Carlsbad, CA—consisting of the San Diego-Carlsbad, CA MSA;

(47) San Jose-San Francisco-Oakland, CA—consisting of the San Jose-San Francisco-Oakland, CA CSA and also including Monterey County, CA;

(48) Seattle-Tacoma, WA—consisting of the Seattle-Tacoma, WA CSA and also including Whatcom County, WA;

(49) St. Louis-St. Charles-Farmington, MO-IL—consisting of the St. Louis-St. Charles-Farmington, MO-IL CSA;

(50) Tucson-Nogales, AZ—consisting of the Tucson-Nogales, AZ CSA and also including Cochise County, AZ;

(51) Virginia Beach-Norfolk, VA-NC—consisting of the Virginia Beach-Norfolk, VA-NC CSA;

(52) Washington-Baltimore-Arlington, DC-MD-VA-WV-PA—consisting of the Washington-Baltimore-Arlington, DC-MD-VA-WV-PA CSA and also including Kent County, MD, Adams County, PA, York County, PA, King George County, VA, and Morgan County, WV; and

(53) Rest of U.S.—consisting of those portions of the United States and its territories and possessions as listed in 5 CFR 591.205 not located within another locality pay area.

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DEPARTMENT OF AGRICULTURE

Office of the Secretary

7 CFR Part 12

[NRCS–2018–0010]

RIN 0578–AA65

Highly Erodible Land and Wetland Conservation

AGENCY: Office of the Secretary, USDA.

ACTION: Interim rule with request for comments.

SUMMARY: The U.S. Department of Agriculture (USDA) is issuing an interim rule for the Highly Erodible Land and Wetland Conservation Compliance provisions of the Food Security Act of 1985, as amended. This rulemaking clarifies how USDA delineates, determines, and certifies wetlands located on subject land in a manner sufficient for making determinations of ineligibility for certain USDA program benefits. USDA is seeking comments from the public about these clarifications that will be considered prior to issuing a final rule.

DATES: Effective December 7, 2018. Comments must be received February 5, 2019.

ADDRESSES: Comments should be submitted, identified by Docket Number NRCS–2018–0010, using any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail or hand-delivery:* Public Comments Processing, Attention: National Leader for Wetland and Highly Erodible Land Conservation, USDA, Natural Resources Conservation Service, 1400 Independence Avenue SW, Washington, DC 20250.

NRCS will post all comments on *http://www.regulations.gov.* In general, personal information provided with comments will be posted. If your comment includes your address, phone number, email, or other personal identifying information (PII), your comments, including PII, may be available to the public. You may ask in your comment that your PII be withheld from public view, but this cannot be guaranteed.

This rule also may be accessed, and comments submitted, via the internet.

FOR FURTHER INFORMATION CONTACT: For specific questions about this document, please contact Jason Outlaw at (202) 720–7838 or *Jason.outlaw@wdc.usda.gov.*

SUPPLEMENTARY INFORMATION:

Regulatory Certifications

Executive Order 12866

This rule is not a ''significant regulatory action'' under Executive Order 12866.

Regulatory Flexibility Act

The Regulatory Flexibility Act is not applicable to this rule because USDA is not required by 5 U.S.C. 533 or any other provisions of law to publish a notice of proposed rulemaking with respect to the subject matter of this rule.

Environmental Evaluation

It has been determined through an environmental assessment that the issuance of this interim final rule will not have a significant impact upon the human environment. Copies of the environmental assessment may be obtained by contacting Karen Fullen at (503) 273–2404 or *Karen.fullen@por.usda.gov.*

Executive Order 12372

Executive Order 12372, ''Intergovernmental Review of Federal Programs,'' requires consultation with State and local officials. The objectives of the Executive Order are to foster an intergovernmental partnership and a strengthened federalism, by relying on State and local processes for State and local government coordination and review of proposed Federal Financial assistance and direct Federal development. This program is not subject to Executive Order 12372, which requires consultation with State and local officials.

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule will not preempt State or local laws, regulations, or policies unless they present an irreconcilable conflict with this rule. Before any judicial action may be brought regarding the provisions of this rule, appeal provisions of 7 CFR parts 11, 614, and 780 must be exhausted.

Executive Order 13132

This rule has been reviewed under Executive Order 13132, ''Federalism.'' The policies contained in this rule do not have any substantial direct effect on 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, nor does this rule impose substantial direct compliance costs on State and local governments; therefore, consultation with the States is not required.

Executive Order 13175

This rule has been reviewed in accordance with Executive Order 13175, ''Consultation and Coordination with Indian Tribal Governments.'' Executive Order 13175 requires Federal agencies to consult and coordinate with Tribes on a government-to-government basis on policies that have Tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

USDA has assessed the impact of this rule on Indian Tribes and determined that this rule does not, to our knowledge, have Tribal implications that require Tribal consultation under Executive Order 13175. If a Tribe requests consultation, the Natural Resources Conservation Service (NRCS) will work with the USDA Office of Tribal Relations to ensure meaningful consultation is provided.

Unfunded Mandates Reform Act of 1995

Pursuant to Title II of the unfunded Mandates Reform Act of 1995, Public Law 104–4, the effects of this rulemaking action on State, local, and Tribal governments, and the public have been assessed. This action does not compel the expenditure of $100 million or more by any State, local, or Tribal governments, or anyone in the private sector; therefore, a statement under Section 202 of the Unfunded Mandates Reform Act of 1995 is not required.

Federal Assistance Programs

This rule has a potential impact on participants for many programs listed in the Catalog of Federal Domestic Assistance in the Agency Program Index under the Department of Agriculture.

Paperwork Reduction Act

Section 1246 of the Food Security Act of 1985 provides that regulations issued under Title XII are exempt from the requirements of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

E-Government Act Compliance

USDA 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.

Discussion of Provisions

Title XII of the Food Security Act of 1985, as amended (the 1985 Act), encourages participants in USDA programs to adopt land management measures by linking eligibility for USDA program benefits to farming practices on highly erodible land and wetlands. In particular, the highly erodible land conservation (HELC) provisions of the 1985 Act provide that after December 23, 1985, a program participant is ineligible for certain USDA program benefits for the production of an agricultural commodity on a field in which highly erodible land is predominant. Additionally, the wetland conservation (WC) provisions of the 1985 Act provide that after December 23, 1985, a program participant is ineligible for certain USDA program benefits for the production of an agricultural commodity on a converted wetland, or after November 28, 1990, for the conversion of a wetland that makes the production of an agriculture commodity possible. The Agricultural Act of 2014 amended the 1985 Act to expand the HELC/WC requirements to encompass crop insurance benefits, and thus, producers obtaining Federally reinsured crop insurance must be in compliance with an NRCS-approved conservation plan for all highly erodible land; not plant or produce an agricultural commodity on a wetland converted after February 7, 2014; and not have converted a wetland after February 7, 2014, to make possible the production of an agricultural commodity. The 1985 Act, however, affords relief to program participants who meet certain conditions identified under the 1985 Act by exempting such actions from the ineligibility provisions.

The USDA regulations implementing the HELC and WC provisions of the 1985 Act are found at 7 CFR part 12. The regulations at 7 CFR part 12 list actions that may result in a determination of ineligibility, the program benefits that are at risk, and the conditions under which these activities can occur without losing program eligibility. The regulations are divided into three subparts. Subpart A describes the terms of ineligibility, USDA programs encompassed by its terms, the list of exemptions from ineligibility, the agency responsibilities, and conditions that apply when persons adversely affected by an agency determination request an appeal. Subpart B describes in greater detail the technical aspects of the HELC provisions, including the technical criteria for identification of highly erodible lands, criteria for highly erodible field determinations, and requirements for the development of conservation plans and conservation systems. Subpart C describes in greater detail the technical aspects of the WC provisions, including the criteria for determining a wetland, the criteria for determining a converted wetland, and the uses of wetlands and converted wetlands that can be made without losing program eligibility.

USDA policy guidance regarding implementation of the HELC and WC provisions is found in the current edition of the NRCS National Food Security Act Manual (NFSAM), including the procedures for how to delineate wetlands and make wetland determinations in accordance with Subpart C of 7 CFR part 12. This rule provides transparency to USDA program participants and stakeholders concerning how USDA delineates, determines, and certifies wetlands. It also allows program participants to better understand whether their actions may result in ineligibility for USDA program benefits. USDA requests public comment and will consider incorporating such public comment into its policy guidance.

Wetland Determination Criteria—Policy and Regulatory Clarifications

The Complexity of Identification of Wetlands in the Agricultural Landscape

The complexity of making a wetland determination in highly altered agricultural landscapes requires flexibility in the approach used to identify wetlands. Since 1986, USDA has provided the internal agency policy on making HELC and WC determinations in the NFSAM. In response to multiple statutory changes and changes to the science, those methods have evolved over the decades since passage of the WC provisions. The regulations and internal agency policy have also been revised many times over this 33-year period. The purpose of this interim rule, with request for comment, is to codify many technical portions of the existing agency policy that have not undergone public review and comment.

Overview of Wetland Determination Procedures

USDA developed the wetland determination procedures from the statutory framework for the WC provisions. In particular, section 1201(a) of the 1985 Act defines ''wetland'' as follows:

(27) The term ''wetland'', except when such term is part of the term ''converted wetland'', means land that—

(A) has a predominance of hydric soils;

(B) is inundated or saturated by surface or groundwater at a frequency and duration sufficient to support a prevalence of hydrophytic vegetation typically adapted for life in saturated soil conditions; and

(C) under normal circumstances does support a prevalence of such vegetation. For purposes of this Act, and any other Act, this term shall not include lands in Alaska identified as having high potential for agricultural development which have a predominance of permafrost soils.

Section 1201(b) of the 1985 Act requires the Secretary to develop ''(1) criteria for the identification of hydric soils and hydrophytic vegetation; and (2) lists of such soils and such vegetation.''

USDA then defined in the regulation that a wetland determination is ''a decision regarding whether or not an area is a wetland, including identification of wetland type and size.'' Thus, the term wetland determination for the WC provisions includes a basic three-step process: (1) Wetland identification; (2) application of exemption criteria from § 12.5(b) of this part, to determine the appropriate wetland conservation label; and (3) determination of size of each area delineated on the certified wetland determination map.

Step One—Wetland Identification. During the first step of wetland identification, NRCS determines whether the site meets the 1985 Act's definition of wetland ''under normal circumstances.'' Normal circumstances are those conditions (vegetation, soils, and hydrology) that would occur in the absence of any post-1985 drainage actions, without regard to whether the vegetation has been removed or significantly altered, and during the wet portion of the growing season under normal climatic conditions.

NRCS staff utilize four different sources of information when deciding whether an area would, under normal circumstances, meet the 1985 Act definition of wetland, including 7 CFR part 12, the 1987 Corps of Engineers Wetland Delineation Manual (Corps Manual), the regional supplements to the Corps Manual, and the Food Security Act Wetland Identification Procedures (FSA Procedures) located in the NFSAM, Part 514. The FSA Procedures are not stand-alone procedures, but rather, they supplement the Corps methods when identifying wetlands for Food Security Act purposes. The Corps Manual provides for three levels:

- A *Level 1* determination is the use of only off-site resources to confirm the presence or absence of a prevalence of hydrophytic vegetation, a predominance of hydric soil, and the occurrence of wetland hydrology. Each of the three factors is assessed independently of the others. In some States, NRCS augments the Corps Level 1 methods with State Off-Site Methods (SOSM), tailored to unique wetland identification challenges in the State. SOSM identify additional off-site indicators and processes that can be used to assist in the determinations of hydrophytic vegetation, hydric soils, and wetland hydrology.
- A *Level 2* determination is based on the use of on-site methods from the Corps Manual and field indicators from the regional supplements for each of the three factors. As appropriate, the FSA Procedures augment the Corps methods. If a Level 2 approach is used, SOSM would not be used since SOSM are designed to augment off-site methods.
- A *Level 3* determination is a combination of the use of on-site and off-site indicators or methods among the three factors, but not within a single factor. For example, a Level 3 determination might utilize off-site methods or indicators for soils, then utilize on-site methods and indicators for vegetation and hydrology. If applicable, SOSM would be limited to the factor(s) where a decision is made exclusively from off-site methods/resources, so in this example, SOSM would be used for soils, but not for vegetation or hydrology.

The findings in Step 1 results are recorded on a wetland identification base map indicating the area(s) in question as either wetland or non-wetland as defined in the 1985 Act.

Step 2—Determination of Food Security Act Exemptions/Labels. In this step, NRCS utilizes the wetland/non-wetland base map produced from Step 1 to assign WC labels. WC labels are based on exemptions to the WC provisions, as provided in § 12.5(b) of this part.

Step 3—Sizing of Wetlands. The last step is to determine the size of each area delineated and assigned a WC label. The delineations, WC labels, and sizes of each delineation are documented on the certified wetland determination map provided to the program participant.

Determining Normal Precipitation

In Step 1 (wetland identification) of the wetland determination process, NRCS applies the FSA Procedures to determine if a site ''under normal circumstances'' meets the 1985 Act wetland definition. ''*Normal circumstances*'' as used in the statutory wetland definition is not defined in § 12.2 (Definitions) of this part but is discussed in § 12.31(b) only as it relates to a determination of hydrophytic vegetation. In the FSA Procedures, the term is defined as it relates to the entire wetland identification process. The consideration of normal circumstances includes assessing how disturbance (*e.g.,* tillage, mowing, grazing, application of herbicides, and drainage) might alter the site conditions, and how climate (*e.g.,* dry season, wet season, snow pack, drought, and excessive precipitation) might alter the site conditions. NRCS policy requires the consideration of normal circumstances for each of the three wetland diagnostic factors.

To determine normal circumstances, NRCS is required to determine if the indicators (on-site or off-site) are reflective of normal climatic conditions. NRCS is identifying in part 12 the criteria that NRCS commonly uses to determine normal climatic conditions.

The NRCS National Water and Climate Center compiles precipitation data using information from National Oceanic and Atmospheric Administration weather stations and publishes normal precipitation data that encompass 30 years of weather data. NRCS uses this weather data in Chapter 19 of the NRCS National Engineering Field Handbook Climate Analysis for Wetlands Tables (WETS). The tables can be updated to encompass the most recent 30-year cycle of data and are available in the Field Office Technical Guide.

The agency is concerned that the forward adjustment of precipitation data will result in unfair and inconsistent determinations and will fail to best represent conditions in or prior to 1985, a critical decision common to many exemptions. To address this concern, NRCS is establishing a fixed precipitation data set. This data set will provide continued certainty to agricultural producers, and the 1985 date of enactment of the WC provisions falls near the mid-point of this data set.

Use of Corps Manual

NRCS utilizes parts of the 1987 Army Corps of Engineers Wetland Delineation Manual and approved regional supplements, subject to agency-defined variances required to implement the 1985 Act provisions. NRCS has received questions about the basis for its use of the 1987 Corps Manual.

In 1980, the Environmental Protection Agency (EPA) issued interim guidance for identifying wetlands under Section 404 of the Clean Water Act. In 1980 and

1982, the Army Corps of Engineers and EPA published a joint rule and provided their definition of a wetland as:

''Those areas that are inundated or saturated by surface or ground water at a frequency and duration sufficient to support, and that under normal circumstances do support, a prevalence of vegetation typically adapted for life in saturated soil conditions. Wetlands generally include swamps, marshes, bogs, and similar areas.'' (33 CFR Section 328.3)

This definition was used by the Corps and EPA as they developed and published the *Technical Report Y–87–1 Corps of Engineers Wetlands Delineation Manual* and *Wetland Identification and Delineation Manual* (EPA 1988 Manual).

In the 1985 Act, Congress defined wetlands subject to the WC provisions as:

land that has a predominance of hydric soils and that is inundated or saturated by surface or groundwater at a frequency and duration sufficient to support, and that under normal circumstances does support, a prevalence of hydrophytic vegetation typically adapted for life in saturated soil conditions.

In the *Urgent Supplemental Appropriation Act,* 1986, Congress added the following to the wetland definition:

this term shall not include lands in Alaska identified as having high potential for agricultural development which have a predominance of permafrost soils.

The 1985 Act definition represents the first time that Congress defined the term ''wetland.'' Also, for the first time in Federal law, Congress also provided a definition for the terms ''hydric soil'' and ''hydrophytic vegetation.'' These three congressional definitions in the 1985 Act only differ slightly from what is used by the Corps and EPA for Section 404 of the Clean Water Act. The Manager's Report to the 1990 Act acknowledges that NRCS used wetland delineation methodology that had been developed in consultation with other Federal and State agencies.

Since the WC provisions contain specific definitions, exemptions, and guidance for its implementation, where these provisions differ from those in the Corps Manual, NRCS identifies these differences in the FSA procedures. Thus, NRCS adopted the use of the Corps methods, but not in their entirety. Where needed to address differences in the two laws, and where needed to address unique challenges of delineating wetlands on agricultural lands, NRCS provides variances to the Corps methods.

To avoid confusion, NRCS clearly informs the program participant that the determinations are for purposes of the WC provisions only, and that the producer should contact the Army Corps of Engineers for clarification about whether a particular activity will require a Clean Water Act Section 404 permit.

Definition of Pothole, Playa, and Pocosin

Current language in 7 CFR part 12 distinguishes farmed wetland hydrology criteria on whether the area is a pothole, playa, or pocosin. These three landforms are not defined in the regulation. Since it is a critical determination about the scope of the restrictions to which a producer will be subject, there is a need for a regulatory definition to provide consistency in the determination of the presence of these special land forms. NRCS has longstanding definitions in policy, located in the appendix to the NFSAM; however, the appendix was not transferred to the current electronic policy document storage system. NRCS is amending § 12.2 to add these definitions to the WC regulation.

Hydrology Criteria for Farmed Wetland, Farmed Wetland Pasture, and Prior Converted Cropland

The prior hydrologic criteria for farmed wetland and farmed wetland pasture was based strictly on the quantification of the number of days that the wetland experienced inundation or saturation during the growing season. Further, for farmed wetland, these criteria differed depending on the landscape position of the wetland, with playa, pothole, and pocosin requiring 7 days of inundation or 14 of saturation, and all other landscape positions requiring 15 consecutive days of inundation.

Quantification of a number-based hydrologic criteria is both inefficient and cost prohibitive, and if practiced, requires the installation of monitoring equipment. For this reason, other Federal agencies with responsibilities for wetland conservation or regulation either did not adopt or have since abandoned such an approach in favor of one that uses more readily observable and easily quantifiable criteria. The agency has itself moved from a number-based approach to such an approach, with criteria that are based on observable conditions resulting from such inundation or saturation and is therefore more consistent with the agency's statutory definition of ''wetland.'' Codifying this indicator-based approach as the current science and approach by NRCS to make a decision on wetland hydrology will improve transparency and understanding by program participants and the general public.

Best Drained Condition

The term ''best drained condition'' is introduced and defined to provide clarity regarding a long-standing and practiced statutory concept that is fundamental to the identification of wetlands that experienced drainage manipulations prior to enactment of the 1985 Act, and to meet congressional intent to provide certainty to persons concerning the status of such land and its future use. This long-standing concept provides that a person has the statutory right to maintain hydrologic conditions on wetlands that were converted to crop production prior to the 1985 Act, and are not abandoned, to the extent that those conditions existed on or before December 23, 1985.

Wetland Hydrology

The definition of wetland requires the presence of hydrology sufficient to support a prevalence of hydrophytic vegetation. Hydrology, as it relates to the definition of ''wetland'' contained in § 12.2, is further referenced throughout part 12 as a diagnostic factor for which consideration is required during the identification of wetlands. To provide clarification concerning this requirement, the definition of wetland hydrology and its related identification procedures are being incorporated into part 12, with associated reference to the underlying considerations of ''best drained condition'' and the determination of normal climatic conditions in § 12.31.

Tract Versus Field

Wetland determinations can be conducted on different areas of an agricultural operation. In some cases, the wetland determinations are conducted on a farm tract, while in other instances only specific farm fields or areas within a field are assessed. The USDA program participant initiates the wetland determination with a request submitted to the Farm Service Agency on an AD–1026. If an activity that could potentially result in a determination of ineligibility is planned, the program participant identifies the location of the activity on a map. NRCS will conduct wetland determinations on a field or sub-field basis except when the producer requests a determination for their entire farm tract. To clarify that NRCS will conduct a wetland determination only on the area specified by the USDA program participant,

NRCS is replacing the term ''tract'' with the term ''field or sub-field'' in 7 CFR 12.30(c), so that it is clear that all wetland determinations will be done on a field or sub-field basis and will be considered certified wetland determinations.

Wetland Minimal Effect Determinations

Part 12 provides for a minimal effect exemption for wetland conversions that have only a minimal effect on the functional hydrological and biological value of the wetland and other wetlands in the area. Current regulatory language requires that the minimal effect determination be based upon a functional assessment made during an on-site evaluation of all wetlands in the area. This requirement is overly burdensome, and on-site evaluations can seldom be made on property not controlled by the subject person. Removing the on-site requirement will better allow USDA to provide this statutory exemption to USDA program participants, and such removal will not provide a substantially different decision as would otherwise occur, especially considering that assessments can be conducted remotely based on a general knowledge of wetland conditions in the area.

Wetland Determination Certification

NRCS began making wetland determinations subsequent to the enactment of the 1985 Act and the interim final rule for 7 CFR part 12 promulgated in 1986. These wetland determinations were completed utilizing soil surveys, U.S. Fish and Wildlife Service National Wetland Inventory maps, and USDA aerial imagery or site visits. Producers were provided appeal rights with these determinations. In the 1990 Farm Bill, the concept of certification of wetland determinations was incorporated into the WC provisions. In particular, as described in the Manager's Report to the 1990 Farm Bill:

> [T]he certification process is to provide farmers with certainty as to which of their lands are to be considered wetlands for purposes of Swampbuster. The Managers note that the current USDA wetland delineation process involves the use of substantial materials to make an initial determination in the field office, developed in consultation with other appropriate Federal and State agencies. Wetlands identified in this process are delineated on maps which are then mailed to producers for review. If the producer finds such map to be in error, and the USDA agrees that an error has been made, then the map is corrected. If the USDA does not agree that there is an error in the map, and the producer continues to believe so, then the producer may appeal such determination. The Managers find that this process is adequate for certification of any new maps delineated after the date of enactment of this Act. For maps completed prior to the date of enactment of this Act, the Managers intend for producers to be notified that their maps are to be certified and that they have some appropriate time for appeal. In this circumstance, producers who had not already been mailed their maps should be given a map for their review.

The changes made to 7 CFR part 12 in 1991 included the following incorporation of certification at § 12.30(c) (1991):

> SCS determinations of wetland status and any applicable exemptions granted under this part shall be delineated on a map of the farm or tract. Notification of the wetland determination, a copy of the wetland delineation and the SCS appeal procedures shall be provided to each person who completes a Form AD–1026. The wetland determination and wetland delineation shall be certified as final by the SCS official 45 days after providing the person notice or, if appeal is filed with SCS, after a final appeal decision is made by SCS.

By statute, as clarified in the 1990 Conference Managers Report, determinations made pursuant to the 1991 rule are certified determinations when the producer was provided a copy of the determination and had been provided appeal rights. The producer was not required to appeal the determination for the determination to become certified. In June of 1991, USDA issued a revised CPA–026 form that included certification language in the agency signature block and contained the applicable appeal rights on the back side of the person copy.

The certification provisions were further strengthened in the 1996 Farm Bill, due in part to a moratorium that had been placed on wetland determinations by the Secretary of Agriculture in 1995. In response to these changes, in the 1996 interim final rule USDA identified that all wetland determinations made after its effective date of July 3, 1996, would be considered a certified wetland determination. A final certification remains valid and in effect as long as the area is devoted to an agricultural use or until such time as the person, affected by the review, requests review of the certification if ''a natural event alters the topography or hydrology of the subject land to the extent that the final certification is no longer a reliable indication of site conditions, or if NRCS concurs with an affected person that an error exists in the current wetland determination.'' 7 CFR 12.30(c)(6).

NRCS, program participants, farm organizations, conservation organizations, and others have long focused upon the certification process for NRCS wetland determinations because of the certainty that such determinations provide to program participants regarding future business decisions. Through this rulemaking, USDA is adding further guidance in the WC regulation to improve clarity on the statutory concept of certification, particularly for those certified determinations issued between 1990 and 1996.

List of Subjects in 7 CFR Part 12

Administrative practice and procedure, Coastal zone, Crop insurance, Flood plains, Loan programs—agriculture, Price support programs, Reporting and recordkeeping requirements, Soil conservation.

For the reasons explained above, USDA amends 7 CFR part 12 as follows:

PART 12—HIGHLY ERODIBLE LAND CONSERVATION AND WETLAND CONSERVATION

■ 1. The authority citation for part 12 continues to read as follows:

Authority: 16 U.S.C. 3801, 3811–12, 3812a, 3813–3814, and 3821–3824.

■ 2. Amend § 12.2(a) as follows:

■ a. Add definitions, for ''Best drained condition'', ''Normal climatic conditions'', ''Playa'', ''Pocosin'', and ''Pothole'', in alphabetical order;

■ b. Revise paragraphs (4), (5), and (8) of the definition for ''Wetland determination''; and

■ c. Add the definition of ''Wetland hydrology'', in alphabetic order.

The additions and revision read as follows:

§ 12.2 Definitions.

(a) * * *

Best drained condition means the hydrologic conditions with respect to depth, duration, frequency, and timing of soil saturation or inundation resulting from drainage manipulations that occurred prior to December 23, 1985, and that exist during the wet portion of the growing season during normal climatic conditions.

* * * * *

Normal climatic conditions means the normal range of hydrologic inputs on a site as determined by the bounds provided in the Climate Analysis for Wetlands Tables or methods posted in the Field Office Technical Guide.

* * * * *

Playa means a usually dry and nearly level lake plain that occupies the lowest parts of closed depressions (basins). Temporary inundation occurs primarily in response to precipitation-runoff

events. Playas may or may not be characterized by high water table and saline conditions. They occur primarily in the Southern Great Plains.

Pocosin means a wet area on nearly level interstream divides in the Atlantic Coastal Plain. Soils are generally organic but may include some areas of high organic mineral soils.

Pothole means a closed depression, generally circular, elliptical, or linear in shape, occurring in glacial outwash plains, moraines, till plains, and glacial lake plains.

* * * * *

Wetland determination * * *

(4) *Farmed wetland* is a wetland that prior to December 23, 1985, was manipulated and used to produce an agricultural commodity, and on December 23, 1985, did not support woody vegetation, and met the following hydrologic criteria:

(i) If not a playa, pocosin, or pothole, experienced inundation for 15 consecutive days or more during the growing season or 10 percent of the growing season, whichever is less, in most years (50 percent chance or more), as determined by having met any of the following hydrologic indicators:

(A) Inundation is directly observed during a site visit conducted under a period of normal climatic conditions or drier;

(B) The presence of any indicator from Group B (Evidence of Recent Inundation) of the wetland hydrology indicators contained in the applicable regional supplement to the Corps of Engineers Wetland Delineation Manual is observed;

(C) The presence of conditions resulting from inundation during the growing season is observed on aerial imagery, and the imagery is determined to represent normal or drier than normal climatic conditions (that is, not abnormally wet); or

(D) The use of analytic techniques, such as the use of drainage equations or the evaluation of monitoring data, demonstrate that the wetland would experience inundation during the growing season in most years (50-percent chance or more).

(ii) If a playa, pocosin, or pothole experienced ponding for 7 or more consecutive days during the growing season in most years (50-percent chance of more) or saturation for 14 or more consecutive days during the growing season in most years (50-percent chance or more) as determined by having met any of the following hydrologic indicators:

(A) Inundation or saturation is directly observed during a site visit conducted under a period of normal climatic conditions or drier;

(B) The presence of one primary or two secondary wetland hydrology indicators contained in the applicable regional supplement to the Corps of Engineers Wetland Delineation Manual is observed;

(C) The presence of conditions resulting from inundation or saturation during the growing season is observed on aerial imagery, and the imagery is determined to represent hydrologic conditions that would be expected to occur under normal or drier than normal climatic conditions (that is, not abnormally wet); or

(D) The use of analytic techniques, such as the use of drainage equations or the evaluation of monitoring data, demonstrate that the wetland would experience inundation or saturation during the growing season in most years (50-percent chance or more).

(5) *Farmed-wetland pasture* is wetland that was manipulated and managed for pasture or hayland prior to December 23, 1985, and on December 23, 1985, experienced inundation or ponding for 7 or more consecutive days during the growing season in most years (50-percent chance or more) or saturation for 14 or more consecutive days during the growing season in most years (50-percent chance or more) as determined by having met any of the following hydrologic indicators:

(i) Inundation or saturation is directly observed during a site visit conducted under a period of normal climatic conditions or drier;

(ii) The presence of one primary or two secondary wetland hydrology indicators contained in the applicable regional supplement to the Corps of Engineers Wetland Delineation Manual is observed;

(iii) The presence of conditions resulting from inundation or saturation during the growing season is observed on aerial imagery, and the imagery is determined to represent hydrologic conditions that would be expected to occur under normal, or drier than normal climatic conditions (that is, not abnormally wet); or

(iv) The use of analytic techniques, such as the use of drainage equations or the evaluation of monitoring data, demonstrate that the wetland would experience inundation or saturation during the growing season in most years (50-percent chance or more).

* * * * *

(8) *Prior-converted cropland* is a converted wetland where the conversion occurred prior to December 23, 1985, an agricultural commodity had been produced at least once before December 23, 1985, and as of December 23, 1985, the converted wetland did not support woody vegetation and did not meet the hydrologic criteria for farmed wetland.

* * * * *

Wetland hydrology means inundation or saturation by surface or groundwater during a growing season at a frequency and duration sufficient to support a prevalence of hydrophytic vegetation.

* * * * *

■ 3. Amend § 12.21 by revising paragraph (c) to read as follows:

§ 12.21 Identification of highly erodible lands criteria.

* * * * *

(c) *Potentially highly erodible.* Whenever a soil map unit description contains a range of a slope length and steepness characteristics that produce a range of LS values that result in RKLS/T quotients both above and below 8, the soil map unit will be entered on the list of highly erodible soil map units as ''potentially highly erodible.'' The final determination of erodibility for an individual field containing these soil map unit delineations will be made by an on-site investigation, or by use of Light Detection and Ranging or other elevation data of an adequate resolution to make slope length and steepness measurements. In any case where a person disagrees with an off-site determination on potentially highly erodible soils, a determination will be made on-site.

■ 4. Amend § 12.30 by revising paragraph (c)(1), and adding paragraph (c)(7), to read as follows:

§ 12.30 NRCS responsibilities regarding wetlands.

(c) * * *

(1) Certification of a wetland determination means that the wetland determination is of sufficient quality to make a determination of ineligibility for program benefits under § 12.4. In order for a map to be of sufficient quality to determine ineligibility for program benefits, the map document must be legible to the extent that areas that are determined wetland can be discerned in relation to other ground features. NRCS may certify a wetland determination without making a field investigation. NRCS will notify the person affected by the certification and provide an opportunity to appeal the certification prior to the certification becoming final. All wetland determinations made after July 3, 1996, will be done on a field or sub-field basis and will be considered certified wetland determinations.

Determinations made after November 28, 1990, and before July 3, 1996, are considered certified if the determination was issued on the June 1991 version of form NRCS–CPA–026 or SCS–CPA–026, the person was notified that the determination had been certified, and the map document was of sufficient quality to determine ineligibility for program benefits. If issued on a different version of the form, a determination will be considered certified if there is other documentation that the person was notified of the certification, provided appeal rights, and the map document was of sufficient quality to make the determination.

* * * * *

(7) The wetland determination process for wetland conservation compliance includes three distinct steps. In Step 1, wetland identification, it is determined if the area of interest supports a prevalence of hydrophytic vegetation, a predominance of hydric soils, and wetland hydrology under normal circumstances. In Step 2, determination of wetland type, it is determined if any exemptions apply from § 12.5(b). The findings are reflected in the assignment of an appropriate wetland conservation compliance label. In Step 3, sizing of the wetland, the boundary of each wetland type determined in Step 2 is delineated on the certified wetland determination map.

■ 5. Amend § 12.31 by revising the section heading, redesignating paragraphs (c) through (e) as paragraphs (d) through (f), adding a new paragraph (c), and revising newly redesignated paragraph (e) to read as follows:

§ 12.31 Wetland identification procedures.

(c) *Wetland Hydrology.* (1) Wetland Hydrology consists of inundation or saturation by surface or groundwater during a growing season at a frequency and duration sufficient to support a prevalence of hydrophytic vegetation.

(2) When a wetland is affected by drainage manipulations that occurred prior to December 23, 1985, wetland hydrology shall be identified on the basis of the best-drained condition resulting from such drainage manipulations.

(3) The determination of wetland hydrology will be made in accordance with the current Federal wetland delineation methodology in use by NRCS at the time of the determination.

(4) When making a decision on wetland hydrology, NRCS will utilize a fixed precipitation date range of 1971–2000 for determining normal climatic conditions.

* * * * *

(e)(1) *Minimal effect determination.* For the purposes of § 12.5(b)(1)(v), NRCS shall determine whether the effect of any action of a person associated with the conversion of a wetland, the conversion of wetland and the production of an agricultural commodity on converted wetland, or the combined effect of the production of an agricultural commodity on a wetland converted by someone else has a minimal effect on the functions and values of wetlands in the area. Such determination shall be based upon a functional assessment of functions and values of the subject wetland and other related wetlands in the area. The assessment of functions and values of the subject wetland will be made through an on-site evaluation. Such an assessment of related wetlands in the area may be made based on a general knowledge of wetland conditions in the area. A request for such determination will be made prior to the beginning of activities that would convert the wetland. If a person has converted a wetland and then seeks a determination that the effect of such conversion on wetland was minimal, the burden will be upon the person to demonstrate to the satisfaction of NRCS that the effect was minimal.

(2) *Scope of minimal-effect determination.* The production of an agricultural commodity on any portion of a converted wetland in conformance with a minimal-effect determination by NRCS is exempt under § 12.5(b)(1)(v). However, any additional action of a person that will change the functions and values of a wetland for which a minimal-effect determination has been made shall be reported to NRCS for a determination of whether the effect continues to be minimal. The loss of a minimal-effect determination will cause a person who produces an agricultural commodity on the converted wetland after such change in status to be ineligible, under § 12.4, for certain program benefits. In situations where the wetland values, acreage, and functions are replaced by the restoration, enhancement, or creation of a wetland in accordance with a mitigation plan approved by NRCS, the exemption provided by the determination will be effective after NRCS determines that all practices in a mitigation plan are being implemented.

Dated: November 28, 2018.

Stephen L. Censky,

Deputy Secretary.

[FR Doc. 2018–26521 Filed 12–6–18; 8:45 am]

BILLING CODE 3410–16–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 317 and 381

[Docket No. FSIS–2018–0049]

RIN 0583–AD77

Uniform Compliance Date for Food Labeling Regulations

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is establishing January 1, 2022, as the uniform compliance date for new meat and poultry product labeling regulations that will be issued between January 1, 2019, and December 31, 2020. FSIS periodically announces uniform compliance dates for new meat and poultry product labeling regulations to minimize the economic impact of label changes.

DATES: This rule is effective December 7, 2018. Comments on this final rule must be received on or before January 7, 2019.

ADDRESSES: FSIS invites interested persons to submit comments on this final rule. Comments may be submitted by one of the following methods:

- *Federal eRulemaking Portal:* This website provides the ability to type short comments directly into the comment field on this web page or attach a file for lengthier comments. Go to *http://www.regulations.gov.* Follow the on-line instructions at that site for submitting comments.
- *Mail, including CD–ROMs, etc.:* Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Room 6065, Washington, DC 20250–3700.
- *Hand- or courier-delivered submittals:* Deliver to 1400 Independence Avenue SW, Room 6065, Washington, DC 20250–3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS–2018–0049. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to *http://www.regulations.gov.*

Docket: For access to background documents or comments received, call (202)720–5627 to schedule a time to visit the FSIS Docket Room at 1400 Independence Avenue SW, Room 6065, Washington, DC 20250–3700.

FOR FURTHER INFORMATION CONTACT: Rosalyn Murphy-Jenkins, Director, Labeling and Program Delivery Staff, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture, Telephone: 301–504–0879.

SUPPLEMENTARY INFORMATION:

Background

On December 14, 2004, FSIS issued a final rule establishing January 1, 2008, as the uniform compliance date for new meat and poultry labeling regulations issued between January 1, 2005, and December 31, 2006. The 2004 final rule also provided that the Agency would set uniform compliance dates for new labeling regulations in 2-year increments and periodically issue final rules announcing those dates. Consistent with the 2004 final rule, the Agency has since published six rules establishing the uniform compliance dates of January 1, 2010, January 1, 2012, January 1, 2014, January 1, 2016, January 1, 2018, and January 1, 2020 (72 FR 9651, 73 FR 75564, 75 FR 71344, 77 FR 76824, 79 FR 71007 and 81 FR 91670).

The Final Rule

The new uniform compliance date will apply only to final FSIS regulations that require changes in the labeling of meat and poultry products and that are published after January 1, 2019, and before December 31, 2020. For each final rule that requires changes in labeling, FSIS will specifically identify January 1, 2022, as the compliance date. All meat and poultry food products that are subject to labeling regulations issued between January 1, 2019, and December 31, 2020, will be required to comply with these regulations on products introduced into commerce on or after January 1, 2022. If any food labeling regulation involves special circumstances that justify a compliance date other than January 1, 2022, the Agency will determine an appropriate compliance date and will publish that compliance date in the rulemaking.

Two-year increments increase industry's ability to make orderly adjustments to new labeling requirements without exposing consumers to outdated labels. This approach allows meat and poultry producers to plan for the use of label inventories and to develop new labeling materials that meet the new requirements. It also serves to reduce the economic impact of changing labels on both producers and consumers.

In the May 4, 2004, proposed rule on uniform compliance dates for labeling requirements, FSIS provided notice and solicited comment (69 FR 24539). In the March 5, 2007, final rule, FSIS received only four comments in response to the proposal, all in support. In the March 5, 2007, final rule, FSIS determined that further rulemaking for uniform compliance dates for labeling requirements is unnecessary (72 FR 9651). The Agency received no comments on the 2007 final rule, the comments FSIS received on the 2012 final rule were outside the scope (77 FR 76824), and FSIS received no comments on the 2014 final rule (79 FR 71007) or the 2016 final rule (81 FR 91670). Consistent with its statement in 2007, FSIS finds that further rulemaking on this matter is unnecessary. However, FSIS is providing an opportunity for comment on the uniform compliance date established in this final rule.

Executive Orders 12866 and 13563, and the Regulatory Flexibility Act

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 benefits, distributive impacts, and equity). Executive Order (E.O.) 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule has been designated as a ''non-significant'' regulatory action under section 3(f) of E.O. 12866. Accordingly, the final rule has not been reviewed by the Office of Management and Budget under E.O. 12866.

This rule does not have a significant economic impact on a substantial number of small entities; consequently, a regulatory flexibility analysis is not required (5 U.S.C. 601–612).

Additional Public Information

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication online through the FSIS web page located at: *http://www.fsis.usda.gov/federal-register.*

FSIS also will make copies of this publication available through the FSIS *Constituent Update,* which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The *Constituent Update* is available on the FSIS web page. Through the web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service, which provides automatic and customized access to selected food safety news and information. This service is available at: *http://www.fsis.usda.gov/subscribe.* Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

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Done at Washington, DC.

Paul Kiecker,

Acting Administrator.

[FR Doc. 2018–26526 Filed 12–6–18; 8:45 am]

BILLING CODE 3410–DM–P

FEDERAL HOUSING FINANCE AGENCY

12 CFR Part 1271

RIN 2590–AA99

Miscellaneous Federal Home Loan Bank Operations and Authorities—Financing Corporation Assessments

AGENCY: Federal Housing Finance Agency.

ACTION: Final rule.

SUMMARY: The Federal Housing Finance Agency (FHFA) is adopting a final rule pertaining to the operation of the Financing Corporation (FICO), a vehicle established by one of FHFA's predecessors to issue bonds, the proceeds of which were used to help fund the resolution of failed savings and loan associations during the 1980s. The last of those FICO bonds will mature in September 2019. By statute, FICO obtains the monies to pay the interest on those bonds by assessing depository institutions (FICO assessments) that are insured by the Federal Deposit Insurance Corporation (FDIC). The final rule addresses the manner in which FICO will conduct the 2019 FICO assessments, which will be the last of those assessments. Specifically, the final rule provides that all payments made by FDIC-insured depository institutions during 2019 are final, and that no adjustments to prior FICO assessments will be permitted after March 26, 2019, the projected date as of which the FDIC will finalize the amounts of the final collection for the 2019 FICO assessments.

DATES: The rule is effective on January 7, 2019.

FOR FURTHER INFORMATION CONTACT: Louis M. Scalza, Associate Director, Examinations, Office of Safety & Soundness Examinations, *Louis.Scalza@fhfa.gov,* (202) 649–3710; Winston Sale, Assistant General Counsel, *Winston.Sale@fhfa.gov,* (202) 649–3081; or Neil R. Crowley, Deputy General Counsel, *Neil.Crowley@fhfa.gov,* (202) 649–3055 (these are not toll-free numbers), Federal Housing Finance Agency, 400 Seventh Street SW, Washington, DC 20219. The telephone number for the Telecommunications Device for the Hearing Impaired is (800) 877–8339.

SUPPLEMENTARY INFORMATION:

I. Background

FHFA is an independent agency of the federal government established to regulate and oversee the Federal National Mortgage Association, the Federal Home Loan Mortgage Corporation, the Federal Home Loan Banks (Banks), and the Bank System's Office of Finance.[1] FHFA also is responsible for overseeing FICO. The Competitive Equality Banking Act of 1987[2] amended the Federal Home Loan Bank Act (Bank Act) and authorized FHFA's predecessor to establish FICO, and authorizes the FHFA Director to select the two Bank presidents that serve on its directorate, to prescribe such regulations as are necessary to carry out the statutory provisions relating to FICO, and to oversee the dissolution of FICO.[3]

FICO is a mixed-ownership, tax-exempt government corporation, chartered in 1987 by the former Federal Home Loan Bank Board, one of FHFA's predecessor agencies, pursuant to the Federal Savings and Loan Insurance Corporation (FSLIC) Recapitalization Act of 1987, as amended (Recapitalization Act).[4] The Recapitalization Act's purpose was to recapitalize the FSLIC insurance fund, which had been significantly depleted by a wave of savings and loan (S&L) failures during the S&L crisis of the 1980s. FICO's mission was to provide funding for FSLIC (and later for the FSLIC Resolution Fund after FSLIC's insolvency and later abolishment by the Financial Institutions Reform, Recovery, and Enforcement Act of 1989 (FIRREA)) by selling bonds to the public. FICO's operations are managed by a directorate composed of the Director of the Office of Finance and two Bank presidents who rotate after serving one year terms.[5] FICO has no permanent staff and utilizes Office of Finance staff to execute its day-to-day functions.

FICO was initially capitalized by issuing stock to the Banks in an aggregate amount of $680 million, apportioned pro rata among the Banks in accordance with a statutory formula.[6] FICO used the proceeds from the stock issuances to purchase U.S. Treasury zero-coupon securities (Zeros), which were to be the sole source of repayment of the principal of the bonds to be issued by FICO. Between 1987 and 1989 FICO issued 14 separate series of 30-year bonds (Obligations) in an aggregate principal amount of approximately $8.2 billion. FICO conveyed the proceeds of the Obligations to FSLIC, to finance its resolution of failed S&Ls.[7] FICO is required by statute to hold the Zeros in a segregated account until they are used to pay the principal due on the Obligations at their maturity.[8] The Obligations began to mature in 2017, and the last Obligation will mature in September 2019.

The Recapitalization Act established a different source for providing the funds needed to service the semiannual interest payments on the FICO Obligations.[9] The statute initially authorized FICO to assess FSLIC-insured depository institutions for the funds needed to pay the interest due on the FICO Obligations.[10] The Deposit Insurance Funds Act of 1996 authorized FICO to assess against institutions with deposits insured by both the Bank Insurance Fund (BIF) and the Savings Association Insurance Fund (SAIF).[11] Pursuant to the Federal Deposit Insurance Reform Act of 2005, effective March 31, 2006, the BIF and SAIF were merged into the newly created Deposit Insurance Fund (DIF), and thus FICO may assess institutions insured by the DIF.[12] FICO is authorized to assess insured depository institutions only for three purposes: For making interest payments on the FICO Obligations; paying issuance costs for the FICO Obligations; and paying custodial fees associated with the FICO Obligations. The Bank Act, as amended by FIRREA, further provides that FICO is to conduct its assessments in the same manner that the FDIC uses when assessing its insured depository institutions for deposit insurance purposes.[13] FICO and the FDIC entered into a memorandum of understanding in 1997 (Memorandum of Understanding), as amended in 1999, pursuant to which the FDIC collects FICO's assessments from its insured

[1] 12 U.S.C. 4511.

[2] Public Law 100–86, 101 Stat. 552.

[3] *See* 12 U.S.C. 1441(a) (establishment of FICO), (b)(1)(B) (selection of directors), (i) (dissolution, and authority for FHFA to exercise any FICO powers, needed to conclude its affairs), and (j) (authority to prescribe regulations).

[4] *See* 12 U.S.C. 1441(a).

[5] *See* 12 U.S.C. 1441(b).

[6] *See* 12 U.S.C. 1441(d)(4). FICO issued the stock in a series of transactions between 1987 and 1989, each in anticipation of an issuance of a particular series of the FICO bonds.

[7] FICO used the net proceeds from the first 13 series of its Obligations to purchase nonredeemable capital certificates and nonredeemable nonvoting capital stock issued by the FSLIC. After the FSLIC was abolished in 1989, FICO used the proceeds from its final series of Obligations to purchase nonredeemable capital certificates issued by the FSLIC Resolution Fund, the statutory successor to the FSLIC. *See* 12 U.S.C. 1821a (establishment of FSLIC Resolution Fund). Those instruments have no value and have been charged to FICO's capital.

[8] *See* 12 U.S.C 1441(g)(2).

[9] Interest on each FICO Obligation is paid on the anniversary of its issuance date, and six months after that date each year.

[10] Public Law 100–86, sec, 302, 101 Stat. 552, 591–592.

[11] Public Law 104–208, sec. 2703, 110 Stat. 3009–479, 3009–485.

[12] Public Law 109–171, sec. 2102, 120 Stat. 9.

[13] 12 U.S.C. 1441(f)(2).

depository institutions quarterly, as agent for FICO.

The FDIC conducts its own Deposit Insurance Fund assessments quarterly (FDIC assessment), with the amount of the FDIC assessment for each insured depository institution being determined based, in part, on data that the institution has submitted to the Federal Financial Institutions Examination Council (FFIEC) in its Consolidated Reports of Condition and Income (call report). If an insured depository institution amends a call report on which a previous FDIC assessment had been calculated and the amendment to the call report would cause the calculation of the prior FDIC assessment to change, the institution may receive an adjustment, which generally appears on an upcoming invoice.[14]

Pursuant to the Memorandum of Understanding, the FDIC collects the FICO assessments from the insured depository institutions quarterly, as agent for FICO, at the same time as the collection of FDIC assessments. FICO assessments are made based on an assessment rate formula adopted by FICO, and approved by the FDIC Board of Directors. One factor in FICO's formula is the deposit insurance assessment base, which (as described above) is calculated using an insured depository institution's call report data. Under the terms of the Memorandum of Understanding, twice per year, FICO notifies the FDIC of the total amounts that would be needed for FICO to make its upcoming Obligation interest payments and annually informs the FDIC of the interest it has earned. Using that information and FICO's assessment rate formula, the FDIC calculates a ''quarterly multiplier'' and applies it to information derived from each institution's call report to determine the FICO assessment for each institution for that calendar quarter. The FDIC then issues an invoice to each insured depository institution detailing both its quarterly FDIC and FICO assessments.[15] Insured depository institutions submit payment for their FDIC and FICO assessments to the FDIC via Automated Clearing House (ACH). The FDIC then transfers the aggregate FICO collections to an account that FICO maintains at the Federal Reserve Bank of New York, from which FICO pays the interest that is due on the FICO Obligations.

In the case of an insured depository institution that amends its call report for a prior period, FICO assessments are adjusted in the same manner as FDIC assessments. Thus, if an amended call report results in an institution having overpaid or underpaid a prior quarter's FICO assessment an adjustment amount will appear on an upcoming invoice, provided that the amendment has been made within three years after the date that the associated FICO payment was due.[16] Pursuant to the Memorandum of Understanding, overpayments arising from amended call reports are generally credited against the next quarter's FICO assessment and underpayments are added to the next quarter's FICO assessment.

With respect to all such refunds for overpayments of prior period FICO assessments, however, FICO has no legal obligation to use its own assets to provide monies to any insured depository institutions to make those refunds and does not do so. Indeed, FICO has no legal authority to assess insured depository institutions for the sole purpose of obtaining monies to provide refunds to other insured depository institutions or to spend its own non-assessment assets for that purpose. As a practical matter, because these refunds are processed as credits against the next FICO assessment, they do not require any cash outlay from FICO and all refunds are effectively paid from the assessments on the other insured depository institutions collectively. The principal effect of such refunds is that they modestly reduce the amount of monies actually collected by the FDIC, as agent for FICO, as part of a particular quarter's FICO assessment. Those refund credits, however, may be offset by the additional amounts that the FDIC collects, as an agent for FICO, from other institutions that had previously underpaid a prior FICO assessment.[17] To the extent overpayment credits exceed underpayment collections, such shortfall is made up the following quarter by increasing the total collection amount accordingly. Moreover, because the determination of the quarterly multiplier for setting the FICO assessment involves rounding, any quarterly collection of the FICO assessment may yield slightly more money than the initially projected assessment amount. Pursuant to the Memorandum of Understanding with the FDIC, FICO also maintains a cash reserve that is available to make up modest shortfalls that might arise during a quarterly collection. FICO has never needed to use the cash reserve, because it has always collected sufficient funds to make all required interest payments when due. FHFA anticipates that FICO will draw down the monies in its cash reserve to fund a portion of the remaining interest payments on its Obligations as they come due, which also would reduce the amount needed to be assessed and collected from insured depository institutions during 2019.

As is evident from the above description, the current practice for adjusting individual FICO assessments—to account for either refunds or additional collections—depends on the existence of a subsequent FICO collection that could serve as the source of funds and the means by which any such adjustments may be processed. The last of the FICO bonds will mature during 2019 and FICO is scheduled to make five different interest payments during 2019.[18] FHFA anticipates that the FDIC, as agent for FICO, will collect one FICO assessment during 2019 and that the amounts received by FICO from the March 2019 collection will be sufficient (when combined with any other available funds that FICO will have on hand) to make all remaining interest payments due during 2019. Accordingly, once the final FICO assessment has been collected, there will be no subsequent billing cycle through which an insured depository institution could have a prior FICO assessment adjusted, *i.e.,* the FDIC, which will cease to be collection agent for FICO, will no longer invoice institutions for FICO assessments that could be adjusted to reflect increases or decreases attributable to amendments to their prior period call reports. Because FICO assessments are collected in the same manner as FDIC assessments, the FDIC's billing practices, as agent for FICO, have long included the above-

[14] *See* 12 U.S.C. 1817(e)(1) (addressing refunds of overpayments of FDIC assessments).

[15] The FDIC provides to each institution a Quarterly Certified Statement Invoice that specifies the total amount of that quarter's assessment, including the FDIC assessment and the FICO assessment for that calendar quarter.

[16] *See* 12 U.S.C. 1817(g)(2) (establishing a three-year statute of limitations on actions by insured depository institutions to recover overpayments from FDIC, and on actions by FDIC to recover underpayments from the insured institutions).

[17] The number of call report amendments submitted during a particular calendar quarter that will affect a FICO assessment will vary, but is small in comparison to the number of insured depository institutions filing call reports with FDIC. Generally speaking, the dollar amounts of the gross FICO refunds and FICO additional collections for any calendar quarter are also small, and the net amounts of such adjustments during a particular quarter often are less than $100,000.

[18] Two interest payments, in the approximate amount of $28 million each, are due during March 2019, and FICO will collect monies needed to make those payments during the December 2018 collection. The remaining three interest payments, in the approximate amounts of $26 million each, are due during April, June, and September 2019, and FICO will collect monies needed to make those payments during the March 2019 collection.

described adjustment provision for the FICO assessments. Thus, FHFA has determined that it is appropriate, as FICO's regulator, to adopt a rule to make clear that such adjustments must cease after FICO has collected its final assessment from the insured depository institutions, and that FICO has no obligation to make any adjustments to prior FICO assessments.

This rulemaking pertains only to the FICO assessments, which the FDIC collects on behalf of FICO. It does not affect the deposit insurance assessments that the FDIC collects from insured depository institutions, which will continue in their normal manner. The sections below describe the history and content of the final rule.

II. The Proposed Rule

On September 26, 2018, FHFA published in the **Federal Register** a Notice of Proposed Rulemaking (proposed rule) to amend 12 CFR 1271.37 of the FHFA regulations, which governs the assessment and collection of monies from FDIC-insured institutions to pay interest on the FICO Obligations. The 30-day comment period for the proposed rule ended on October 26, 2018. FHFA received no comments on the substance of the proposed rule or on its discussion relating to the applicability of the Regulatory Flexibility Act. FHFA's interpretation of the facts and legal authorities governing FICO's assessments in view of its impending dissolution remain unchanged. Thus, this final rule adopts without change all of the regulatory additions set forth in the proposed rule.

III. The Final Rule

Content of the Final Rule. The final rule does four things. First, it provides that all FICO assessments collected during 2019 will be final, meaning that there will be no possibility of any subsequent adjustments to those assessment amounts. Second, it provides that after the collection of the final FICO assessment (which is expected to occur on March 29, 2019) no insured depository institution will be entitled to any adjustment of any prior FICO assessment that arises as a result of an amendment to the call report on which the prior assessment had been based. This recognizes the fact that adjustments to prior FICO assessments can only be made as part of the process of collecting a subsequent FICO assessment. Third, it preserves the existing adjustment practice through the final FICO assessment collection, *i.e.,* it would allow the FDIC, as agent for FICO, to adjust the March 2019 FICO assessment for any institution to reflect amendments that the institution has made to its call reports for any calendar quarters prior to and including the fourth quarter of 2018. This provision is phrased in terms of setting March 26, 2019—the projected date as of which the FDIC will finalize the amounts due for the March 2019 FICO assessment—as the last date for any such call report amendments to affect the institution's FICO assessments.[19] Fourth, this final rule includes a provision that is intended to address the possibility, which FHFA believes to be small, that FICO may need to conduct another assessment in June 2019, which would occur only if the March collection did not yield sufficient monies to make the remaining interest payments on the FICO bonds. This provision has been drafted to preserve the current practice of allowing an insured depository institution to amend the call report on which its June FICO assessments will be based up until the date on which the FDIC finalizes the amounts due from each institution for that quarter. This paragraph provides that any amendments to the call reports for the calendar quarter ending on March 31, 2019 that are submitted after June 25, 2019, the anticipated date on which the FDIC would finalize payments for the collection, will not affect the institution's FICO assessment. Any amended call reports for the first quarter of 2019 submitted prior to that date will be used to calculate the June assessments. This is consistent with current practice for FICO assessments, under which payment amounts for FICO assessments are finalized three days prior to the date of collection.

Analysis. In the absence of an ongoing FICO assessment process continuing after March 2019, there will be no funding mechanism for FICO to provide an insured depository institution a credit for any overpayment of a prior FICO assessment or to bill it for any underpayment of a prior assessment. FHFA has therefore determined to provide clarity and finality by affirmatively declaring the FICO assessment adjustment practices terminated, effective with the collection of the final FICO assessment. FHFA is mindful of the statutory requirement that FICO should assess the depository institutions for its interest costs in the same manner as the FDIC assesses those institutions for deposit insurance purposes. FHFA also understands, however, that the FDIC has an established practice of allowing insured depository institutions to have adjustments made to their prior FDIC assessments if they later amend the call report data on which those assessments were based, provided it occurs within the three-year statutory period, a practice that will not be available when the FICO assessments cease.

A key difference between the FICO assessments and the FDIC assessments is that the FDIC assessments are continual, with no predetermined termination date. The FICO assessment authority, however, is required by statute to cease after FICO has collected sufficient monies to pay the interest and related costs on its Obligations. In light of that difference, FHFA believes that the statutory language requiring FICO to conduct its assessments in the same manner as the FDIC assessments is best read as requiring FICO to follow the FDIC practice for prior period adjustments only for so long as FICO actually is collecting assessments from the insured depository institutions. FHFA has drafted the final regulation in that manner, *i.e.,* the final rule would preserve the existing FDIC adjustment process through and including what is expected to be the final collection of the FICO assessment in March 2019. Until that final collection has been completed, all insured depository institutions that are eligible to be credited a refund for any prior overpayment of their FICO assessment or to be billed for any prior underpayment of their FICO assessment will be able to continue to have the appropriate adjustment included in the calculation of the amount they are required to pay.

For the foregoing reasons, FHFA does not believe that the ''in the same manner'' language of the Bank Act can reasonably be construed to require FICO to provide refunds to, or to collect monies from, insured depository institutions that amend a prior period call report after FICO has ceased its assessments. As noted above, there will be no practical way to process such adjustments because there will be no invoiced amount against which a credit could be applied or to which a surcharge could be added. Moreover, there is no source of funds from which FICO could pay cash refunds because FICO will have used all monies received from its prior assessments to pay the interest and other costs due on its Obligations. FICO also could not assess insured depository institutions to obtain additional monies to provide refunds to

[19] For example, an insured depository institution that amends a prior period call report on or before March 26, 2019 will receive an appropriate adjustment to the assessment amount anticipated to be collected on March 29, 2019. An institution that amends a prior period call report after that date will not receive any adjustment to its prior FICO assessment because there is not expected to be another FICO assessment after that date.

other institutions because its authority is limited to assessing the institutions only for monies needed for interest payments, issuance costs, and custodial fees. Finally, Congress has mandated that FHFA dissolve FICO as soon as practicable after it has repaid the last of its Obligations, which evidences an intent that FICO may not undertake any new activities, such as facilitating collections from and payments to insured institutions, after FICO has repaid its Obligations.

FHFA believes that the most appropriate reading of the Bank Act in these circumstances is that it allows insured depository institutions to continue to receive refunds for prior overpayments (and to continue to be billed for prior underpayments) in the same manner as FDIC assessments through and including the final FICO assessment. That approach gives appropriate effect to the ''in the same manner'' language of the statute without creating any conflict with the provision requiring the prompt dissolution of FICO, and without imposing on FICO any obligations that are not expressly mandated by the Bank Act.

FHFA also does not believe that this final rule will have a significant effect on FDIC-insured institutions. As an initial matter, the number of insured depository institutions amending call reports in any calendar quarter that affect their prior FICO assessments typically is small. For example, the number of such amended call reports for the fourth quarter of 2017 was 91, out of approximately 5,600 FDIC-insured depository institutions filing call reports. Moreover, the dollar amount of FICO assessment adjustments also is generally small. For that same period, the gross amount of refunds of prior FICO assessments related to those amended call reports was approximately $24,000, while the gross amount of collections of prior FICO underpayments was approximately $170,000, resulting in a net surplus of collections over refunds of approximately $146,000, *i.e.,* the insured depository institutions generally owe more for underpayments than they are entitled to receive in refunds. From mid-2011 through the last 2017 assessment period, the average net quarterly adjustment of prior FICO assessments resulting from all institutions' amendments to their prior call reports was approximately $95,000 of additional collections of prior FICO underpayments. As noted previously, and notwithstanding the typically modest numbers involved, this final rule has been drafted so as to preserve, through the date of the final FICO collection, the current practice of allowing all insured depository institutions to have their FICO assessments adjusted to reflect amendments to their prior call reports up until the date that FDIC finalizes the amount of each institution's final FICO assessment in March 2019.

IV. Paperwork Reduction Act

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

V. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires that, in connection with a notice of final rulemaking, an agency prepare a Final Regulatory Flexibility Act analysis describing the impact of the rule on small entities.[20] A Final Regulatory Flexibility Act analysis is not required, however, if the agency certifies that the rule will not have a significant economic effect on a substantial number of small entities, and publishes its certification and a short explanatory statement in the **Federal Register** together with the final rule. The SBA has defined ''small entities'' to include banking organizations with total assets less than or equal to $550 million.[21] As discussed further below, FHFA certifies that this final rule will not have a significant impact on a substantial number of FDIC-insured small entities.

Description of Need and Policy Objectives

By statute, FHFA must dissolve FICO as soon as practicable after it has made the final payments of principal and interest due on its Obligations, the last of which matures in September 2019. To facilitate FICO's prompt and orderly dissolution, and for the other reasons described in Section III above, this final rule will make all 2019 FICO assessments final and will terminate FICO assessment adjustments as of March 26, 2019.

Description of the Final Rule

A description of this final rule is presented in Section III: Final Rule. Please refer to it for further information.

Other Federal Rules

FHFA has exclusive regulatory authority over FICO and has sole responsibility for interpreting and applying the provisions of the Bank Act that govern FICO's operations and dissolution. For the reasons described in Section III, FHFA has determined that the most appropriate way to interpret the provisions of the Bank Act that refer to the manner in which the FDIC conducts its own assessments is to read them as applying only while FICO is conducting its own assessments. FHFA has not identified any likely duplication, overlap, and/or potential conflict between the final rule and any other federal rule.

Economic Impacts on Small Entities

This final rule applies to FICO and the manner in which it conducts its assessments, and may indirectly affect any FDIC-insured depository institutions that have been assessed to pay interest on the FICO's obligations. As of March 2018, the FDIC insured 5,606 depository institutions, of which 4,492 are defined as small banking entities for purposes of the RFA.[22] Each insured depository institution's share of the FICO assessment is based on the insured depository institution's self-reported call report data, which the depository institution may amend after their initial filing with the FFIEC. Because decisions to amend previously filed call reports are solely within the control of the insured depository institution, it is not possible to predict how many depository institutions may amend a prior period call report during any calendar quarter, how many of those institutions amending a prior call report would be small entities for RFA purposes, whether the call report amendments would affect the calculation of an individual institution's prior FICO assessment, the dollar amount by which a prior FICO assessment had changed as a result of an amended call report, or the net amount of all such changes for all insured depository institutions, *i.e.,* whether the dollar amount of all refunds for prior overpayments was greater or less than the dollar amount of all billings for prior underpayments. Based on historical FFIEC data relating to call report amendments that affected individual institution FICO assessments, however, it appears that this final rule will not affect a substantial number of small entities, and that the economic effect on those small entities that may be affected by this final rule will not be significant.

[20] 5 U.S.C. 601 *et seq.*

[21] 13 CFR 121.201 (as amended, effective December 2, 2014).

[22] Call Report data as of March 31, 2018.

Indeed, the potential net economic effect on those small entities will most likely be positive, meaning that more of them would receive a financial benefit—being relieved of the obligation to pay for any prior underpayment of a FICO assessment—than would experience the negative effect of losing refunds for prior overpayment of FICO assessments.

Between March 2012 and December 2017, there has been an average of approximately 205 FICO assessments amended per calendar quarter, split evenly between refunds and additional collections. Based on the proportion of small entities to the total number of FDIC-insured depository institutions, FHFA has deemed approximately 80 percent of those amendments to have been attributable to small entities. The actual number of small entities amending call reports that affect their FICO assessments is apt to be lower, however, because each institution may amend multiple quarters' call reports at one time. For example, an institution amending a call report from a particular calendar quarter two years ago may also amend some or all of the subsequent call reports. Of the 164 FICO assessment amendments attributable to small banking entities per quarter, if each entity submits an average of two amendments per quarter, approximately 82, or slightly less than two percent, of FDIC-insured small banking entities would be affected per quarter by this final rule.

During the same period, the average gross FICO refunds to institutions due to their overpayments of prior FICO assessments was approximately $139,000 per quarter, or an average of about $1,350 per amendment. The average gross additional FICO collection for underpayment of prior FICO assessments was $243,000 per quarter, or $2,370 per amendment. Based on those numbers, and assuming the largest possible estimated refunds, *i.e.,* where an institution amended call reports for each of the twelve calendar quarters in the three year period and was entitled to an overpayment credit for each quarter of $1,350 each, the potential cost to that institution would be $16,200. In a similar fashion, assuming the largest possible estimated billings, *i.e.,* where the institution amended its twelve most recent call reports and had underpaid each of the FICO assessments for those periods, the potential savings to that institution would be $28,440. These figures indicate that this final rule will likely not have a significant economic effect on even the smallest banking entities. When viewed in the aggregate, it appears that the most likely net effect on all FDIC insured institutions, including small entities, will be positive because the available data indicates that most adjustments to prior FICO assessments result in the depository institution paying additional amounts to make up for prior underpayments of its prior period FICO assessments, and that the amounts of such billings are greater than the amounts of any refunds.

This final rule poses no regulatory costs for FDIC insured small entities, as their FDIC assessment process will remain in place as currently implemented. Overall assessment costs will be permanently reduced to the extent each entity's FICO assessment is no longer collected. Further, FDIC assessment adjustments will be unaffected by this final rule, which typically represent 90 percent of an insured institution's total potential adjustment value. For these reasons and based on the figures cited above, FHFA finds that this final rule will not have a significant economic impact on a substantial number of small entities.

Alternatives Considered

As discussed previously, FHFA is promulgating this final rule to provide clarity and finality to an issue—the status of future adjustments to prior FICO assessments—that is not otherwise addressed by the statute. FHFA has considered three other approaches to addressing this issue. First, FHFA considered taking no action. That approach likely would have resulted in insured depository institutions being in the same situation as will be the case under the final rule—without any mechanism to process adjustments to their prior FICO assessments—but neither they nor FICO would have had any guidance as to the status of their prior FICO assessments. By providing that all FICO assessments become final and nonrefundable when FICO completes its 2019 assessments, the final rule provides certainty to those institutions that they would not have otherwise, and without placing them in any different situation than would be the case if FHFA took no action.

Second, FHFA considered whether, after all FICO obligations are paid, FICO could assess all FDIC-insured institutions or use its own assets to obtain the monies needed to pay refunds to any insured depository institutions whose FICO assessments had changed due to amendments to their prior period call reports. FHFA concluded that further assessments are not legally permissible because Congress has authorized FICO to assess FDIC-insured institutions only for three specific purposes—to pay interest on the FICO Obligations, issuance costs, and custodian fees—which means that FICO's assessment authority does not extend to obtaining monies for paying refunds of prior FICO assessments. FICO also could not use its own assets to provide such monies because, as described previously, FICO has no legal obligation under any statute to reimburse insured institutions for their prior overpayments of FICO assessments, and has no authority to spend its assets for any purposes beyond those authorized by statute.

Third, FHFA considered whether FICO could direct the FDIC, as collection agent, to continue to process adjustments to prior FICO assessments on its own, but deemed that approach not to be legally permissible. The FDIC acts solely as FICO's agent when collecting the FICO assessments, and as such FDIC's authority derives from, and can be no greater than, FICO's own assessment authority.

List of Subjects in 12 CFR Part 1271

Accounting, Community development, Credit, Federal home loan banks, Government securities, Housing, Miscellaneous federal home loan bank operations and authorities, Reporting and recordkeeping requirements.

Authority and Issuance

Accordingly, for reasons stated in the **SUPPLEMENTARY INFORMATION** and under the authority of 12 U.S.C. 1431(a), 1432(a), 4511(b), 4513, 4526(a), FHFA amends subchapter D of chapter XII of title 12 of the Code of Federal Regulations as follows:

PART 1271—MISCELLANEOUS FEDERAL HOME LOAN BANK OPERATIONS AND AUTHORITIES

■ 1. The authority citation for part 1271 continues to read as follows:

Authority: 12 U.S.C. 1430, 1431, 1432, 1441(b)(8), (c), (j), 1442, 4511(b), 4513(a), 4526.

■ 2. Amend § 1271.37 by adding paragraph (d) to read as follows:

§ 1271.37 Non-administrative expenses; assessments.

* * * * *

(d)(1) *Final assessments.* All Financing Corporation assessments collected during 2019 shall be final. Subsequent to March 29, 2019, no insured depository institution shall have any right to receive refunds for any overpayment of any prior Financing Corporation assessments nor shall it be billed for any underpayment of any prior Financing Corporation assessments that arise as a result of an amendment to any Consolidated Reports

of Condition and Income on which the prior Financing Corporation assessment had been based.

(2) *Amendments to call reports.* Amendments to an institution's Consolidated Reports of Condition and Income for quarters prior to and including the fourth quarter of 2018 shall not affect an institution's Financing Corporation assessments after March 26, 2019.

(3) *June 2019 assessment.* In the event Financing Corporation assessments are collected in June 2019, amendments to an institution's first quarter 2019 Consolidated Reports of Condition and Income that are submitted after June 25, 2019 shall not affect the institution's Financing Corporation assessment.

Dated: November 26, 2018.

Melvin L. Watt,

Director, Federal Housing Finance Agency.

[FR Doc. 2018–26449 Filed 12–6–18; 8:45 am]

BILLING CODE 8070–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2018–0843]

RIN 1625–AA00

Safety Zone; Barters Island Bridge, Back River, Barters Island, ME

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for the navigable waters within a 50 yard radius from the center point of the Barters Island Bridge, on the Back River, ME, approximately 4.6 miles north of the mouth of the waterway. The safety zone is necessary to protect personnel, vessels, and the marine environment from potential hazards which could pose as imminent hazard to persons and vessels operating in the area created by the demolition, subsequent removal, and replacement of the Barters Island Bridge and a temporary bridge. When enforced, persons and vessels are prohibited from being in the safety zone during bridge replacement operations unless authorized by the Captain of the Port Northern New England or a designated representative.

DATES: This rule is effective without actual notice from December 7, 2018 through January 31, 2021. For the purposes of enforcement, actual notice will be used from December 1, 2018 through December 7, 2018.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2018–0843 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rulemaking, call or email LT Matthew Odom, Waterways Management Division, U.S. Coast Guard Sector Northern New England, telephone 207–347–5015, email *Matthew.T.Odom@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code
MEDOT Maine Department of Transportation

II. Background, Purpose, and Legal Basis

On April 27, 2018, the Maine Department of Transportation (MEDOT) applied for a bridge construction permit for Barter's Island Bridge with the Coast Guard. On June 22, 2018, the Coast Guard issued Public Notice 1–164, published it on the USCG Navigation Center website, and solicited comments through July 23, 2018. Three comments were received in response to the public notice: One commenter requested the project be stopped if any human remains, archaeological properties or other items of historical importance are unearthed and we report the findings. A second commenter notified us this project will not affect any Penobscot cultural/historic properties or interests and had no objection. A third commenter stated that Tennessee Gas Pipeline currently does not have facilities within the area. There were no statements of objection.

On August 22, 2018, MEDOT requested by letter that the Coast Guard impose waterway restrictions on the Back River around the Barters Island Bridge between Hodgdon Island and Barters Island in Boothbay Harbor in support of the bridge improvements. The project includes the replacement of the swing span of the bridge and the existing center pier. A temporary fixed bridge will be used to maintain vehicle traffic during construction of the new bridge. The temporary fixed bridge will reduce the vertical clearance of the channel to 6.8 feet mean high water (MHW) from approximately November 1, 2019 through May 31, 2020. On or about June 1, 2020, the new swing bridge is expected to be operating with unlimited clearance in the open position. The anticipated date for removal of the temporary bridge is August 2020. A bridge protection system and bridge lighting will be installed as part of the new bridge. Captain of the Port (COTP) Northern New England has determined that hazards associated with the bridge replacement project will be a safety concern for anyone within a 50-yard radius from the center point of the Barters Island bridge. It is anticipated that the Back River will be closed because of this safety zone for a total of 85 non-continuous days.

On October 9, 2018, the Coast Guard published a notice of proposed rulemaking (NPRM) titled ''Safety Zones; Barters Island Bridge, Back River, Barters Island, ME'' (83 FR 50545). There we stated why we issued the NPRM, and invited comments on our proposed regulatory action related to this safety zone. During the comment period that ended November 8, 2018, we received one comment.

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

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. The COTP Northern New England has determined that potential hazards associated with the demolition, subsequent removal, and replacement of the Barters Island Bridge and a temporary bridge will be a safety concern for anyone transiting within a 50 yard radius of the center point of the Barters Island Bridge. The purpose of this rule is to ensure safety of vessels and the navigable waters in the safety zone before, during, and after the bridge demolition, removal, and replacement. During times of enforcement, no vessel or person would be permitted to enter the safety zone without obtaining permission from the COTP Northern New England or a designated representative.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received one comment on our NPRM published October 9, 2018. The comment was not related to this rulemaking nor does it fall within the scope of this rulemaking. There are no changes in the regulatory text of this rule from the proposed rule in the NPRM.

This rule establishes a safety zone from 12:01 a.m. on December 1, 2018 through 11:59 p.m. on January 31, 2021. While the safety zone would be effective throughout this period, it would only be enforced during operations on replacement of the Barters Island Bridge. The safety zone would include all navigable waters from surface to bottom within a 50 yard radius from the center point of the Barters Island Bridge on the Back River, ME. During times of enforcement, no vessel or person would be permitted to enter the safety zone without obtaining permission from the COTP Northern New England or a designated representative. The duration of the zone is intended to ensure the safety of vessels and these navigable waters before, during, and after operations on replacement of the Barters Island Bridge. The Coast Guard will notify the public and local mariners of this safety zone through appropriate means, which may include, but are not limited to, publication in the **Federal Register**, the Local Notice to Mariners, and Broadcast Notice to Mariners via marine Channel 16 (VHF–FM) in advance of any enforcement.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, the rule has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the following reasons: (1) The safety zone only impacts a small designated area of Back River, (2) the safety zone will only be enforced during certain construction activities necessitating a full waterway closure for safety purposes, which is only anticipated to occur on 85 days over a two year period, or if there is an emergency, (3) persons or vessels desiring to enter the safety zone may do so with permission from the COTP Northern New England or a designated representative, (4) the Coast Guard will notify the public of the enforcement of this rule via appropriate means, such as via Local Notice to Mariners and Broadcast Notice to Mariners via marine Channel 16 (VHF–FM).

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received no comments from the Small Business Administration on this rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule would not have a significant economic impact on a substantial number of small entities.

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

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone that would prohibit entry within a 50 yards radius from the center point of the Barters Island Bridge during its removal and replacement over an approximately two year period. It is categorically excluded from further review under paragraph L60 (a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. A

Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T01–0843 to read as follows:

§ 165.T01–0843 Safety Zone; Barters Island Bridge, Back River, Barters Island, ME.

(a) *Location.* The following area is a safety zone: All navigable waters on Back River, within a 50-yard radius of the center point of the Barters Island Bridge that spans Back River between Barters Island and Hodgdon Island in position 43°52′51″ N, 069°40′19″ W (NAD 83).

(b) *Definitions.* As used in this section:

Designated representative means any Coast Guard commissioned, warrant, petty officer, or any federal, state, or local law enforcement officer who has been designated by the Captain of the Port (COTP) Northern New England, to act on his or her behalf. The designated representative may be on an official patrol vessel or may be on shore and will communicate with vessels via VHF–FM radio or loudhailer. In addition, members of the Coast Guard Auxiliary may be present to inform vessel operators of this regulation.

Official patrol vessels means any Coast Guard, Coast Guard Auxiliary, state, or local law enforcement vessels assigned or approved by the COTP Northern New England to enforce this section.

(c) *Effective and enforcement period.* This rule is effective without actual notice from December 7, 2018 through 11:59 p.m. on January 31, 2021. For the purposes of enforcement, actual notice will be used from 12:01 a.m. on December 1, 2018 through December 7, 2018. This rule will only be enforced during operations on replacement of the Barters Island Bridge or other instances which may cause a hazard to navigation, or when deemed necessary by the Captain of the Port (COTP), Northern New England.

(d) *Regulations.* The general regulations contained in § 165.23, as well as the following regulations, apply:

(1) No person or vessel may enter or remain in this safety zone without the permission of the COTP or the COTP's designated representative.

(2) To obtain permission required by this regulation, individuals may reach the COTP or the COTP's designated representative via Channel 16 (VHF–FM) or (207) 741–5465 (Sector Northern New England Command Center).

(3) During periods of enforcement, any person or vessel permitted to enter the safety zone shall comply with the directions and orders of the COTP or the COTP's designated representative.

(4) During periods of enforcement, upon being hailed by a U.S. Coast Guard vessel by siren, radio, flashing lights, or other means, the operator of a vessel within the zone must proceed as directed. Any person or vessel within the safety zone shall exit the zone when directed by the COTP or the COTP's designated representative.

Dated: November 30, 2018.

B.J. LeFebvre,

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

[FR Doc. 2018–26578 Filed 12–6–18; 8:45 am]

BILLING CODE 9110–04–P

LIBRARY OF CONGRESS

Copyright Office

37 CFR Parts 201, 203, and 210

[Docket No. 2018–10]

Notices of Intention and Statements of Account Under Compulsory License To Make and Distribute Phonorecords of Musical Works

AGENCY: U.S. Copyright Office, Library of Congress.

ACTION: Interim rule with request for comments.

SUMMARY: The U.S. Copyright Office is issuing interim regulations pursuant to the Musical Works Modernization Act, title I of the recently enacted Orrin G. Hatch–Bob Goodlatte Music Modernization Act. This interim rule amends the Office's existing regulations pertaining to the compulsory license to make and distribute phonorecords of musical works so as to conform the existing regulations to the new law, including with respect to the operation of notices of intention and statements of account, and to make other minor technical updates. To be clear, this interim rule is generally directed at the present transition period before a blanket license is offered by a mechanical licensing collective and does not include regulatory updates that may be required in connection with the future offering of that blanket license; such updates will be the subject of future rulemakings. These regulations are issued on an interim basis with opportunity for public comment to avoid delay in making these necessary updates and clarifications and because they are technical in nature. The Office welcomes comment on these interim regulations.

DATES: The effective date of the interim regulations is December 7, 2018. Written comments must be received no later than 11:59 p.m. Eastern Time on January 22, 2019.

ADDRESSES: For reasons of government efficiency, the Copyright Office is using the *regulations.gov* system for the submission and posting of public comments in this proceeding. All comments are therefore to be submitted electronically through *regulations.gov.* Specific instructions for submitting comments are available on the Copyright Office's website at *https://www.copyright.gov/rulemaking/mma-115-techamend/.* If electronic submission of comments is not feasible due to lack of access to a computer and/or the internet, please contact the Office using the contact information below for special instructions.

FOR FURTHER INFORMATION CONTACT: Regan A. Smith, General Counsel and Associate Register of Copyrights, by email at *regans@copyright.gov,* Steve Ruwe, Assistant General Counsel, by email at *sruwe@copyright.gov,* or Jason E. Sloan, Assistant General Counsel, by email at *jslo@copyright.gov.* Each can be contacted by telephone by calling (202) 707–8350.

SUPPLEMENTARY INFORMATION:

I. Background

On October 11, 2018, the president signed into law the Orrin G. Hatch–Bob

Goodlatte Music Modernization Act (''MMA'').[1] This bipartisan and unanimously enacted legislation represents the realization of years of effort by a wide array of policymakers and stakeholders, as well as the U.S. Copyright Office, to update the music licensing landscape to better facilitate legal licensing of music by digital services.[2]

Title I of the MMA, the Musical Works Modernization Act, substantially modifies the compulsory ''mechanical'' license for making and distributing phonorecords of nondramatic musical works available under 17 U.S.C. 115. Prior to the MMA, a compulsory license was obtained by licensees on a per-work, song-by-song basis, whereby a licensee was required to serve a notice of intention to obtain a compulsory license (''NOI'') on the relevant copyright owner (or file the NOI with the Copyright Office if the Office's public records did not identify the copyright owner and include an address at which notice could be served) and then pay applicable royalties accompanied by accounting statements.[3]

The MMA amends this regime in multiple ways, most significantly by establishing a new blanket compulsory license that digital music providers may obtain to make digital phonorecord deliveries (''DPDs'') of musical works, including in the form of permanent downloads, limited downloads, or interactive streams.[4] Instead of licensing one song at a time by serving NOIs on individual copyright owners, the blanket license will cover all musical works available for compulsory licensing and will be centrally administered by a new entity called the mechanical licensing collective (''MLC''), to be designated by the Register of Copyrights.[5] Under the MMA, compulsory licensing of phonorecords that are not DPDs (*e.g.,* CDs, vinyl, tapes, and other types of physical phonorecords) continues to operate on a per-work, song-by-song basis, the same as before.[6]

The new blanket license created by the MMA will not become available until the license availability date, which is January 1 following the expiration of the 2-year period after the enactment date, or January 1, 2021.[7] Until that time, the MMA ''creates a transition period in order to move from the current work-by-work license to the new blanket license.''[8] During this current transition period, anyone seeking to obtain a compulsory license to make DPDs must continue to do so on a song-by-song basis by serving NOIs on copyright owners ''if the identity and location of the musical work copyright owner is known,'' and paying them applicable royalties accompanied by statements of account.[9] If the musical work copyright owner is unknown, a digital music provider may no longer file a NOI with the Copyright Office, but must ''continue[] to search for the musical work copyright owner'' using good-faith, commercially reasonable efforts.[10] The digital music provider must eventually either account for and pay accrued royalties to the relevant musical work copyright owner(s) when found or, if they are not found before the end of the transition period, account for and transfer the royalties to the MLC at that time.[11] A digital music provider complying with these requirements can avail itself of a limitation on liability for making an unauthorized DPD to the royalties that would be due under the compulsory license.[12]

On and after the license availability date, a compulsory license to make DPDs will generally only be available through the new blanket license, subject to a limited exception for record companies to continue using the song-by-song licensing process to make and distribute, or authorize the making and distribution of, permanent downloads embodying a specific individual musical work (called an ''individual download license'').[13] As the legislative history notes, the MMA ''maintains the 'pass-through' license for record labels to obtain and pass through mechanical license rights for individual permanent downloads,'' but eliminates the pass-through license for digital music providers ''to engage in activities related to interactive streams or limited downloads.''[14]

II. Interim Rule

The Office promulgates the following interim rule to make technical amendments to its existing section 115-related regulations to harmonize them with the MMA's requirements, and to make other minor technical updates. These amendments largely fall into two categories: Those affecting NOIs and those affecting statements of account.[15] The Office declines at this time to substantively amend the existing regulations beyond the statutorily required updates. The intent of the legislation does not signal to the Office that it should be overhauling its existing regulations during the transition period before the blanket license becomes available; such changes could alter private companies' long-established business practices and expectations with respect to NOIs and royalty statements during the transition period beyond what the statute requires. Having said that, the Office welcomes public comment on these amendments and any other specific technical amendments that stakeholders would like the Office to consider.

A. Notices of Intention

Under the interim rule, 37 CFR 201.18 is primarily updated to implement 17 U.S.C. 115(b), as amended by the MMA. As outlined above, as of enactment of the MMA on October 11, 2018: (1) NOIs pertaining to phonorecords that are not DPDs (*i.e.,* physical phonorecords such as CDs, vinyl, or tapes) may still be served on copyright owners or, if the registration or other public records of the Copyright Office do not identify the copyright owner and include an address at which the NOI can be served, filed with the Copyright Office, the same as

[1] Public Law 115–264, 132 Stat. 3676 (2018).

[2] *See* S. Rep. No. 115–339, at 1–2 (2018); Report and Section-by-Section Analysis of H.R. 1551 by the Chairmen and Ranking Members of Senate and House Judiciary Committees, at 1 (2018), *https://judiciary.house.gov/wp-content/uploads/2018/04/Music-Modernization-Act.pdf; see also* H.R. Rep. No. 115–651, at 2–3 (2018) (detailing the House Judiciary Committee's efforts to review music copyright laws).

[3] *See* 17 U.S.C. 115(b)(1), (c)(5) (2017); U.S. Copyright Office, Copyright and the Music Marketplace 28–31 (2015), *https://www.copyright.gov/policy/musiclicensingstudy/copyright-and-the-music-marketplace.pdf* (describing operation of prior section 115 license).

[4] 17 U.S.C. 115(d)(1), (e)(7); *see* H.R. Rep. No. 115–651, at 4–6 (describing operation of the blanket license and the new mechanical licensing collective); S. Rep. No. 115–339, at 3–6 (same).

[5] 17 U.S.C. 115(d)(1), (3).

[6] *Id.* 115(b)(1); *see* H.R. Rep. No. 115–651, at 3 (noting ''[t]his is the historical method by which record labels have obtained compulsory licenses''); S. Rep. No. 115–339, at 3 (same); *see also* U.S. Copyright Office, Orrin G. Hatch–Bob Goodlatte Music Modernization Act, *https://www.copyright.gov/music-modernization/.*

[7] 17 U.S.C. 115(d)(2)(B), (e)(15).

[8] H.R. Rep. No. 115–651, at 10; S. Rep. No. 115–339, at 10.

[9] 17 U.S.C. 115(b)(2)(A), (c)(2)(I); H.R. Rep. No. 115–651, at 4; S. Rep. No. 115–339, at 3.

[10] 17 U.S.C. 115(b)(2)(A), (d)(9)(D)(i), (d)(10)(A)–(B); H.R. Rep. No. 115–651, at 4, 10; S. Rep. No. 115–339, at 3, 10, 22.

[11] 17 U.S.C. 115(d)(10)(B); *see* H.R. Rep. No. 115–651, at 4, 10; S. Rep. No. 115–339, at 3, 10.

[12] 17 U.S.C. 115(d)(10)(A)–(B); *see* H.R. Rep. No. 115–651, at 4, 10; S. Rep. No. 115–339, at 3, 10.

[13] 17 U.S.C. 115(b)(2)(B), (b)(3), (e)(12); *see* H.R. Rep. No. 115–651, at 4; S. Rep. No. 115–339, at 3–4.

[14] H.R. Rep. No. 115–651, at 4; S. Rep. No. 115–339, at 4.

[15] This interim rule also makes minor technical changes to other provisions relating to section 115, such as updating the description of the Office's Licensing Division in its FOIA-related regulations. The Office is also taking this opportunity to make an additional technical update to its FOIA-related regulations to reflect the Office's current organizational structure.

before enactment of the MMA; (2) NOIs pertaining to DPDs (*e.g.,* permanent downloads, limited downloads, or interactive streams) may still be served on copyright owners until the license availability date, but not afterward, except in the case of a record company seeking an individual download license; and (3) NOIs pertaining to DPDs can no longer be filed with the Copyright Office under any circumstances.[16] The definition of ''digital phonorecord delivery'' is also updated in the regulation to match the amended definition in the MMA.

Under the interim rule, the Office is not making any changes to the form, content, or manner of service for NOIs. In addition to the conforming amendments necessitated by the MMA, the Office is taking this opportunity to make two minor clarifying technical updates. First, the regulations previously stated that the Office does not provide forms to use for serving or filing NOIs, but since 2016, the Office has had a required form that must be used to file NOIs electronically with the Office.[17] The interim rule acknowledges this electronic form. Second, the interim rule clarifies the Office's current practice, as detailed in a 2017 policy statement, of charging a filing fee for so-called ''returned-to-sender NOIs'' [18] submitted to the Office.[19] Of course, both of these updates only apply to NOIs pertaining to phonorecords that are not DPDs.

B. Statements of Account

Under the interim rule, the Office is not making any amendments to the form, content, or manner of service for monthly or annual statements of account under subpart B of part 210 of the Office's regulations. But the interim rule clarifies that on and after the license availability date, these regulations will not apply to any DPDs made under a compulsory license, unless they are made by a record company under an individual download license.[20] This means that the regulations will not apply to digital music providers reporting and paying royalties under a blanket license (such activity will be the subject of a separate, future rulemaking).[21]

The interim rule also details the requirements for digital music providers to report and pay royalties regarding previously unmatched works for purposes of eligibility for the limitation on liability for making unauthorized DPDs during the transition period before the blanket license becomes available. As noted, once a digital music provider has identified and located a musical work copyright owner, the statute requires the provider to pay the copyright owner all accrued royalties accompanied by a cumulative statement of account that includes all of the information that would have been provided in monthly statements of account from the initial use of the work, had the copyright owner been previously identified and located.[22] If the digital music provider has not located the musical work copyright owner by the license availability date, the accrued royalties and cumulative statement must be provided to the MLC.[23] The interim regulations follow the statute, specifying that the digital music provider must pay royalties and provide cumulative statements under subpart B of part 210 as if they were a compulsory licensee. In providing these cumulative statements, the interim rule also requires digital music providers to identify the total period covered by the cumulative statement and the total royalty payable for the period. This addition is meant to assist the copyright owner or the MLC, as the case may be, to quickly ascertain the sum of the contents of the cumulative statement. As mandated by the MMA, the interim rule also requires that such cumulative statements include the certification required for monthly statements of account under Copyright Office regulations.[24]

III. Request for Comments

These interim regulations will go into effect immediately after publication of this document in the **Federal Register**. Comments will be due 45 days thereafter. The Copyright Office is issuing these interim regulations after finding, for good cause, that notice and comment prior to their issuance would be contrary to the public interest.[25] The changes to section 115 made by the MMA were effective on October 11, 2018, and this interim rule conforms the regulations to the new law and clarifies for the public the operation of the Office's existing section 115-related regulations during the current transition period before the license availability date. The rule also must be issued without delay because it specifies the information to be contained in statements of account provided by digital music providers seeking to avail themselves of the limitation on liability available during this transition period. Moreover, the amendments made by this interim rule are meant to be technical in nature, as they are largely non-discretionary and merely make statutorily mandated modifications to existing rules.

The Copyright Office notes that this is only the first of what will be a number of rulemakings required by the MMA that concern the section 115 license. Over the next few months, the Office will be issuing additional notices to address other issues presented by the MMA, including the designation of the MLC and the filing by digital music providers of notices of license and reports of usage with the MLC under the blanket license. This interim rule, in contrast, does not cover the MLC or activity under the blanket license, and comments on such matters should not be submitted in response to it. Rather, comments submitted in response to this notice should be limited to the subjects of this interim rule. The Office looks forward to hearing from all who are interested in these important issues as the process continues.

List of Subjects

37 CFR Part 201

Copyright, General provisions.

37 CFR Part 203

Freedom of information.

[16] 17 U.S.C. 115(b), (d)(9)(D)(i).

[17] *See Section 115 NOIs May Now Be Filed With Office In Bulk Electronic Form,* U.S. Copyright Office NewsNet No. 618 (Apr. 13, 2016), *https://www.copyright.gov/newsnet/2016/618.html.*

[18] A ''returned-to-sender NOI'' is one that is sent to the last address for the copyright owner shown by the Office's records, but that is returned to the sender because the copyright owner is no longer located at that address or refused to accept delivery. In such cases, the original NOI can be filed with the Office. *See* 37 CFR 201.18(f)(2).

[19] *See* 82 FR 52221, 52223 (Nov. 13, 2017).

[20] *See* 17 U.S.C. 115(b)(3).

[21] *See id.* 115(d)(4)(A)(i).

[22] *Id.* 115(d)(10)(B)(iv)(II)(aa).

[23] *Id.* 115(d)(10)(B)(iv)(III)(aa).

[24] *See id.* 115(d)(10)(B)(iv)(II)(aa), (III)(aa) (cumulative statements to be provided ''in accordance with this section and applicable regulations, including the requisite certification under subsection (c)(2)(I)'').

[25] In the past, the Copyright Office has similarly issued interim rules upon the enactment of legislation before soliciting public comments. *See, e.g.,* Filing of Schedules by Rights Owners and Contact Information by Transmitting Entities Relating to Pre-1972 Sound Recordings, 83 FR 52150, 52153 (Oct. 16, 2018) (issuing interim rule regarding certain new types of filings because ''[t]he MMA requires swift action by the Office'' and ''a prompt interim rule best serves the legal interests of all relevant stakeholders as well as the general public''); Freedom of Information Act Regulations, 82 FR 9505, 9506 (Feb. 7, 2017) (issuing interim rule to implement the FOIA Improvement Act of 2016 because ''allowing for notice and public procedure prior to the issuance of . . . interim regulations would be impracticable''); Designation of Agent to Receive Notification of Claimed Infringement, 63 FR 59233, 59234 (Nov. 3, 1998) (issuing interim rule regarding designation of agent after enactment of the Digital Millennium Copyright Act because ''online service providers may wish immediately to designate agents to receive notification of claimed infringement'').

37 CFR Part 210

Copyright, Phonorecords, Recordings.

Interim Regulations

For the reasons set forth in the preamble, the Copyright Office amends 37 CFR parts 201, 203, and 210 as follows:

PART 201—GENERAL PROVISIONS

■ 1. The authority citation for part 201 continues to read as follows:

Authority: 17 U.S.C. 702.

■ 2. Amend § 201.18 as follows:
■ a. Revise paragraphs (a)(1) and (2).
■ b. In paragraph (a)(3):
■ i. Remove ''is each'' and add in its place ''means each''.
■ ii. Remove ''which results'' and add in its place ''that results''.
■ iii. Remove ''nondramatic''.
■ iv. Add two sentences at the end of the paragraph.
■ c. In paragraph (a)(4) introductory text:
■ i. Remove ''A Notice of Intention shall'' and add in its place ''As eligible under paragraph (a)(2) of this section, a Notice of Intention shall''.
■ ii. Remove ''(f)(3)'' and add in its place ''(f)(2) or (3)''.
■ d. In paragraph (a)(6), remove ''Notwithstanding paragraph (a)(2) of this section, a'' and add in its place ''A''.
■ e. Revise paragraph (c).
■ f. In paragraph (d)(1)(iii), remove ''(for example: a record company or digital music service)''.
■ g. In paragraph (d)(1)(v)(D), remove ''delivery, or'' and add in its place ''delivery (if eligible under paragraph (a)(2) of this section), or''.
■ h. In paragraph (f)(1):
■ i. Remove ''If the'' and add in its place ''As eligible under paragraph (a)(2) of this section, if the''.
■ ii. Remove the second sentence.
■ i. In paragraph (f)(2):
■ i. Remove ''If the Notice is'' and add in its place ''If a Notice of Intention seeking a compulsory license to make and distribute phonorecords of a musical work other than by means of digital phonorecord delivery is''.
■ ii. Remove ''accompanied by a'' and add in its place ''accompanied by the fee specified in § 201.3(e) and a''.
■ j. In paragraph (f)(3), remove ''in the Notice of Intention, the'' and add in its place ''in a Notice of Intention seeking a compulsory license to make and distribute phonorecords of a musical work other than by means of digital phonorecord delivery, the''.
■ k. In paragraph (f)(4), remove ''section 115(b)(1) of title 17 of the United States Code'' and add in its place ''17 U.S.C. 115(b)''.
■ l. In paragraph (g), add three sentences at the end of the paragraph.
■ m. In paragraph (h), remove ''section 115(b)(1) of title 17 of the United States Code'' and add in its place ''17 U.S.C. 115(b)''.

The revisions and additions read as follows:

§ 201.18 Notice of intention to obtain a compulsory license for making and distributing phonorecords of nondramatic musical works.

(a) *General.* (1) A ''Notice of Intention'' is a Notice identified in section 115(b) of title 17 of the United States Code. If the eligibility requirements of 17 U.S.C. 115(a) are satisfied, then, subject to 17 U.S.C. 115(b), a person may serve on a copyright owner or file with the Copyright Office, as applicable, a Notice of Intention and thereby obtain a compulsory license pursuant to 17 U.S.C. 115.

(2)(i) To obtain a compulsory license to make and distribute phonorecords of a musical work other than by means of digital phonorecord delivery, a Notice must be served on the copyright owner or, if the registration or other public records of the Copyright Office do not identify the copyright owner and include an address at which Notice can be served, filed with the Copyright Office, before, or not later than 30 calendar days after, making, and before distributing, any phonorecord of the work.

(ii) Prior to the license availability date, as defined in 17 U.S.C. 115(e), to obtain a compulsory license to make and distribute phonorecords of a musical work by means of digital phonorecord delivery, a Notice must be served on the copyright owner, before, or not later than 30 calendar days after, first making any such digital phonorecord delivery. On and after the license availability date, as defined in 17 U.S.C. 115(e), to obtain such a compulsory license, the procedure described in 17 U.S.C. 115(d)(2) must be followed. As of October 11, 2018, the Copyright Office does not accept Notices that pertain to digital phonorecord deliveries, regardless of whether such a Notice also pertains to phonorecords that are not digital phonorecord deliveries.

(iii) Notwithstanding paragraph (a)(2)(ii) of this section, a record company, as defined in 17 U.S.C. 115(e), may, on or after the license availability date, as defined in 17 U.S.C. 115(e), obtain an individual download license, as described in 17 U.S.C. 115(b)(3) and defined in 17 U.S.C. 115(e), by serving a Notice on the copyright owner, before, or not later than 30 calendar days after, first making any digital phonorecord delivery in the form of a permanent download.

(3) * * * Notwithstanding the foregoing, a permanent download, a limited download, or an interactive stream, as defined in 17 U.S.C. 115(e), is a digital phonorecord delivery. A digital phonorecord delivery does not include the digital transmission of sounds accompanying a motion picture or other audiovisual work as defined in 17 U.S.C. 101.

* * * * *

(c) *Form.* The Copyright Office does not provide physical printed forms for the use of persons serving or filing Notices of Intention, but Notices filed electronically must be submitted to the Office in the form and manner prescribed in instructions on the Office's website.

* * * * *

(g) * * * Notwithstanding the foregoing, the Copyright Office will examine Notices to ensure that they do not pertain to digital phonorecord deliveries. Any Notice submitted to the Office that does pertain to digital phonorecord deliveries, regardless of whether such a Notice also pertains to phonorecords that are not digital phonorecord deliveries, will be rejected. The Office's decision to accept or reject such a Notice is without prejudice to any party claiming that the Notice does or does not pertain to digital phonorecord deliveries, including before a court of competent jurisdiction.

* * * * *

PART 203—FREEDOM OF INFORMATION ACT: POLICIES AND PROCEDURES

■ 3. The authority citation for part 203 continues to read as follows:

Authority: 5 U.S.C. 552.

■ 4. Amend § 203.3 as follows:
■ a. Remove paragraph (b)(2).
■ b. Redesignate paragraph (b)(3) as paragraph (b)(2).
■ c. Revise paragraphs (h) and (i).

The revisions read as follows:

§ 203.3 Organization.

* * * * *

(h) The Copyright Modernization Office (''CMO'') is headed by the Director, who is the Register's top advisor on Copyright Office modernization and oversees the development and implementation of technology initiatives affecting registration and recordation. This Office directs and coordinates all modernization activities on behalf of the

U.S. Copyright Office, including resources, communications, stakeholder engagement, and business project management. The CMO ensures that modernization activities are continuously aligned with the Office's and the Library of Congress's strategic goals, and collaborates with the Office and the Library to drive modernization efforts. The CMO provides project management, data management/analytics, and business analysis. It also serves as the primary liaison with the Library of Congress's Office and Chief Information Officer (''OCIO'') and serves in a leadership function on the Office's Modernization Governance Board.

(i) The Chief Financial Officer (''CFO'') is a senior staff position that serves under the Register and oversees all fiscal, financial, and budgetary activities for the Copyright Office. The CFO also oversees the Licensing Division, which administers certain statutory licenses set forth in the Copyright Act. The Division collects royalty payments and examines statements of account for the cable statutory license (17 U.S.C. 111), the satellite statutory license for retransmission of distant television broadcast stations (17 U.S.C. 119), and the statutory license for digital audio recording technology (17 U.S.C. chapter 10). The Division also accepts and records certain documents associated with the use of the mechanical statutory license for making and distributing phonorecords of nondramatic musical works (17 U.S.C. 115) and the statutory licenses for publicly performing sound recordings by means of digital audio transmission (17 U.S.C. 112, 114).

* * * * *

PART 210—COMPULSORY LICENSE FOR MAKING AND DISTRIBUTING PHYSICAL AND DIGITAL PHONORECORDS OF NONDRAMATIC MUSICAL WORKS

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

Authority: 17 U.S.C. 115, 702.

■ 6. Amend subpart B by revising the heading to read as follows:

Subpart B—Royalties and Statements of Account Under Non-Blanket Compulsory License

■ 7. Amend § 210.11 by adding a sentence at the end of the paragraph to read as follows:

§ 210.11 General.

* * * On and after the license availability date, this subpart shall not apply with respect to any digital phonorecord delivery made pursuant to the compulsory license unless such digital phonorecord delivery is made by a record company under an individual download license under 17 U.S.C. 115(b)(3), which must be reported and paid for in accordance with § 210.21; that is, this subpart shall not apply where a digital music provider reports and pays royalties under a blanket license under 17 U.S.C. 115(d)(4)(A)(i).

§ 210.12 [Amended]

■ 8. Amend § 210.12 as follows:

■ a. In paragraphs (a) and (b), remove ''115(c)(5)'' and add in its place ''115(c)(2)(I)''.

■ b. In paragraph (c):

■ i. Remove ''is each'' and add in its place ''means each''.

■ ii. Remove ''which results'' and add in its place ''that results''.

■ iii. Remove ''nondramatic''.

■ iv. Add two sentences at the end of the paragraph.

■ c. Add paragraphs (k) through (o).

The additions read as follows:

§ 210.12 Definitions.

(c) * * * Notwithstanding the foregoing, a permanent download, a limited download, or an interactive stream, as defined in 17 U.S.C. 115(e), is a digital phonorecord delivery. A digital phonorecord delivery does not include the digital transmission of sounds accompanying a motion picture or other audiovisual work as defined in 17 U.S.C. 101.

* * * * *

(k) The term *license availability date* shall have the meaning given in 17 U.S.C. 115(e)(15).

(l) The term *digital music provider* shall have the meaning given in 17 U.S.C. 115(e)(8).

(m) The term *blanket license* shall have the meaning given in 17 U.S.C. 115(e)(5).

(n) The term *record company* shall have the meaning given in 17 U.S.C. 115(e)(26).

(o) The term *individual download license* shall have the meaning given in 17 U.S.C. 115(e)(12).

§ 210.16 [Amended]

■ 9. Amend § 210.16(d)(3) by removing ''115(c)(5)'' and adding in its place ''115(c)(2)(I)''.

§ 210.19 [Amended]

■ 10. Amend § 210.19 by removing ''115(c)(6)'' and adding in its place ''115(c)(2)(J)''.

■ 11. Add §§ 210.20 and 210.21 to read as follows:

§ 210.20 Statements required for limitation on liability for digital music providers for the transition period prior to the license availability date.

This section specifies the requirements for a digital music provider to report and pay royalties for purposes of being eligible for the limitation on liability described in 17 U.S.C. 115(d)(10). Terms used in this section that are defined in 17 U.S.C. 115(e) shall have the meaning given those terms in 17 U.S.C. 115(e).

(a) If the required matching efforts are successful in identifying and locating a copyright owner of a musical work (or share thereof) by the end of the calendar month in which the digital music provider first makes use of the work, the digital music provider shall provide statements of account and pay royalties to such copyright owner as a compulsory licensee in accordance with this subpart.

(b) If the copyright owner is not identified or located by the end of the calendar month in which the digital music provider first makes use of the work, the digital music provider shall accrue and hold royalties calculated under the applicable statutory rate in accordance with usage of the work, from initial use of the work until the accrued royalties can be paid to the copyright owner or are required to be transferred to the mechanical licensing collective, as follows:

(1) Accrued royalties shall be maintained by the digital music provider in accordance with generally accepted accounting principles.

(2) If a copyright owner of an unmatched musical work (or share thereof) is identified and located by or to the digital music provider before the license availability date, the digital music provider shall—

(i) Not later than 45 calendar days after the end of the calendar month during which the copyright owner was identified and located, pay the copyright owner all accrued royalties, such payment to be accompanied by a cumulative statement of account that includes all of the information that would have been provided to the copyright owner had the digital music provider been providing Monthly Statements of Account as a compulsory licensee in accordance with this subpart to the copyright owner from initial use of the work, and including, in addition to the information and certification required by § 210.16, a clear identification of the total period covered by the cumulative statement and the total royalty payable for the period;

(ii) Beginning with the accounting period following the calendar month in

which the copyright owner was identified and located, and for all other accounting periods prior to the license availability date, provide Monthly Statements of Account and pay royalties to the copyright owner as a compulsory licensee in accordance with this subpart; and

(iii) Beginning with the monthly royalty reporting period commencing on the license availability date, report usage and pay royalties for such musical work (or share thereof) for such reporting period and reporting periods thereafter to the mechanical licensing collective, as required under 17 U.S.C. 115(d) and applicable regulations.

(3) If a copyright owner of an unmatched musical work (or share thereof) is not identified and located by the license availability date, the digital music provider shall—

(i) Not later than 45 calendar days after the license availability date, transfer all accrued royalties to the mechanical licensing collective, such payment to be accompanied by a cumulative statement of account that includes all of the information that would have been provided to the copyright owner had the digital music provider been serving Monthly Statements of Account as a compulsory licensee in accordance with this subpart on the copyright owner from initial use of the work, accompanied by a certification by a duly authorized officer of the digital music provider that the digital music provider has fulfilled the requirements of 17 U.S.C. 115(d)(10)(B)(i) and (ii) but has not been successful in locating or identifying the copyright owner, and further including, in addition to the information and certification required by § 210.16, a clear identification of the total period covered by the cumulative statement and the total royalty payable for the period; and

(ii) Beginning with the monthly royalty reporting period commencing on the license availability date, report usage and pay royalties for such musical work (or share thereof) for such period and reporting periods thereafter to the mechanical licensing collective, as required under 17 U.S.C. 115(d) and applicable regulations.

§ 210.21 Record companies using individual download licenses.

A record company that obtains an individual download license under 17 U.S.C. 115(b)(3) shall provide statements of account and pay royalties as a compulsory licensee in accordance with this subpart.

Dated: November 30, 2018.

Karyn A. Temple,

Acting Register of Copyrights and Director of the U.S. Copyright Office.

Approved by:

Carla D. Hayden,

Librarian of Congress.

[FR Doc. 2018–26579 Filed 12–6–18; 8:45 am]

BILLING CODE 1410–30–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 721

[EPA–HQ–OPPT–2018–0649; FRL–9987–43]

RIN 2070–AB27

Significant New Use Rules on Certain Chemical Substances; Withdrawal

AGENCY: Environmental Protection Agency (EPA).

ACTION: Withdrawal of direct final rule.

SUMMARY: EPA is withdrawing significant new use rules (SNURs) promulgated under the Toxic Substances Control Act (TSCA) for 28 chemical substances, which were the subject of premanufacture notices (PMNs). EPA published these SNURs using direct final rulemaking procedures, which requires EPA to take certain actions if an adverse comment is received. EPA received adverse comments regarding the SNURs identified in the direct final rule. Therefore, the Agency is withdrawing the direct final rule SNURs identified in this document, as required under the direct final rulemaking procedures.

DATES: The direct final rule published at 83 FR 50838 on October 10, 2018 (FRL–9984–65) is withdrawn effective December 7, 2018.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPPT–2018–0649, is available at *http://www.regulations.gov* or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. 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 OPPT Docket is (202) 566–0280. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Kenneth Moss, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–9232; email address: *moss.kenneth@epa.gov.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Does this action apply to me?

A list of potentially affected entities is provided in the **Federal Register** of October 10, 2018 (83 FR 50838) (FRL–9984–65). If you have questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

II. What direct final SNURs are being withdrawn?

In the **Federal Register** of October 10, 2018 (83 FR 50838) (FRL–9984–65), EPA issued direct final SNURs for 28 chemical substances that are identified in the document. Because the Agency received adverse comments regarding the SNURs identified in the document, EPA is withdrawing the direct final SNURs issued for these 28 chemical substances, which were the subject of PMNs. In addition to the Direct Final SNURs, elsewhere in the same issue of the **Federal Register** of October 10, 2018 (83 FR 50872) (FRL–9984–67), EPA issued proposed SNURs covering these 28 chemical substances. EPA will address all adverse public comments in a subsequent final rule, based on the proposed rule.

III. Good Cause Finding

EPA determined that this document is not subject to the 30-day delay of effective date generally required by the Administrative Procedure Act (APA) (5 U.S.C. 553(d)) because of the time limitations for publication in the **Federal Register**. This document must publish on or before the effective date of the direct final rule containing the direct final SNURs being withdrawn.

IV. Statutory and Executive Order Reviews

This action withdraws regulatory requirements that have not gone into effect and which contain no new or amended requirements and reopens a comment period. As such, the Agency has determined that this action will not have any adverse impacts, economic or

otherwise. The statutory and Executive Order review requirements applicable to the direct final rules were discussed in the October 10, 2018 **Federal Register** (83 FR 50838). Those review requirements do not apply to this action because it is a withdrawal and does not contain any new or amended requirements.

V. Congressional Review Act (CRA)

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule 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**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). Section 808 of the CRA allows the issuing agency to make a rule effective sooner than otherwise provided by CRA if the agency makes a good cause finding that notice and public procedure is impracticable, unnecessary, or contrary to the public interest. As required by 5 U.S.C. 808(2), this determination is supported by a brief statement in Unit III.

List of Subjects

40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: November 30, 2018.

Lance Wormell,

Acting Director, Chemical Control Division, Office of Pollution Prevention and Toxics.

Accordingly, the amendments to 40 CFR parts 9 and 721 published on October 10, 2018 (83 FR 50838), are withdrawn effective December 10, 2018.

[FR Doc. 2018–26686 Filed 12–6–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–HQ–SFUND–1990–0011; FRL–9987–05–Region 5]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List: Partial Deletion of the Beloit Corporation Superfund Site

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) Region 5 announces the partial deletion of all media at the 20-acre Former Research Center Property of the Beloit Corporation Superfund Site (Site), in Rockton, Illinois 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 remainder of the Site will remain on the NPL and is not being considered for deletion as part of this action. EPA and the State of Illinois through the Illinois Environmental Protection Agency (IEPA), have determined that all appropriate response actions under CERCLA, other than operation and maintenance, monitoring and five-year reviews, have been completed. However, the deletion of this parcel does not preclude future actions under Superfund.

DATES: This action is effective December 7, 2018.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–HQ–SFUND–1990–0011. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information may not be 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 *https://www.regulations.gov* or in hard copy at the site information repositories. Locations, contacts, phone numbers and viewing hours are:

U.S. Environmental Protection Agency, Region 5, Superfund Records Center, 77 West Jackson Boulevard, 7th Floor South, Chicago, IL 60604, Phone: (312) 886–0900, Hours: Monday through Friday, 8 a.m. to 4 p.m., excluding Federal holidays.

Talcott Free Library, 101 East Main Street, Rockton, IL 61072, Phone: (815) 624–7511, Hours: Monday, Tuesday and Thursday, 9:00 a.m. to 8:00 p.m., Wednesday and Friday 9 a.m. to 5:30 p.m., and Saturday 9 a.m. to 3 p.m.

FOR FURTHER INFORMATION CONTACT: Randolph Cano, NPL Deletion Coordinator, U.S. Environmental Protection Agency Region 5 (SR–6J), 77 West Jackson Boulevard, Chicago, IL 60604, (312) 886–6036, or via email at *cano.randolph@epa.gov.*

SUPPLEMENTARY INFORMATION: The portion of the Beloit Corporation (Beloit Corp.) Site to be deleted from the NPL is the Former Beloit Corp. Research Center Property, PIN 03–12–452–003, located at 1155 Prairie Hill Road, in Rockton, Illinois. A Notice of Intent for Partial Deletion for the Beloit Corp. Site was published in the **Federal Register** on July 16, 2018 (83 FR 32825). A Direct final rule approving the deletion was concurrently published in the **Federal Register** (83 FR 32798). The partial deletion was to automatically take effect on September 14, 2018, if no adverse public comments were received.

EPA was required to withdraw the Direct final rule of July 16, 2018 (83 FR 32826), effective September 14, 2018, to prevent the Direct final rule from taking effect, because EPA did not provide timely notice of the publication of the Direct final rule through publication of an advertisement in a local newspaper as required by EPA policy.

The closing date for comments on the Notice of Intent for Partial Deletion as published in the Notice was August 15, 2018. EPA informally extended the public comment period until October 15, 2018, through advertisements published in two local newspapers, The Rockton Hearld and The Rockford Register Star on September 13, 2018.

EPA received one public comment on the partial deletion. Upon review of the comment, EPA finds that the comment is not related to the rule-making, is not site-specific and, as such, is not adverse. Therefore, EPA Region 5 is proceeding with the partial deletion of the Beloit Corp. Site. EPA prepared a memorandum responding to the public comment and placed the memorandum in the docket, EPA–HQ–SFUND–1990–0011, on *www.regulations.gov,* and in the local information repositories listed above.

EPA maintains the NPL as the list of sites that appear to present a significant risk to public health, welfare, or the environment. Deletion of a site 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 portions 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: October 29, 2018.

Cathy Stepp,

Regional Administrator, Region 5.

For the 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 ''IL'', ''Beloit Corp.'', ''Rockton'' to read as follows:

Appendix B to Part 300—[Amended]

TABLE 1—GENERAL SUPERFUND SECTION

State	Site name	City/county	Notes ([a])
*	*	*	*
IL	Beloit Corp	Rockton	* P
*	*	*	*

([a]) * * *
* P = Sites with partial deletion(s).

[FR Doc. 2018–26480 Filed 12–6–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–HQ–SFUND–1987–0002; FRL–9987–16–Region 5]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List: Deletion of the Tomah Armory Landfill Superfund Site

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) Region 5 is publishing a direct final Notice of Deletion of the Tomah Armory Landfill Superfund Site (Tomah Armory Site), located in Tomah, Wisconsin, 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). This direct final deletion is being published by EPA with the concurrence of the State of Wisconsin, through the Wisconsin Department of Natural Resources (WDNR), because EPA has determined that all appropriate response actions under CERCLA, other than operation and maintenance, monitoring and five-year reviews, have been completed. However, this deletion does not preclude future actions under Superfund.

DATES: This direct final deletion is effective February 5, 2019 unless EPA receives adverse comments by January 7, 2019. If adverse comments are received, EPA will publish a timely withdrawal of the direct final deletion in the **Federal Register** informing the public that the direct final deletion will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–SFUND–1987–0002, by one of the following methods: *https://www.regulations.gov.* Follow the on-line instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www2.epa.gov/dockets/commenting-epa-dockets.*

Email: cano.randolph@epa.gov.

Mail: Randolph Cano, NPL Deletion Coordinator, U.S. Environmental Protection Agency Region 5 (SR–6J), 77 West Jackson Boulevard, Chicago, IL 60604, (312) 886–6036.

Hand deliver: Superfund Records Center, U.S. Environmental Protection Agency Region 5, 77 West Jackson Boulevard, 7th Floor South, Chicago, IL 60604, (312) 886–0900. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information. The normal business hours are Monday through Friday, 8 a.m. to 4 p.m., excluding Federal holidays.

Instructions: Direct your comments to Docket ID no. EPA–HQ–SFUND–1987–0002. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (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. The *https://www.regulations.gov* website is an ''anonymous access'' system, which means 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 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, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the *https://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statue. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *https://www.regulations.gov* or in hard copy at:

U.S. Environmental Protection Agency, Region 5, Superfund Records Center, 77 West Jackson Boulevard, 7th Floor South, Chicago, IL 60604, Phone: (312) 886–0900, Hours: Monday through Friday, 8 a.m. to 4 p.m., excluding Federal holidays.

Tomah Public Library, 716 Superior Avenue, Tomah, WI 54660, Phone: (608) 374–7470. Hours: Monday through Wednesday, 9 a.m. to 8 p.m., Thursday through Saturday, 9 a.m. to 5 p.m., Sunday, 1 p.m. to 5 p.m.

FOR FURTHER INFORMATION CONTACT:

Randolph Cano, NPL Deletion Coordinator, U.S. Environmental Protection Agency Region 5 (SR–6J), 77 West Jackson Boulevard, Chicago, IL 60604, (312) 886–6036, or via email at *cano.randolph@epa.gov.*

SUPPLEMENTARY INFORMATION:

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I. Introduction
II. NPL Deletion Criteria
III. Deletion Procedures
IV. Basis for Site Deletion
V. Deletion Action

I. Introduction

EPA Region 5 is publishing this direct final Notice of Deletion of the Tomah Armory Site, from the NPL. The NPL constitutes Appendix B of 40 CFR part 300, which is the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), which EPA promulgated pursuant to Section 105 of the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) of 1980, as amended. EPA maintains the NPL as the list of sites that appear to present a significant risk to public health, welfare, or the environment. Sites on the NPL may be the subject of remedial actions financed by the Hazardous Substance Superfund (Fund). As described in 40 CFR 300.425(e)(3) of the NCP, sites deleted from the NPL remain eligible for Fund-financed remedial actions if future conditions warrant such actions.

Section II of this document explains the criteria for deleting sites from the NPL. Section III discusses procedures that EPA is using for this action. Section IV discusses the Tomah Armory Site and demonstrates how it meets the deletion criteria. Section V discusses EPA's action to delete the Tomah Armory Site from the NPL unless adverse comments are received during the public comment period.

II. NPL Deletion Criteria

The NCP establishes the criteria that EPA uses to delete sites from the NPL. In accordance with 40 CFR 300.425(e), sites may be deleted from the NPL where no further response is appropriate. In making such a determination pursuant to 40 CFR 300.425(e), EPA will consider, in consultation with the state, whether any of the following criteria have been met:

i. Responsible parties or other persons have implemented all appropriate response actions required;

ii. all appropriate Fund-financed response under CERCLA has been implemented, and no further response action by responsible parties is appropriate; or

iii. the remedial investigation has shown that the release poses no significant threat to public health or the environment and, therefore, the taking of remedial measures is not appropriate.

Pursuant to CERCLA Section 121(c) and the NCP, EPA conducts five-year reviews to ensure the continued protectiveness of remedial actions where hazardous substances, pollutants, or contaminants remain at a site above levels that allow for unlimited use and unrestricted exposure. EPA conducts such five-year reviews even if a site is deleted from the NPL. EPA may initiate further action to ensure continued protectiveness at a deleted site if new information becomes available that indicates it is appropriate. 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.

III. Deletion Procedures

The following procedures apply to deletion of the Tomah Armory Site:

(1) EPA consulted with the State of Wisconsin prior to developing this direct final Notice of Deletion and the Notice of Intent to Delete co-published today in the ''Proposed Rules'' section of the **Federal Register**.

(2) EPA has provided the State 30 working days for review of this notice and the parallel Notice of Intent to Delete prior to their publication today, and the State, through the WDNR, has concurred on the deletion of the Tomah Armory Site from the NPL.

(3) Concurrently with the publication of this direct final Notice of Deletion, a notice of the availability of the parallel Notice of Intent to Delete is being published in a major local newspaper, the Tomah Monitor-Herald. The newspaper advertisement announces the 30-day public comment period concerning the Notice of Intent to Delete the Tomah Armory Site from the NPL.

(4) The EPA placed copies of documents supporting the proposed deletion in the deletion docket and made these items available for public inspection and copying at the Tomah Armory Site information repositories identified above.

(5) If adverse comments are received within the 30-day public comment period on this deletion action, EPA will publish a timely notice of withdrawal of this direct final Notice of Deletion before its effective date and will prepare a response to comments and continue with the deletion process on the basis of the Notice of Intent to Delete and the comments already received.

Deletion of a site from the NPL does not itself create, alter, or revoke any individual's rights or obligations. Deletion of a site from the NPL does not in any way alter EPA's right to take enforcement actions, as appropriate. The NPL is designed primarily for informational purposes and to assist EPA management. Section 300.425(e)(3) of the NCP states that the deletion of a site from the NPL does not preclude eligibility for future response actions, should future conditions warrant such actions.

IV. Basis for Site Deletion

The following information provides EPA's rationale for deleting the Tomah Armory Site from the NPL:

Site Background and History

The Tomah Armory Site (CERCLS ID: WID980610299) is approximately 9.6

acres and is located in the northeastern section of the City of Tomah, Monroe County, Wisconsin. The Tomah Armory Site is bordered on the north by the former City of Tomah sewage disposal and treatment facility, to the east by Mill Street and a residential area, to the south by Arthur Street and a mixed use residential and business area, and to the west by Woodard Avenue, which separates the Tomah Armory Site from open fields and an apartment complex. The original landfill area covered the majority of the Armory property, a portion of the former City of Tomah sewage treatment plant property, a portion of a former museum property which is currently commercial, and a small area west of Woodard Avenue. See Tomah Armory Site Map, Docket Document ID No. EPA–HQ–SFUND–1987–0002–0389 in the Docket.

The City of Tomah owned the Tomah Armory Site property until 1968. The City used the Tomah Armory Site as a landfill from 1950 until sometime between 1955 and 1960. Waste disposal methods consisted of excavating six to eight feet of surface soil, disposing waste in the excavated area, covering the waste with previously excavated topsoil, and final grading. Some of the material disposed in the landfill may have been burned before it was buried. Records regarding the types (residential, commercial, or industrial) and quantities of landfilled waste are not available.

The Wisconsin Army National Guard (WIARNG) purchased 5.9 acres of the Tomah Armory Site in July of 1968 to support WIARNG activities associated with the administration, logistical support, and readiness of the unit. Prior to the purchase of the property by WIARNG, a portion of the landfill was excavated and disposed of off-site to construct the Armory building. Subsequently, several additional areas of the landfill were excavated. These areas included: An area west of Woodard Avenue, the northern 100 feet of a former telephone museum property in the southwest corner of the Tomah Armory Site deeded to WIARNG in 1997, and for a southern expansion of the Armory building. Excavated areas were filled and graded and seeded, or built over.

WDNR and EPA inspected the Tomah Armory Site in 1984 to obtain information about past waste disposal activities at the Tomah Armory Site. EPA prepared a Site Inspection Report in 1984 and scored the Tomah Armory Site using EPA's Hazard Ranking System. EPA's primary concern in the Tomah Armory Site Inspection Report was the potential for groundwater contamination and contaminated water supplies due to waste disposal into an unlined landfill.

EPA proposed the Tomah Armory Site to the NPL on January 22, 1987 (52 FR 2492). EPA finalized the Tomah Armory Site on the NPL on July 22, 1987 (52 FR 27620), effective August 21, 1987.

Current land use and occupants of the Tomah Armory Site include WIARNG (6.6 acres), a commercial property in the southwest corner of the Tomah Armory Site (1.717 acres) and the Tomah Fire Department (0.91 acres). Two residential properties are located in the southeast corner of the Tomah Armory Site (0.13 and 0.24 acres), however, these properties are not located within the landfilled area.

The landfilled area north of the Tomah Armory Site, which was the location of the former Tomah sewage disposal and wastewater treatment plant, is owned by the City of Tomah and is zoned as ''other''. A recreational path for pedestrians and non-motorized bicycles runs along the northern portion of the City's property adjacent to the South Fork Lemonweir River.

Remedial Investigation (RI) and Feasibility Study (FS)

EPA conducted a Phase I Remedial Investigation (RI) at the Tomah Armory Site in 1993 in cooperation with WDNR and the United States Geological Survey. The purpose of the Phase I RI was to collect groundwater and soil samples to characterize the nature and extent of contamination and evaluate associated risks. The results of the Phase I RI determined there was a need for additional data. WIARNG conducted a Phase II RI from 1995 to 1997.

The Phase I and II RI involved the sampling and analysis of groundwater, air, and surface and subsurface soil. The RI included groundwater sampling at residential wells and groundwater monitoring wells around the Tomah Armory Site. Surface and subsurface soil samples were collected within the landfill area and outside the landfill to determine background conditions.

The RI included a geophysical investigation. The geophysical investigation consisted of a magnetic survey and an electromagnetic survey. The results of the geophysical investigation and the data collected from the soil borings and test pits were used to determine the approximate boundaries of the landfill, shown in the Tomah Armory Site Map, Docket Document ID No. EPA–HQ–SFUND–1987–0002–0839 in the Docket.

The Phase I groundwater investigation identified inorganic groundwater contaminants inside the boundaries of the landfill. The concentration of lead exceeded the Federal action level (AL) for lead of 15 micrograms/liter (μg/L). EPA also detected lead in a groundwater monitoring well at one location outside the boundary of the landfill at a concentration slightly above the AL.

Phase II groundwater sampling performed outside the boundaries of the landfill in 1995 and 1996 did not detect lead in any wells above the AL. Multiple rounds of groundwater sampling performed at the Tomah Armory Site in 1999, 2000, 2001, 2010 and 2011 confirmed that lead levels outside the boundaries of the landfill are well below the AL.

The RI identified organic groundwater contamination at the Tomah Armory Site from a source upgradient of the landfill. The Phase I sampling detected trichloroethene (TCE) in groundwater below the landfill at concentrations above the Maximum Contaminant Level (MCL) for TCE of 5 μg/L. The Phase II sampling confirmed the presence of TCE, and detected TCE and other organic contaminants outside the boundaries of the landfill in upgradient wells at greater concentrations. Based on this, EPA determined that the organic groundwater contamination detected at the Tomah Armory Site was not site-related.

EPA evaluated the threats to human health and the environment posed by the Tomah Armory Site from ingestion and/or direct contact with contaminants in surface and subsurface soil. The contaminants of concern were benzo(a)pyrene (BAP) and lead in surface soil, and BAP, beryllium, chromium, arsenic and lead in subsurface soil.

Exposure to surface and subsurface soil did not pose any unacceptable risks. The calculated risks from exposure to surface soil were within EPA's acceptable range for cancer risk (10^{-4} to 10^{-6}) under a residential use scenario, and the calculated exposure point concentrations of lead in surface soil were below EPA's residential soil screening levels. None of the subsurface soil contaminants exceeded risk-based concentrations for non-carcinogenic effects or the cancer risk range. Subsurface soil exposure point concentrations for lead were above EPA's residential soil screening level of 400 milligrams/kilogram (mg/kg), but were below the site-specific industrial risk-based concentration for lead in surface soil of 36,000 mg/kg calculated using the adult lead cleanup model and assuming an exposure frequency of 28 days/year at the Tomah Armory Site.

The risk assessment noted that waste material underlay the surface of the

Tomah Armory Site and that groundwater under the landfill did not meet the AL level for lead. The concentrations of lead outside the landfill, however, did not exceed the AL, and the organic groundwater contamination detected in groundwater below the landfill was due to an upgradient source.

The Tomah Armory Site property and the City of Tomah are served by municipal water service. Given that the municipal water supply system had adequate capacity for expansion, EPA concluded that any potential future on-site development would also use municipal water.

Selected Remedy

EPA determined that the contamination at the landfill did not pose any significant risks to human health or the environment under current or reasonably anticipated future land use based upon the results of the Tomah Armory Site investigations and risk assessment. Additionally, institutional controls (ICs) to prevent inappropriate land and groundwater use at the Tomah Armory Site were already in place in the form of restrictive covenants enforceable by the WDNR.

EPA determined that remedial action at the Tomah Armory Site was not warranted, and recommended no action for the Tomah Armory Site. EPA proposed, however, that additional groundwater monitoring be conducted to ensure that groundwater conditions continued to pose no significant risk. EPA issued a Record of Decision (ROD) for no action with groundwater monitoring for the Tomah Armory Site on September 23, 1997.

EPA executed an Explanation of Significant Differences (ESD) modifying the Tomah Armory Site remedy in September 2014. The purpose of the ESD was to document EPA's decision to formally incorporate ICs as part of the remedy and to modify the requirement for groundwater monitoring.

The ESD noted the ICs that were already in place at the Tomah Armory Site, and added additional ICs in the form of Wisconsin Continuing Obligations regulations and a Long-Term Stewardship (LTS) Plan to the selected remedy. The ESD also changed the groundwater monitoring component of the remedy from being ''required'' to being conducted ''as needed''.

Response Actions

WIARNG conducted seven rounds of post-ROD groundwater monitoring at the Tomah Armory Site from May 1999 through April 2011. WIARNG collected the groundwater samples from six monitoring locations around the Tomah Armory Site during the first six rounds of sampling, and follow-up groundwater sampling at three locations during the last round of sampling. WIARNG analyzed the groundwater samples for dissolved lead.

None of the groundwater samples exceeded the lead AL of 15 μg/L. Most of the groundwater monitoring results were at or below the detection limit. The highest value observed was 4.1 μg/L in 2010 at groundwater monitoring well MW–3. WIARNG resampled MW–3 in 2011 and did not detect any lead.

WIARNG collected, analyzed and reviewed all groundwater monitoring data in accordance with the Quality Assurance Project Plan for the Tomah Armory and Tomah Fairgrounds Remedial Investigation (U.S. Environmental Protection Agency, June 1993).

WIARNG conducted a landfill cap evaluation in November 2010. The purpose of the evaluation was to assess areas of potential settlement and areas of potential contamination and stressed vegetation. WIARNG did not find any evidence of settlement or visible contamination in the paved or gravel covered areas of the Tomah Armory Site. WIARNG did not find any evidence of exposed refuse on the surface of the Tomah Armory Site or across the alleyway to the west. There were several areas of stressed vegetation in lawn-covered areas on the west side of the Tomah Armory Site. WIARNG personnel maintain the Tomah Armory Site by mowing the property, filling the occasional depression, and re-seeding areas of stressed vegetation as needed.

WIARNG requested EPA's concurrence with WDNR's recommendations to abandon the remaining monitoring wells around the Tomah Armory Site in December 2015. EPA reviewed WIARNG's request and concurred with removing the wells in April 2016. WIARNG properly abandoned the groundwater monitoring wells in June 2016.

WIARNG completed a Remedial Action (RA) Report in August 2016. The RA Report documents the successful implementation of the Landfill Cap Maintenance Plan and the Institutional Control Plan (ICP), including a Long-Term Stewardship (LTS) Plan for the Tomah Armory Site. A copy of the Landfill Cap Maintenance Plan, the ICP and the LTS Plan are included in Attachment 1 and Appendix H of the 2016 RA Report.

EPA completed a Final Close Out Report (FCOR) documenting the completion of all appropriate response actions at the Tomah Armory Site on February 7, 2018.

Cleanup Levels

The Tomah Armory Site ROD is a no-action ROD with groundwater monitoring and does not establish any cleanup levels for soil or groundwater. During monitoring, EPA compared detected concentrations of lead in the groundwater to the Federal AL and Wisconsin Administrative Code (WAC) Natural Resources (NR) Chapter 140 limit for lead of 15 μg/L.

Eight rounds of groundwater samples collected from six groundwater monitoring locations around the Tomah Armory Site from 1995 to 2010, and a follow-up round of sampling at three wells in 2011, did not detect any lead concentrations above the AL for lead. The majority of the lead results were at or below the detection limit. The highest observed values for lead were 4.7 μg/L at MW–4 in 1996 and 4.1 μg/L in MW–3 in 2010.

Subsequent groundwater samples collected from MW–4 from 1999 to 2010 and from MW–3 in 2010 did not contain lead. The results of the groundwater monitoring confirm that EPA's no action remedy for the Tomah Armory Site selected in the 1997 ROD, as modified by the 2014 ESD, is appropriate. A summary of the groundwater monitoring data for the Tomah Armory Site is provided in Table 3 of the 2018 FCOR, Docket Document ID No. EPA–HQ–SFUND–1987–0002–0384 in the Docket.

Operation and Maintenance

WIARNG conducts operation and maintenance (O&M) in accordance with the Landfill Cap Maintenance Plan and the ICP and LTS Plan. WIARNG inspects the Tomah Armory Landfill annually, at a minimum. WIANRG mows and maintains the property throughout the year, and addresses maintenance issues such as filling occasional depressions, re-seeding areas of stressed vegetation, and evaluating the landfill cap for subsidence. If subsidence is observed indicating possible degradation of the landfill cap, the cap will be evaluated and potential problems addressed as soon as possible. Property owners must contact WDNR at least 45 days prior to making any removal, replacement or changes to the landfill cap.

The remedy for the Tomah Armory Site includes ICs to ensure long term protectiveness to human health and the environment. Several types of proprietary and government controls including deed restrictions, zoning, municipal ordinances, and Wisconsin state regulations are in place to provide

multiple layers of protection at the Tomah Armory Site.

Declarations of Restrictions are implemented on the four properties where the majority of the historical extent of the landfill is located. These include parcels 286–00061–0000 and 286–00059–2000 owned by WIARNG (armory property), 286–02710–0000 owned by the City of Tomah (former waste water treatment plant/current bike path property), and the commercial property in the southwest corner of the Tomah Armory Site (286–00059–0000). See Tomah Armory Site Map, Docket Document ID No. EPA–HQ–SFUND–1987–0002–0389 in the Docket.

The deed restrictions subject the owner to the following limitation and restrictions unless prior written approval is obtained from the Wisconsin Department of Natural Resources or its successor: (1) Excavating or grading of the land surface, (2) filling on the capped area, (3) plowing for agricultural cultivation, and (4) construction or installation of a building or other structure with a foundation that would sit on, or be placed within, the cap or which would interfere with the existing cap. Copies of the Declarations of Restrictions are available in Appendix G of the 2016 RA Report, Docket Document ID No. EPA–HQ–SFUND–1987–0002–0383 in the Docket.

Other implemented ICs include zoning, municipal ordinances and state regulations. Current zoning prohibits residential use of the landfill area. The armory property is zoned X2, state; the city property to the north and the Fire Department property are zoned X4, other; and the parcel to the southwest is zoned G2, commercial. Two Tomah Armory Site properties in the southeast corner of the Tomah Armory Site are zoned for residential use, however, these properties are outside the limits of the landfill. Tomah Armory Site zoning designations are shown in Figure 3 of the 2016 RA Report, Docket Document ID No. EPA–HQ–SFUND–1987–0002–0383 in the Docket.

A zoning district designation may be changed; however, this requires a petition for change to be filed with the city clerk and reviewed by the planning commission. A recommendation by the planning commission is then given to the city council, and requires a public hearing prior to the zoning change.

Tomah City Ordinance Section 46–101 restricts the installation and use of private wells and cross connections between municipal well lines and private wells. Private wells located on parcels served by the City municipal water supply were also to be properly abandoned by January 1, 1989 (Tomah Ordinance Section 46–529).

Private well operation is allowable in the city with a Well Operation Permit if the well meets the requirements of Tomah Ordinance Section 46–530. One of the requirements for obtaining a Well Operation Permit is that the well and pump installation meet the requirements of Chapter NR 812 of the WAC. The proposed well would also have to be necessary, considering the mandatory Tomah water supply system (Tomah Ordinance Section 46–50). Permits are also considered an Enforcement and Permit Tool control.

Well head protection areas are delineated for all City of Tomah municipal wells. The City of Tomah enacted a Wellhead Protection Ordinance that prohibits the issuance of a well operation permit for a 200-foot radius around the Tomah Armory Site (Tomah Ordinance Section 46–531; Code 1993, § 13.37(3)).

Changes and amendments to zoning district designations are governed by Tomah Ordinance Section 52–256. City of Tomah Ordinances apply to parcels within the municipal boundaries. Copies of pertinent ordinances are available in Appendix D in the 2016 RA Report, Docket Document ID No. EPA–HQ–SFUND–1987–0002–0383 in the Docket.

The State of Wisconsin through the WAC specifies the regulations applicable to waters of the state and land use. WDNR regulates the design and operation of municipal water systems through Chapter NR 811 WAC. Section NR 811.06 WAC prohibits unprotected cross-connections and Section NR 811.07 WAC prohibits interconnections between public water supply systems and other sources of water unless permitted by WDNR.

Chapter NR 812 WAC regulates construction and installation of new and existing water systems and drill holes (excepting certain monitoring wells, community water systems, and nonpotable surface water systems). Section NR 812.08 WAC (Table A) specifies a minimum separation distance between potable and nonpotable wells, reservoirs, springs, and landfills. This distance is measured from the nearest fill area, if known, otherwise to the property line. The 1,200-foot set-back distance for the Tomah Armory Site is indicated on Figure 4 in the RA Report, Docket Document ID No. EPA–HQ–SFUND–1987–0002–0383 in the Docket.

Chapter NR 504 WAC regulates landfill location, performance, design, and construction. Specifically, Section NR 504.07(9) prohibits the use of covered landfill sites which are no longer in operation for agricultural use, the establishment of construction of any buildings over the waste disposal area, or excavation of the final cover of any waste materials. A copy of the relevant state regulations for the Tomah Armory Site is provided in Appendix E of the RA Report, Docket Document ID No. EPA–HQ–SFUND–1987–0002–0383 in the Docket.

Five Year Review

The Tomah Armory Site requires statutory five-year reviews (FYRs) because hazardous substances remain at the Tomah Armory Site above levels that allow for unrestricted use and unlimited exposure. EPA conducted FYRs of the Tomah Armory Site in 2001, 2006, 2011, and 2016.

EPA's most recent FYR of the Tomah Armory Site, in August 2016, determined that the remedy at the Tomah Armory Site is protective of human health and the environment. The remedy is functioning as intended, groundwater standards continue to be met, there has been compliance with groundwater and land use restrictions on the property, and no incompatible groundwater or land use has occurred at the Tomah Armory Site. ICs that restrict groundwater use and the disturbance of the cap and buried waste remain in place, and are effectively monitored and maintained through the implementation of the ICP, which includes a LTS Plan.

The FYR did not identify any issues or recommendations that would affect the current or future protectiveness of the remedy for the Tomah Armory Site. The most important tasks to continue are maintaining the landfill cover and ensuring that the ICs remain in place and are effective.

Finally, the FYR recommended deleting the Tomah Armory Site from the NPL.

Community Involvement

EPA satisfied public participation activities for the Tomah Armory Site required in Sections 113(k) and 117 of CERCLA, 42 U.S.C. 9613(k) and 9617. EPA hosted a ''kick-off'' public meeting for the Tomah Armory Site in July 1993 at the Tomah City Hall Council Chambers. During the meeting, EPA informed local residents about the Tomah Armory Site, the Superfund process and the work to be performed as part of the RI.

EPA established an information repository for the Tomah Armory Site in 1993 at the Tomah Public Library, 716 Superior Avenue, Tomah, Wisconsin 54660. EPA maintains a copy of the administrative record documents for the

Tomah Armory Site in the information repository and at EPA's Region 5 office.

EPA released the RI Report to the public in April 1997. EPA made its Proposed Plan for cleaning up the Tomah Armory Site available to the public on July 22, 1997. EPA held a public meeting on August 18, 1997 to discuss the RI and EPA's Proposed Plan. EPA placed advertisements in local newspapers announcing EPA's proposed cleanup plan for the Tomah Armory Site, the public meeting and the comment period.

EPA held a public comment period on its Proposed Plan from July 25, 1997 to August 25, 1997. The public generally supported the selected remedy. EPA considered the public comments received during the public meeting and public comment period prior to selecting a final remedy for the Tomah Armory Site in the ROD. EPA's responses to the comments received are included in a Responsiveness Summary, which is part of the ROD. EPA also placed a copy of the 2014 ESD in the information repositories for the Tomah Armory Site.

EPA placed advertisements announcing the FYRs for the Tomah Armory Site in local newspapers including the Tomah Monitor-Herald (November 27, 2006 and November 23, 2015), the Tomah Journal (November 30, 2006 and February 2011), and the Tri-County Foxxy Shopper East Edition (November 27, 2006). EPA made the results of the FYRs available at the Tomah Armory Site information repositories and at the following website: *http://www.epa.gov/superfund/tomah-armory.*

EPA arranged to publish an advertisement announcing the publication of this proposed direct final Notice of Deletion in the Tomah Journal prior to its publication in the **Federal Register**.

Documents in the deletion docket which EPA relied on to support the deletion of the Tomah Armory Site from the NPL are available to the public in the Tomah Armory Site information repositories and at *http://www.regulations.gov.*

Determination That the Tomah Armory Site Meets the Criteria for Deletion From the NCP

The February 7, 2018, Final Close Out Report (FCOR) documents that EPA, the WIARNG and the WDNR have successfully implemented all appropriate response actions at the Tomah Armory Site in accordance with the 1997 EPA Record of Decision (ROD), the 2014 EPA Explanation of Significant Differences (ESD) and the *Guidance for Management of Superfund Remedies in Post Construction* (OLEM Directive 9200.3–105, February 2017), and *Close Out Procedures for National Priorities List Sites* (OLEM Directive 9320.2–22, May, 2011).

Cleanup actions specified in the ROD and ESD for the Tomah Armory Site have been implemented and the Tomah Armory Site meets acceptable risk levels for all media and exposure pathways. The ongoing IC and LTS actions required at the Tomah Armory Site are consistent with EPA policy and guidance.

Groundwater sampling results confirm that the Tomah Armory Site does not pose any threat to human health or the environment. Therefore, the EPA has determined that no further Superfund response is necessary at the Tomah Armory Site to protect human health and the environment.

The NCP (40 CFR 300.425(e)) states that a site may be deleted from the NPL when no further response action is appropriate. EPA, in consultation with the State of Wisconsin, has determined that all required response actions have been implemented at the Tomah Armory Site and that no further response action by the responsible parties is appropriate.

V. Deletion Action

The EPA, with concurrence of the State of Wisconsin through the WDNR, has determined that all appropriate response actions under CERCLA, other than operation and maintenance, monitoring and five-year reviews have been completed. Therefore, EPA is deleting the Tomah Armory Site from the NPL.

Because EPA considers this action to be noncontroversial and routine, EPA is taking it without prior proposal. This action will be effective February 5, 2019 unless EPA receives adverse comments by January 7, 2019. If adverse comments are received within the 30-day public comment period, EPA will publish a timely withdrawal of this direct final notice of deletion before the effective date of the deletion, and it will not take effect. EPA will prepare a response to comments and continue with the deletion process on the basis of the notice of intent to delete and the comments already received. There will be no additional opportunity to comment.

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: October 30, 2018.

Cathy Stepp,

Regional Administrator, Region 5.

For the 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.

Appendix B to Part 300—[Amended]

■ 2. Table 1 of Appendix B to part 300 is amended by removing the entry ''WI'', ''Tomah Armory'', ''Tomah''.

[FR Doc. 2018–26486 Filed 12–6–18; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 0

[MD Docket No. 18–3; FCC 18–7]

Establishment of the Office of Economics and Analytics

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: Establishment of the Office of Economics and Analytics. This action is taken to enhance the role of economic analysis, the design and implementation of auctions, and the use and management of data at the Federal Communications Commission (the Commission or FCC). The Commission determined that the proper dispatch of its business and the public interest will be served by creating an Office of Economics and Analytics (the Office or OEA). In the Order, the Commission amended its Rules to reflect the new organizational structure, describe the Office's functions and delegated authority, and make other conforming changes. The Commission found it appropriate to make these organizational changes to integrate the use of economics and data analysis into the Commission's various rulemakings and other actions in a more comprehensive and thorough manner.

DATES: Effective December 7, 2018.

FOR FURTHER INFORMATION CONTACT: Wayne Leighton, 202–418–0950.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Order, in MD Docket No. 18–3; FCC 18–7, adopted on January 30, 2018 and released on January 31, 2018. The full text of this document is available at *https://docs.fcc.gov/public/attachments/FCC-18-7A1.pdf.* Key objectives of this organizational change are to expand and deepen the use of economic analysis into Commission policy making, to enhance the development and use of auctions, and to implement consistent and effective agency-wide data practices and policies.

The Office will be charged with ensuring that economic analysis is deeply and consistently incorporated into the agency's regular operations, and will support work across the FCC and throughout the decision-making process. Specifically, it will: (A) Provide economic analysis, including cost-benefit analysis, for rulemakings, transactions, adjudications, and other Commission actions; (B) manage the FCC's auctions in support of and in coordination with FCC Bureaus and Offices; (C) develop policies and strategies to help manage the FCC's data resources and establish best practices for data use throughout the FCC in coordination with FCC Bureaus and Offices; and (D) conduct long-term research on ways to improve the Commission's policies and processes in each of these areas.

To accomplish these objectives and functions, the Office of Economics and Analytics will combine economists, attorneys, and data professionals from across the Commission. In particular, we intend for the majority of the Commission's economists currently in multiple Bureaus and Offices to staff the Office of Economics and Analytics.

To accomplish this organizational change, the following actions are taken.

- The Commission will eliminate the Office of Strategic Planning and Policy Analysis (OSP) and generally shift OSP authorities and functions to the Office of Economics and Analytics.
- The Commission will create an Economic Analysis Division within the Office of Economics and Analytics. The Economic Analysis Division will provide analytical and quantitative support as needed to Bureaus and Offices engaged in rulemakings, transactions, auctions, adjudications, and other matters.
- The Commission will create an Industry Analysis Division within the Office of Economics and Analytics. To accomplish this, the Commission will generally shift the functions of the Industry Analysis and Technology Division of the Wireline Competition Bureau (WCB) to OEA. Through its Industry Analysis Division, OEA will serve as the Commission's principal resource with regard to designing and administering significant, economically-relevant data collections used by a variety of Bureaus and Offices, providing support to Bureaus and Offices with respect to these data collections as well as support using the data for Continuity of Operations (COOP)/Emergency Response Group (ERG)/Incident Management Team (IMT), and performing analyses and studies.
- The Commission will create an Auctions Division within the Office of Economics and Analytics. To accomplish this, the Commission will generally shift the functions of the Auctions and Spectrum Access Division in the Wireless Telecommunications Bureau (WTB) to OEA. Through its Auctions Division and in consultation with WTB and WCB, OEA will serve as the Commission's principal resource with regard to all auction design and implementation issues. OEA will collaborate with other Bureaus involved in establishing and conducting auctions, such as spectrum or universal service auctions.
- The Commission will create a Data Division within the Office of Economics and Analytics. The Data Division will help develop and implement best practices, processes, and standards for data management in order to meet the needs of Commission staff who rely on data to inform policymaking and other core activities of the Commission.

Paperwork Reduction Act

This document does not contain new or modified information collection requirements subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. In addition, therefore, it does not contain any new or modified information collection burden for small business concerns with fewer than 25 employees, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4).

Congressional Review Act

The Commission will not send a copy of this Order pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A), because the adopted rules of agency organization, procedure, or practice that do not ''substantially affect the rights or obligations of non-agency parties.''

The amendments adopted herein pertain to agency organization, procedure, and practice. Consequently, the notice and comment and effective date provisions of the Administrative Procedure Act contained in 5 U.S.C. 553(b) and (d) do not apply.

Consistent with the Consolidated Appropriations Act, 2017, this reorganization will not become effective until the appropriate clearance has been obtained, and the Order has thereafter been published in the **Federal Register**.

Ordering Clauses

Accordingly, *it is ordered that*, pursuant to sections 1, 4, 5(b), 5(c), 201(b), and 303(r) of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154, 155(b), 155(c), 201(b), 303(r), this Order *is adopted*.

It is further ordered that part 0 of the Commission rules *is amended* as set forth in the Final Rules section.

It is further ordered that this Order *will become effective* December 7, 2018 in accordance with paragraph 7 of the Order (MD Docket No. 18–3; FCC 18–7, adopted on January 30, 2018 and released on January 31, 2018).

List of Subjects in 47 CFR Part 0

Classified information, Freedom of information, Government publications, Infants and children, Organization and functions (Government agencies), Postal Service, Privacy, Reporting and recordkeeping requirements, Sunshine Act.

Federal Communications Commission.

Katura Jackson,

Federal Register Liaison Officer, Office of the Secretary.

Final Rules

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR part 0 as follows:

PART 0—COMMISSION ORGANIZATION

■ 1. The authority citation for part 0 continues to read as follows:

Authority: Secs. 5, 48 Stat. 1068, as amended; 47 U.S.C. 155, 225, unless otherwise noted.

■ 2. Amend § 0.5 by revising paragraph (a)(4) to read as follows:

§ 0.5 General description of Commission organization and operations.

(a) * * *

(4) Office of Economics and Analytics.

* * * * *

■ 3. Revise § 0.21 and the undesignated center heading immediately preceding it to read as follows:

Office of Economics and Analytics

§ 0.21 Functions of the Office.

The Office of Economics and Analytics advises and makes recommendations to the Commission in the areas of economic and data analysis and data management policy. The Office reviews all Commission actions involving significant economic or data analysis and provides expertise, guidance, and assistance to the Bureaus and other Offices in applying the principles of economic and data analysis. The Office coordinates the Commission's research and development activities relating to economic and data analysis and data management policy. In addition, the Office serves, in close coordination with other relevant Bureaus and Offices, as a principal resource for policy and administrative staff of the Commission with regard to the design, implementation, and administration of auctions. The Office also establishes and implements Commission data management policies in conjunction with the relevant Bureaus and Offices and with the Office of Managing Director and Office of General Counsel. The Office of Economics and Analytics has the following duties and responsibilities:

(a) Identifies and evaluates significant communications policy issues, based on the principles and methods of economics and data analysis.

(b) Collaborates with and advises other Bureaus and Offices in the areas of economic and data analysis and with respect to the analysis of benefits, costs, and regulatory impacts of Commission policies, rules, and proposals.

(c) Prepares a rigorous, economically-grounded cost-benefit analysis for every rulemaking deemed to have an annual effect on the economy of $100 million or more.

(d) Confirms that the Office of Economics and Analytics has reviewed each Commission rulemaking to ensure it is complete before release to the public.

(e) Reviews and comments on all significant issues of economic and data analysis raised in connection with actions proposed to be taken by the Commission and advises the Commission regarding such issues.

(f) Develops, recommends, and implements data management policies in conjunction with the Office of Managing Director, the Office of General Counsel, and relevant Bureaus and Offices, and collaborates with and advises other Bureaus and Offices with respect to data management and data analysis.

(g) Manages the Commission's economic and data analysis research programs, recommends budget levels and priorities for these programs, and serves as central account manager for all contractual economic and data analysis research studies funded by the Commission.

(h) Conducts economic, statistical, cost-benefit, and other data analysis of the impact of existing and proposed communications policies and operations, including cooperative studies with other staff units and consultant and contract efforts as appropriate.

(i) Coordinates the Commission's evaluation of government (state and federal), academic, and industry-sponsored research affecting Commission policy.

(j) Coordinates with other Bureaus and Offices in making recommendations to the Commission on communications policy issues that involve economic and data analysis, to include cost-benefit analysis; represents the Commission at appropriate discussions and conferences.

(k) Develops and recommends procedures and plans for effective economic and data analysis, to include cost-benefit analysis, within the Commission.

(l) Seeks to ensure that FCC policy encourages and promotes competitive markets by providing Bureaus and Offices with the necessary support to identify, evaluate, and resolve competition issues.

(m) In conjunction with the relevant subject matter Bureau, serves as the Commission's principal policy and administrative staff resource with regard to the design, implementation, and administration of auctions and other types of competitive bidding.

(n) Administers Commission spectrum auctions for wireless telecommunications in conjunction with the Wireless Telecommunications Bureau. Administers Commission spectrum auctions for broadcasting in conjunction with the Media Bureau. Works with the Wireless Telecommunications Bureau to develop recommendations to the Commission on policies, programs and rules concerning auctions of spectrum for wireless telecommunications. In conjunction with the Wireless Telecommunications Bureau, Media Bureau, Wireline Competition Bureau, and other relevant Bureaus and Offices, advises the Commission on policy relating to auctions and competitive bidding to achieve other Commission policy objectives. Administers procurement of auction-related services from outside contractors. Provides policy, administrative and technical assistance to other Bureaus and Offices on auction issues.

(o) In conjunction with the Wireline Competition Bureau and Wireless Telecommunications Bureau, provides policy and administrative staff resources for the use of market-based mechanisms, including competitive bidding, to distribute universal service support.

(p) With respect to applicable data and reporting duties assigned to the Office, coordinates with the Public Safety and Homeland Security Bureau and other relevant Bureaus and Offices on all matters affecting public safety, homeland security, national security, emergency management, disaster management, and related issues.

(q) With respect to applicable data and reporting duties assigned to the Office, and in coordination with the Wireline Competition Bureau and the Wireless Telecommunications Bureau, provides federal staff support for the Federal-State Joint Board on Universal Service and the Federal-State Joint Board on Jurisdictional Separations.

(r) In coordination with other relevant Bureaus and Offices, provides economic, financial, and technical analyses of communications markets and provider performance.

(s) In coordination with the Wireline Competition Bureau, provides technical support for *de novo* review of decisions of the Administrative Council for Terminal Attachments regarding technical criteria pursuant to § 68.614.

(t) Prepares briefings, position papers, and proposed Commission actions, as appropriate.

(u) In coordination with other relevant Bureaus and Offices, develops and recommends responses to legislative, regulatory or judicial inquiries and proposals concerning or affecting matters within the purview of its functions.

■ 4. Amend § 0.31 by revising paragraph (g) to read as follows:

§ 0.31 Functions of the Office.

* * * * *

(g) In cooperation with the relevant Bureaus and Offices, including the Office of General Counsel and the Office of Economics and Analytics, to advise the Commission, participate in and coordinate staff work with respect to general frequency allocation proceedings and other proceedings not within the jurisdiction of any single Bureau, and render service and advice

with respect to rule making matters and proceedings affecting more than one Bureau.

* * * * *

■ 5. Amend § 0.91 by revising paragraph (p) to read as follows:

§ 0.91 Functions of the Office.

* * * * *

(p) In coordination with the Office of Economics and Analytics and Wireless Telecommunications Bureau, serves as the Commission's principal policy and administrative staff resource with respect to the use of market-based mechanisms, including competitive bidding, to distribute universal service support. Develops, recommends and administers policies, programs, rules and procedures concerning the use of market-based mechanisms, including competitive bidding, to distribute universal service support.

■ 6. Amend § 0.131 by revising paragraphs (a), (c), and (r) to read as follows:

§ 0.131 Functions of the Bureau

* * * * *

(a) Advises and makes recommendations to the Commission, or acts for the Commission under delegated authority, in all matters pertaining to the licensing and regulation of wireless telecommunications, including ancillary operations related to the provision or use of such services; any matters concerning wireless carriers that also affect wireline carriers in cooperation with the Wireline Competition Bureau; and, in cooperation with the Office of Economics and Analytics, all matters regarding spectrum auctions and, in cooperation with the Wireline Competition Bureau, USF mechanisms affecting wireless carriers. These activities include: Policy development and coordination; conducting rulemaking and adjudicatory proceedings, including licensing and complaint proceedings for matters not within the responsibility of the Enforcement Bureau; acting on waivers of rules; acting on applications for service and facility authorizations; compliance and enforcement activities for matters not within the responsibility of the Enforcement Bureau; determining resource impacts of existing, planned or recommended Commission activities concerning wireless telecommunications, and developing and recommending resource deployment priorities.

* * * * *

(c) Serves as a staff resource, in coordination with the Office of Economics and Analytics, with regard to the development and implementation of spectrum policy through spectrum auctions. Develops, recommends and administers policies, programs and rules concerning licensing of spectrum for wireless telecommunications through auctions. Advises the Commission on policy, engineering and technical matters relating to auctions of spectrum used for other purposes.

* * * * *

(r) In coordination with the Wireline Competition Bureau and the Office of Economics and Analytics, develops and recommends policies, programs, rules and procedures concerning the use of market-based mechanisms, including competitive bidding, to distribute universal service support.

* * * * *

■ 7. Revise § 0.271 and the undesignated center heading immediately preceding it to read as follows:

Office of Economics and Analytics

§ 0.271 Authority delegated.

(a) Insofar as authority is not delegated to any other Bureau or Office, the Chief, Office of Economics and Analytics, is delegated authority to carry out the performance of functions and activities described in § 0.21, provided that the following matters shall be referred to the Commission en banc for disposition:

(1) Notices of proposed rulemaking and of inquiry, final orders in rulemaking proceedings and inquiry proceedings and non-editorial orders making changes, and any reports arising from any of the foregoing;

(2) Any petition, pleading, request, or other matter presenting new or novel questions of fact, law, or policy that cannot be resolved under existing precedents and guidelines; and

(3) Applications for review of actions taken to delegated authority, except that the Chief may dismiss any such application that does not comply with the filing requirements of § 1.115(d) and (f) of this chapter.

(4) Any applications that are in hearing status.

(b) Insofar as authority is not delegated to any other Bureau or Office, and with respect only to matters that are not in hearing status, the Chief, Office of Economics and Analytics, is delegated authority to deny requests for extension of time or to extend the time within which comments may be filed in dockets over which the Office of Economics and Analytics has primary authority.

(c) Insofar as authority is not delegated to any other Bureau or Office, the Chief, Office of Economics and Analytics, is authorized to dismiss or deny petitions for rulemaking that are repetitive or moot or that for other reasons plainly do not warrant consideration by the Commission.

(d) The Chief, Office of Economics and Analytics, is authorized to dismiss or deny petitions for reconsideration to the extent permitted by § 1.429(l) of this chapter and, jointly with the Wireless Telecommunications Bureau, to the extent permitted by § 1.106 of this chapter.

(e) The Chief, Office of Economics and Analytics, is delegated authority to make nonsubstantive, editorial revisions to the Commission's rules and regulations contained in part 1, subparts Q, V, W, and AA, of this chapter.

■ 8. Add § 0.272 to read as follows:

§ 0.272 Record of actions taken.

The application and authorization files and other appropriate files of the Office of Economics and Analytics are designated as the Commission's official records of action of the Chief, Office of Economics and Analytics, pursuant to authority delegated to the Chief. The official records of action are maintained in the Reference Information Center in the Consumer and Governmental Affairs Bureau.

■ 9. Add § 0.273 to read as follows:

§ 0.273 Actions taken under delegated authority.

In discharging the authority conferred by § 0.271, the Chief, Office of Economics and Analytics, shall establish working relationships with other Bureaus and staff Offices to assure the effective coordination of actions taken in the analysis of regulatory impacts, including assessments of paperwork burdens and initial and final regulatory flexibility assessments.

[FR Doc. 2018–26423 Filed 12–6–18; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1 and 96

[GN Docket No. 17–258; FCC 18–149]

Promoting Investment in the 3550–3700 MHz Band

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Federal Communications Commission

(Commission) adopts limited changes to the rules governing Priority Access Licenses (PALs) that will be issued in the 3500–3700 MHz Band (3.5 GHz band)—including larger license areas, longer license terms, renewability, and performance requirements—as well as changes to the competitive bidding rules for the issuance of PALs and to the ability to partition and disaggregate areas within PALs. These changes are consistent with the rules that helped foster the development of 4G and LTE services in the United States, and adopting similar rules in this band will help promote additional investment in the next generation of wireless services. The Commission also adopts changes to the technical rules to facilitate transmissions over wider bandwidth channels without significant power reduction and changes to the information security requirements to better safeguard commercially sensitive information and protect critical infrastructure. These targeted changes will spur additional investment and broader deployment in the band, promote robust and efficient spectrum use, and help ensure the rapid deployment of advanced wireless technologies—including 5G—in the United States.

DATES: *Effective Date:* January 7, 2019.

Compliance Date: Compliance will not be required for § 96.23(a) or for § 96.25(b) or for § 96.32(b) until after approval by the Office of Management and Budget. The Commission will publish a document in the **Federal Register** announcing that compliance date.

FOR FURTHER INFORMATION CONTACT: Jessica Greffenius at *jessica.greffenius@fcc.gov,* of the Wireless Telecommunications Bureau, Mobility Division, (202) 418–2896.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Report and Order* in GN Docket No. 17–258, FCC 18–148 adopted October 23, 2018 and released October 24, 2018. The full text of the *Report and Order,* including all Appendices, is available for inspection and copying during normal business hours in the FCC Reference Center, 445 12th Street SW, Room CY–A157, Washington, DC 20554, or by downloading the text from the Commission's website at *https://docs.fcc.gov/public/attachments/FCC-18-149A1.pdf.* Alternative formats are available for people with disabilities (Braille, large print, electronic files, audio format), by sending an email to *FCC504@fcc.gov* or calling the Consumer and Government Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

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

Synopsis

I. Background

1. In 2015, the Commission adopted rules for shared commercial use of the 3.5 GHz band. It created a three-tiered access and authorization framework to coordinate shared federal and non-federal use of the band. Incumbents comprise the first tier (Incumbent Access) and receive protection from all other users, followed by PALs, the second tier (Priority Access), and General Authorized Access (GAA), the third tier. Over half of the band—a minimum of 80 megahertz—is reserved for GAA use. PALs receive protection from GAA operations but must protect and accept interference from Incumbent Access tier users. GAA is licensed-by-rule and must avoid causing harmful interference to higher tier users and accept interference from all other users, including other GAA users. GAA users can operate throughout the entire 150 megahertz of the 3.5 GHz band on any frequencies not in use by PALs. Automated frequency coordinators, known as Spectrum Access Systems (SASs), will coordinate operations between and among users in different access tiers. The Commission adopted service and technical rules governing the 3.5 GHz band as the new part 96 of its rules.

2. In June 2017, CTIA and T-Mobile filed petitions for rulemaking, which asked the Commission to reexamine several of the part 96 rules related to PALs. CTIA proposed several changes to the PAL licensing rules, including much larger license areas, longer license terms, and renewability. T-Mobile supported CTIA's proposals and made additional proposals, including changes to the amount of spectrum available for PALs and to the technical rules governing the 3.5 GHz band. Both petitioners argued that these requested changes were necessary to promote additional investment to facilitate 5G network deployment in the band. On June 22, 2017, the Wireless Telecommunications Bureau and Office of Engineering and Technology sought comment on the Petitions and on related issues raised in *ex parte* communications, and they received comments and reply comments from more than 120 parties.

3. On October 24, 2017, the Commission issued a *Notice of Proposed Rulemaking* (82 FR 56193, Nov. 28, 2017) (*2017 NPRM*) seeking comment on potential changes to the PAL rules, including significantly larger geographic license areas, longer license terms, PAL renewability, and changes to the way in which PALs are assigned and auctioned. The Commission also sought comment on relaxing the emissions limits for Citizens Broadband Radio Service Devices (CBSDs) and/or End User Devices to allow operation over wider bandwidths without power reduction. The Commission simultaneously adopted an *Order Terminating the Petitions,* in which it declined to seek comment on discrete proposals from T-Mobile's Petition that would have fundamentally altered the sharing framework of the band, including its proposal to reapportion the amount of spectrum available for GAA versus PAL use and designating the entire band for PAL use.

4. The Commission received nearly 200 comments and 40 reply comments in response to the *2017 NPRM,* including from mobile wireless service providers, Wireless Internet Service Providers (WISPs) and other fixed wireless service providers, cable providers, Internet of Things (IoT) providers, energy and utility associations, and consumer groups.

III. Discussion

A. PAL Licensing Rules

1. Geographic Licensing Area

5. *Background.* In the *2015 Report and Order* (80 FR 36164, June 23, 2015), the Commission defined the geographic license area for each PAL as one census tract. In the *2017 NPRM,* the Commission proposed to increase the geographic license area to ''stimulate additional investment, promote innovation, and encourage efficient use of spectrum resources.'' The Commission sought comment on petitioners' specific request to increase the license size to Partial Economic Areas (PEAs), asking whether the larger size and the ability to combine and partition licenses would strike the right balance between supporting targeted deployments and incentivizing additional investment in the band. Noting concerns in the record about whether PEAs would incent diverse auction participants, differing technologies, and rural deployments, the Commission also sought comment on alternative or hybrid approaches, such as licensing PEAs in urban areas and census tracts in rural areas, or

offering PALs of different sizes in each market.

6. Several commenters support increasing the PAL license area significantly, from census tracts to PEAs, as a way to simplify the auction process, reduce interference risks and coordination complications at border areas, and encourage investment by all providers. Other commenters argue that the Commission should retain census tracts as the geographic licensing unit for PALs, arguing that using census tracts would increase the likelihood of localized services reaching rural and underserved areas, and open up PAL auctions to a wider variety of potential users and uses. Other commenters support using county-sized PALs as a compromise between census tracts and PEAs. Some commenters suggest that the Commission rely on a hybrid approach and to adopt multiple, different-sized PAL license areas. After the comment cycle closed, many stakeholders worked to find a hybrid solution for the size of the PAL license area.

7. *Discussion.* After review of the extensive record on this issue and in light of the changed circumstances since adoption of the 2015 rules, the Commission finds that increasing the size of the PAL license area to counties will better serve the public interest.

8. In 2015, the Commission determined that larger license areas were inconsistent with its desire to promote innovative, low power uses in the band, such as small cells, which align well with small, targeted geographic areas, and that census tracts would permit intensive use of the band and support a variety of use cases. The Commission now reassesses these determinations in the wake of the changed technological landscape, with efforts here and abroad to prioritize mid-band spectrum as part of the spectrum portfolio that will support next generation wireless networks, including 5G. While the decision to use census tracts may well support the deployment of targeted use cases—particularly fixed uses—as discussed below, the record shows that census tracts could disadvantage flexible mobile use, including 5G, and other wide-area network deployments, which in turn would decrease investment in the band. Increasing the PAL license area slightly from 714,000 census tracts to about 3,200 counties strikes a more appropriate balance and will more effectively support next generation mobile network deployments, while still retaining the ability to support small, targeted uses, included fixed uses. In contrast, increasing the PAL license area size further (*i.e.,* from 3,200 counties to 416 PEAs) could disproportionately favor mobile use cases and hinder investment in innovative fixed networks and localized deployments. The 3.5 GHz band will be the first mid-band spectrum suited for 5G uses that will be made available domestically, and the band will play a key role as part of the low-, mid-, and high-band spectrum toolkit for 5G uses. While census tracts seemed like an appropriate ''middle ground'' in 2015, since that time, the balance has shifted.

9. *First,* given the increasing importance of mid-band spectrum for 5G—and the importance of maximizing auction participation to ensure this band is put to its highest and best use—it is important for the size of PAL license areas not to preclude a mobile 5G use case. The record in this proceeding now demonstrates that retaining census tracts as the size of the PAL license areas would cause significant difficulties in deployment of large-scale networks for mobile 5G use. In light of this, it is necessary to reassess the Commission's decision in the *2015 Report and Order* that census tract-sized PALs were large enough to support a variety of use cases. After reviewing the record, the Commission finds that increasing the size of PAL license areas to counties is more likely to ensure that mobile 5G deployments are feasible in the 3.5 GHz band.

10. The Commission agrees with certain commenters' arguments that licensing PALs using census tracts could raise insurmountable technical issues in urban areas. These commenters stress that the number of PALs under a census tract regime—and the number of license borders in particular—will cause unnecessarily challenging border coordination issues and create network deployment complexities. In New York City, for example, there are 2,168 census tracts, spanning an average of less than one-sixth of a square mile. This appears to be far smaller than the area necessary for a single CBSD to operate in its coverage area on at least 20 megahertz of PAL spectrum. Some commenters argue that there are engineering and cost challenges to using census tracts, and stress that, in order to cover the border areas of census tracts, Priority Access Licensees will need to severely limit their power and deploy many more CBSDs than what may be actually needed. They also argue that TDD–LTE technology requires coordination among co-channel and adjacent channel systems at the border, and that synchronization of uplink and downlink operations with neighbors would be almost impossible to implement in census tracts in large urban areas.

11. Further, the smaller the license area, the more the interference protection requirements will limit a licensee's ability to use its assigned spectrum throughout its service area. This is because there is a much higher likelihood that when a licensee seeks to deploy a CBSD, there will be a nearby PAL Protection Area that requires protection, forcing the licensee to reduce power or take other steps to protect the transmitter deployed in the adjacent geographic area. Some commenters argue that licensing PALs by census tract will add tremendous administrative overhead to the process of acquiring PALs and building networks to align with areas where licensees actually want to operate, and also express concern over the cost of designing and deploying networks under a census tract licensing regime. The Commission finds this evidence credible that census-tract based licensing risks intractable interference problems at PAL borders, potentially precluding the use of this spectrum for mobile 5G services.

12. Other commenters argue that these border interference concerns are overstated, because a licensee can operate within its entire PAL Protection Area, which may consist of several aggregated PAL licenses areas, and because the signals from CBSDs whose service contours form the PAL Protection Area would be treated as GAA outside of the PAL area. The Commission is unconvinced that these factors fully mitigate the problem. For instance, commenters describe scenarios illustrating that there is no guarantee that a licensee will have a common channel assignment in adjacent markets. And with respect to potentially extending a licensee's service contours outside of its license area on a GAA basis, some providers note that they cannot make network deployment decisions that are premised on not having to protect adjacent operations because they might not be deployed, and will need to assume that adjacent markets are robustly utilized by PAL (or GAA) licensees to the fullest extent possible.

13. Nor is the Commission persuaded by the argument that it need not worry about these interference concerns because they will not affect a licensee with a geographically targeted LTE deployment, such as within a hotel, convention center, or business campus. If relying on census tracts precludes wide-area use of the 3.5 GHz band (and thus prevents its use for 5G or rural broadband deployments), the

Commission would be improperly tipping the scales towards one use case over others rather than allowing a neutral market mechanism—an auction—to ensure that this valuable spectrum is put to its highest and best use.

14. The Commission further finds that the requirement that the SAS assign geographically contiguous PALs held by the same Priority Access Licensee to the same channel block in each geographic area does not mitigate these concerns. This requirement applies only ''to the extent feasible,'' and doing so may not be feasible when, for example, multiple licensees want common channels across overlapping aggregate PAL Protection Areas. The smaller the license area, the greater the likelihood of such conflicts occurring. For example, a carrier seeking to offer 5G mobile broadband throughout the New York area would be required to bid on 28,000 licenses and be the auction winner 4,000 times in a single geographic area; this would increase dramatically the likelihood that, instead of taking advantage of the contiguous-area rule, an auction winner with a checkerboard of census tract-based licenses would be able to use none of them. Further, even if some form of package or combinatorial bidding could mitigate such risks, licensees would still face potentially discontiguous channel assignments.

15. Although other commenters, in disputing these claims, stress the legal obligation of the SAS to protect a licensee's PAL Protection Area, they do not persuasively refute the demonstration that the use of census tracts is likely in practice to increase dramatically the number of potential border conflicts and related engineering and coordination challenges, potentially precluding next generation mobile services, including 5G, in the 3.5 GHz band. As the Commission recognized in 2015, licensees may have a legitimate need to coordinate with holders of both geographically and spectrally adjacent licenses in order to maximize the utility of the band and facilitate efficient network planning. The record presents serious concerns that, for large scale deployments, such coordination could involve a prohibitive number of co-channel and adjacent channel licensees.

16. *Second,* county-based licensing will allow Priority Access Licensees to take advantage of economies of scale, which will reduce deployment costs. Economic analysis submitted in the record suggests that the population of a census tract is likely not sufficiently large to take advantage of possible economies of scale for many of the potential uses of the band, particularly for the deployment of 5G. Counties—in contrast—are large enough for network deployers to achieve scale economies for both fixed and mobile services. Indeed, counties cover a large enough geographic footprint to incentivize investment in wider area geographic deployments that take full advantage of the CBSD power limits in the 3.5 GHz band, a particularly important issue for 5G networks.

17. *Third,* counties will service the needs of rural communities and will allow new and innovative services to reach underserved and unserved communities, consistent with the Act's objectives. County-sized PALs will provide small, rural providers with a reasonable opportunity to obtain spectrum and promote more effective use of spectrum for actual service delivery in rural areas. Senators of Montana, Wyoming, and Alaska argue that use of counties for licensing PALs in rural areas would serve the needs of their rural communities because it will provide small carriers with an opportunity to access PALs that best fit their targeted service at a price that fits their budget. Several small, rural carriers note that census tract licensing would render the spectrum useless for many small carriers in rural areas, arguing that county-sized licenses will make logical sense in rural communities. And many commenters support using counties to license at least some PALs, particularly in rural communities. The Commission agrees with this ample record that county-based license areas will enable a wide variety of use cases needed to ensure deployment of the 3.5 GHz band in rural areas.

18. *Fourth,* the Commission finds that counties will serve a variety of innovative use cases for urban, suburban, and rural deployments, including IoT deployments and those by new entrants. Several parties stress the importance of access to PALs for IoT and other innovative spectrum uses in suburban and urban areas, and they note that 5G will be replete with these type of targeted uses cases regardless of whether the community is urban or more rural. These commenters argue that counties strike a balance between enabling efficient deployment of services and remaining small enough to ensure economic viability for a variety of businesses and technical plans. Other commenters also note that while they may prefer other license sizes, counties would nonetheless be compatible with their business cases. The Commission agrees that the Priority Access licensing structure should be flexible enough to support and encourage next-generation applications like 5G and IoT and believes that county-based licensing will help to accomplish this goal. Licensing PALs by county will help foster flexible and innovative use of the 3.5 GHz band in all areas by providing a consistent, relatively small license size appropriate for a wide range of possible network deployments. Indeed, the Commission adopted county-size PALs for the 28 GHz band for these same reasons, which likewise will be an important part of the next generation wireless ecosystem, including 5G and IoT applications. In that proceeding, the Commission found that ''a county-based license affords a licensee the flexibility to develop localized services, allows for targeted deployments based on market forces and customer demand, and facilitates access by both smaller and larger carriers.'' As in that context, the Commission anticipates that this approach in the 3.5 GHz band will support diverse network deployments and business models and will fulfill the Act's objectives by fostering the development and rapid deployment of new technologies, promoting economic opportunity and competition, and disseminating licenses among a wide variety of applicants.

19. Counties are sufficiently small to support the small cell deployments and localized types of service the Commission anticipates will be an important part of this band. They are also small enough to allow licensees to target their deployments where they need capacity. At the same time, as the Commission and commenters have recognized, counties are the basic ''building blocks'' of many geographic areas, making them suitable for aggregation for licensees that wish to operate over larger areas. This flexibility makes counties an appropriate middle ground for this band, given that the characteristics of 3.5 GHz band spectrum are favorable to support both localized and wide-area deployments, and thus to entities wanting to provide a variety of innovative services—some more targeted than others—to the public.

20. *Fifth,* the Commission finds that licensing PALs on a county basis will simplify the licensing regime in a way that minimizes burdens imposed on licensees, and that promotes administrative and spectral efficiency consistent with its statutory objectives including speeding the ''development and rapid deployment of new technologies, products, and services'' and ''efficient and intensive use'' of the spectrum. With just 3,200 counties nationwide (compared to about 74,000 census tracts), the Commission can

reduce the administrative burden more than 20-fold by using counties as the PAL license area. It anticipates that this reduction, in turn, will reduce network design complexity and minimize border coordination issues.

21. The Commission also anticipates that fewer license areas and fewer overall biddable items available through the PAL auction will reduce auction complexity and will enable it to move forward more quickly to offer all available PALs in one multiple round auction conferring significant benefits to the public. Historically, the Commission has preferred to use a specific simultaneous multiple round (SMR) auction format for offering spectrum licenses. In the forward auction portion of the broadcast incentive auction (Auction 1002), the Commission used a clock auction format which, like the SMR, also offers all items simultaneously in multiple bidding rounds. These auction formats allow bidders to engage in price discovery and pursue backup strategies as prices ascend, which, for many license inventories, are important benefits for bidders. The Commission's current bidding systems for multiple round spectrum auctions were designed so as to offer these bidder advantages given historically typical inventories of geographic areas. While a county-based geographic license area gives us an inventory with the largest number of areas that the Commission has ever auctioned or licensed, it is a far smaller number than an inventory based on 74,000 census tracts. Accordingly, licensing PALs on the basis of counties will enable the Commission to use an auction system that offers bidders important benefits, as well as allow it to auction them more quickly with a bidding system that is manageable for bidders.

22. Relatedly, if providers with larger-area needs have to turn to the secondary market to aggregate additional licenses, the smaller the license area used, the larger the number of transactions that would be required, thus increasing transaction costs. The Commission believes that this balance will not only promote Section 309's goal of ''efficient and intensive use of the electromagnetic spectrum,'' but also encourage investment by a wider array of users than under the census tract regime by removing unnecessary administrative hurdles and associated costs.

23. Several parties, including those representing small and rural interests, also agree that counties will minimize administrative burdens imposed on licensees, while still being small enough to support rural deployment, reduce barriers of entry, and encourage localized use cases. They stress that, as compared to census tracts, counties will simplify license management burdens and border coordination issues, while still supporting rural deployment preserving low barriers to entry.

24. *Sixth,* international developments confirm the importance of creating an environment that encourages domestic investment in next generation mobile networks in the 3.5 GHz band to effectively leverage the economies of scale created by international investments in the band. Numerous other countries have begun to auction spectrum in the 3.5 GHz range and several others are poised to do so in the near future. It is important for the United States to create a robust marketplace in the band, particularly as the band is standardized for next-generation, 5G technology. By making sure that the PAL license area will foster investment in the band, including by those seeking to use it for mobile 5G use, the Commission is better aligning itself with global developments and preparing to be a leader in the 5G ecosystem, as it has been in the LTE space. Service providers often determine their investments on a global scale, not just a domestic one, and adjustments to the Commission's approach on the geographic licensing area will better facilitate service providers including offerings to U.S. customers in their plans. Specifically, the Commission finds that its revised approach to the geographic licensing area will better align the band with global developments, and with other bands in the U.S. that the Commission has found will play a role in the 5G ecosystem, including the millimeter wave bands and the 3.7–4.2 GHz band. This consistent approach will ensure that the 3.5 GHz band in the United States is ripe for robust investment.

25. *Finally,* while no approach to license sizes will satisfy all stakeholders, counties represent a more appropriate middle ground that will address many of the concerns raised by stakeholders in this proceeding. The Commission finds that adopting counties as the geographic unit for PAL licensing balances the concerns that some commenters have raised about licensing PALs as small as a census tract with the concerns that other commenters have raised about licensing PALs as large as a PEA. In fact, across the various compromise proposals and hybrid approaches submitted in this proceeding, the main commonality is support for the use of counties as part of the PAL licensing scheme. As such, the Commission finds that increasing the size of the geographic license area from census tracts to counties will be more likely to unlock the potential for existing and new technologies and services to thrive in the 3.5 GHz band, while preserving the incentives and ability of smaller innovators to make use of PALs, reserved GAA spectrum, and unreserved GAA use as appropriate.

26. The Commission disagrees with the argument that census tract licensing is necessary for localized use cases, or that these localized use cases should be the primary focus of the balance struck by its rules. Some commenters argue that counties are too large for localized deployments such as those intended by colleges, industrial parks, manufacturing plants, sports arenas and other similar users, and that census tracts are the least costly way to support targeted use cases. The Commission finds that the public interest best served by ensuring that all potential use cases are technically and economically feasible, and by using competitive bidding to allocate the 3.5 GHz band to its highest and best use.

27. Further, county-sized licenses will still enable the construction of localized, private networks using 3.5 GHz spectrum. Targeted use cases are already encouraged by the ''use-or-share'' nature of the band and the GAA tier. A minimum of 80 out of 150 megahertz—more than half the band—will be available for GAA use even if all of the potential PAL channels are occupied, and the Commission previously denied T-Mobile's request to change the apportionment of PAL to GAA spectrum. Even census tracts are already significantly larger than a single campus, hotel, factory, or other similar enterprise, and the demands of such targeted applications can be addressed in ways that provide interference protection without using license areas as small as census tracts, including entering into transactions tailored to the area or amount of spectrum needed through leasing, partitioning, or disaggregation, or entering into commercial agreements with PAL licensees in which the licensee manages the spectrum. What is more, network deployers, manufacturers, and technology companies are well positioned to aggregate demand across counties to coordinate the deployment of localized use cases. This *Report and Order* also opens up the PAL market to partitioning and disaggregation, which should provide additional secondary market avenues for targeted uses and users. And the decision to impose end-of-term performance requirements will incentivize Priority Access Licensees to enter into the commercial transactions

with entities that have targeted-sized uses that fall within their license areas.

28. The Commission also disagrees that increasing the size of PAL license areas will ''strand'' investments in the band. Those making this argument either are incumbents with grandfathered licenses in one portion of the band or they have made those investments in reliance on the 2015 rules. For one, the Commission does not find any such reliance expectations to be reasonable. It had neither scheduled nor even sought comment on how to design a competitive bidding system for PALs before seeking comment on the petitions for rulemaking to change the 2015 rules—and no provider is ever guaranteed to win protected spectrum at auction in a given market, regardless of the size of the geographic license area. For another, the unique structure and technical rules governing the 3.5 GHz band reduce the risk of stranded investment for all entrants and largely obviate the need to rely solely on auctioned licenses for access to the band. As stated previously, a minimum of 80 megahertz of the band will be available for use on a GAA basis in any area, by any entity that registers with the SAS. Additional spectrum will also be made available when it is not in use by Priority Access Licensees. The technical rules are the same for GAA and PAL users, meaning entities can use the same equipment in either tier, and can rely on both PAL and GAA spectrum, one or the other, or switch between the two to meet their business needs. And so any entity that deploys in the band prior to the PAL auction would need to operate on a GAA basis for some period of time and would be able to continue to do so after the auction, regardless of the outcome. Moreover, counties are small enough that the Commission anticipates rural providers and WISPs will actively seek county-sized PALs at auction, or enter arrangements to partition or disaggregate county-sized areas into smaller ones. Additionally, the opportunities for small entities and rural carriers to win will be supported by the bidding credits that have been successful in other Commission proceedings.

29. The Commission rejects arguments that it should adopt PEAs nationwide, as petitioners and some commenters support, or Metropolitan Statistical Areas (MSAs) in urban areas, as suggested in multiple hybrid proposals. The incremental benefit for 5G mobile use of going from counties to MSAs or PEAs would be far less than the incremental costs incurred by other potential users of the band. In particular, the Commission agrees with those commenters that cite the potential negative effects of adopting license areas as large as PEAs. Many WISPs express concerns that the incongruity between PEAs and WISP service footprints will diminish or foreclose their ability to win PALs at auction. In response to these concerns, the Commission has decided not to increase the size of the PAL license area to PEAs.

30. Nevertheless, to provide greater flexibility to PAL applicants interested in serving larger areas, the Commission will seek comment in the pre-auction process on allowing package bids to facilitate bidding for the counties that comprise a complete MSA in the top 305 markets. Several commenters argue that MSAs in urban areas will promote investment in the band in those markets, and—in combination with counties—provide an opportunity for parties to acquire PAL spectrum in areas that best fit their business models and investment plans and minimize burdens for applicants interested in a larger footprint in urban areas. The Commission expects that the proposed procedures for the auction will include specific procedures for a form of package bidding consistent with proposals for other bidding procedures proposed in the pre-auction public notice process. Licensing PALs by county, and seeking comment on the best flexible auction mechanism that may allow bidders to aggregate MSA bids, including possibly using package bidding for all of the counties in an MSA, could reduce secondary market transaction costs while still promoting an active secondary market.

31. The Commission rejects hybrid approaches that offer multiple size PALs in every market, such as licensing 50 megahertz of PALs by county and 20 megahertz by census tract. As discussed above, using counties nationwide will support licensee diversity and increased investment. Further, there are already significant complexities inherent to the 3.5 GHz band authorization and spectrum coordination model, which involve the SAS coordinating access between and among the three tiers of users, including the protection of multiple discrete types of Incumbent users. While SASs may be—and likely are—capable of modifying their systems to address multiple sizes of PALs in a given geographic area, on balance, it is not in the public interest to add yet another layer of complexity to the SAS's spectrum coordination responsibilities at this time. Such additional requirements could delay SAS certification and, possibly, affect the deployment timeline for the band. No party has articulated a compelling argument for the benefits of such a hybrid model (vis-à-vis nationwide use of counties) that would outweigh the potential costs inherent in increasing the complexity of the licensing and authorization framework at this stage of the SAS development cycle. The Commission also agrees with certain commenters that, given the specific characteristics of the 3.5 GHz band, licensing all PALs available in a market using the same geographic area will avoid unnecessarily complicating network management burdens for all users. Using the same license area in both rural and urban areas, as opposed to a hybrid approach licensing different sized PALs in urban and rural areas, will minimize complexities in a band that has a unique tiered access structure with dynamic spectrum sharing.

2. License Term and Renewal

32. *Background.* The rules adopted in the *2015 Report and Order* established a three-year license term for PALs. Under the current rules, during the first application window, an applicant may apply for up to two consecutive three-year terms for a given PAL. During subsequent regular application windows, however, an applicant will be able to apply for only a single three-year license term for any given PAL.

33. In the *2017 NPRM,* the Commission proposed to revise its rules by increasing the PAL license term from three years to 10 years and eliminating the requirement that PALs automatically terminate at the end of the license term. The Commission sought comment on this change and on the appropriate performance requirements and renewal standards for PALs. The Commission noted that its proposed approach was consistent with other wireless services and would afford licensees sufficient time to design and acquire the necessary equipment and devices and to deploy facilities across the license area.

34. The Commission traditionally has licensed many wireless services on a 10-year renewable basis. For example, the Commission issues 10-year renewable licenses in Personal Communications Services, Wireless Communications Services, 700 MHz Services, and Advanced Wireless Services. Since it adopted the *2016 Report and Order* (81 FR 49024, July 26, 2016), the Commission extended this licensing paradigm to the millimeter wave spectrum bands that make up the Upper Microwave Flexible Use Service (UMFUS), which, like the 3.5 GHz band, has been identified as important spectrum for 5G deployment.

35. *Discussion.* The Commission finds that it is in the public interest to extend PAL license terms to 10 years and make such licenses renewable. The service rules for the 3.5 GHz band must create incentives for investment, encourage efficient spectrum use, support a variety of different use cases, and promote network deployments in both urban and rural communities. As the Commission determined with regard to the license area size, it finds that the rapid changes in the mobile marketplace, including the growing importance of mid-band spectrum for large-scale 5G mobile service, necessitate that it revises the license term for PALs to best advance these goals. Since the Commission adopted the 3.5 GHz band licensing rules in 2015, it has become apparent that supporting the rapid deployment of next generation mobile networks, including 5G, will require a combination of low-, mid-, and high-band spectrum, and that the 3.5 GHz band will play a significant role as one of the core mid-range bands for 5G network deployments throughout the world, as well as the first mid-band spectrum to be commercially available in this country for such deployments. Considering the critical importance this band will play in the United States' competitiveness in the global 5G arena, it is also important to ensure that the Commission's rules for the 3.5 GHz band support robust investment in large scale mobile deployments like 5G, as well as other use cases. For the reasons discussed below, the Commission concludes that 10-year renewable license terms will strike the right balance of providing the certainty needed to foster robust investment in next generation wireless networks—including 5G networks—while still maintaining the flexibility needed to support innovative and localized opportunities for a wide variety of entrants.

36. First, review of the record persuades the Commission that longer, renewable license terms will provide Priority Access Licensees with the level of certainty needed to promote robust investment and widespread deployment in the band. Many commenters maintain that longer, renewable license terms are necessary to incentivize robust investment in the band. They emphasize that successful network buildout is a multi-year process that includes standardizing a new frequency band, developing and certifying equipment, introducing a new band into end-user devices, and deploying infrastructure. They likewise maintain that 10-year renewable licenses would provide the long-term certainty required to invest in solutions utilizing the CBRS spectrum, and allow PAL holders to work with equipment manufacturers to lower equipment costs, the savings from which can in turn can be reinvested in networks to achieve higher speeds and additional rollout. Other commenters argue that the investment that larger entities have already made in 3.5 GHz band technology demonstrates that a three-year, non-renewable term will not deter their participation in the band. Such preparatory efforts certainly reflect an encouraging interest in the band, but do not guarantee a robust level of investment and deployment going forward. The Commission believes that the certainty provided by a 10-year, renewable license is warranted to help ensure the kind of robust investment and deployment that will achieve global leadership in next generation wireless technologies, including 5G.

37. The conclusion that a longer, renewable PAL license term is necessary to support robust investment in the band is further supported by economic analyses in the record. For instance, one such analysis argues that infrastructure investment decisions depend on the present value of the expected increase in profits on the investment. It explains that expected profits are a function of revenues and costs over the period a firm expects to use the investment, and thus, with shorter non-renewable licenses, expected profits will decrease. As such, it contends that three-year license terms, even when coupled with the option to obtain two consecutive three-year terms in the first license period, would provide insufficient time for investment returns in an infrastructure-heavy industry. Another analysis similarly finds that short term licenses discourage long-term investments in comparison to long-term licenses and the utilization of secondary markets. One study finds that shorter, non-renewable license terms are listed as one of the factors likely to decrease market value for PALs by as much as 50 to 95 percent overall relative to similarly licensed spectrum in the 2.5–2.6 GHz band.

38. Second, the Commission's experience managing other commercial spectrum supports adopting this modification. A 10-year renewable license term is consistent with the time-tested licensing frameworks that have proven successful in many other bands. Further, the Commission recently concluded in the *Spectrum Frontiers* (81 FR 79909, Nov. 14, 2016) proceeding that this framework was particularly appropriate for a band important for 5G, finding that ''a 10-year license term will give licensees sufficient certainty to invest in their systems, particularly as the new technology is still nascent and will require time to fully develop.'' The record in this proceeding reaffirms that conclusion. Further, the next generation flexible use deployments envisioned for this band—including 5G networks—involve large numbers of small cells, which add complexity and siting delays to roll out, particularly given that these deployments will often require new sites (*e.g.,* street lights, billboards, sides of buildings) with new power and backhaul requirements. Longer, renewable license terms will provide time for licensees to contend with these complexities and challenges, and help to position the band for robust network development.

39. Third, the adoption of larger license areas for PALs further supports the modification to PAL license terms. The Commission in 2015 adopted a three-year, non-renewable term partly based on the conclusion that the economics and upgrade cycles for the small use case ''in the context of census tract license areas'' might resemble those for enterprise and Wi-Fi deployments rather than the large mobile deployments in other bands. The Commission expects the larger license areas now adopted to be more attractive to wide area network operators than census tracts and, as such, anticipates more large scale mobile deployments, including 5G. Given the nature and scale of such investments, the economics and upgrade cycles of such deployments will likely be closer to those in other bands used for mobile broadband, such as those bands addressed in *Spectrum Frontiers,* for which the Commission also adopted a ten-year renewable license term, and find that a longer period is appropriate to ensure a sufficient return-on-investment.

40. Fourth, as with the adoption of counties as the license area size for PALs, the Commission finds that 10-year, renewable terms are suited for a wide variety of entrants in both urban and rural areas. Ten-year renewable terms were supported by a diverse group of commenters, including mobile wireless providers, rural telecommunications and electric cooperatives, fixed wireless broadband providers, and equipment manufacturers. Further, a large number of other parties, as part of a multi-stakeholder consensus, support adoption of a renewable license term, albeit with a term of seven years rather than 10. The Commission finds their support for renewability and a term only somewhat shorter than the one it adopts

in the *Report and Order* as further evidence that a 10-year, renewable term will serve a wide diversity of entrants. Regarding access by rural providers in particular, the Commission's Mobility Fund II, which funds wireless broadband buildout, provides support in 10-year terms ''in light of the significant capital and effort needed to deploy and upgrade broadband networks and [because it] is consistent with the timeframe used by rural carriers to plan and schedule network upgrades.'' Indeed, some commenters maintain that longer license terms and renewability are necessary to incentivize rural service providers and utilities to invest in 3.5 GHz band networks.

41. The Commission is not persuaded by commenters who argue that the longer term and renewability will make PALs broadly uneconomical for rural and innovative investments or lead to a less efficient use and distribution of the band. As discussed in economic analysis in the record, a licensee's expected profits from license acquisition should generally increase with a longer term and renewability. While some commenters challenge this assertion, arguing that extending the term will force prospective licensees to acquire spectrum for a longer period than they need, they offer no evidence that there is any mismatch between the longer term and the use cases discussed in the record. Numerous parties with various use cases, including rural WISPs and industrial entities, assert that they seek to deploy with the use of PALs, and they do not assert that their need for or use of such priority access will terminate by some fixed period, or that they plan to switch to GAA spectrum after that period. The Commission anticipates that the longer, renewable term will provide additional value to small and rural entities seeking to use spectrum for commercial broadband networks and other uses that involve significant long-term investments, and that the greater value to small and rural entities will help such entities absorb a higher acquisition cost at auction to the extent it may result from such terms.

42. Other aspects of the revised framework should further help ensure that small and rural providers have affordable access to the 3.5 GHz band. The bidding credits the Commission adopts for small businesses and rural providers will directly help them to compete for PALs at auction without compromising the certainty needed for substantial long-term investment. Expanded access through the secondary market will also help facilitate access to PALs. As discussed elsewhere, the Commission is not persuaded by commenters' claims that small entities will be unable to participate in secondary market transactions. Further, GAA spectrum will continue to be available on an opportunistic basis, and may be particularly suitable for short-term investments. Taking all these factors into account, to the extent a change to a longer-term, renewable license might still result in some reduction in liquidity in the market for priority spectrum access or otherwise raise the cost of access, the benefits of longer, renewable terms outweigh these concerns.

43. Finally, while commenters advocate for a variety of license terms shorter than 10 years, with limited or no renewability, these other options would not encourage investment as effectively and efficiently as a 10-year renewable license. Many commenters maintain that less than a 10-year license term is insufficient for investors to obtain a return on investment. Several commenters also contend that, without reasonable expectancy of license renewal, many potential entrants may be dissuaded from investing in the band because of the risk of stranded investment. The Commission concludes that its revised framework, when taken as a whole, appropriately addresses the needs of a wide variety of stakeholders, including those that wish to use the band for short-term purposes and those providers that require more certainty and stability, and will result in greater overall investment and deployment while still providing a wide variety of stakeholders with the opportunity to participate in this innovative band.

44. Regarding license renewal, last year, the Commission adopted a unified renewal framework for Wireless Radio Services (WRS) to replace the then-existing patchwork of service-specific rules for renewal. Consistent with that reform, the Commission finds it appropriate to include PALs in the unified WRS renewal framework rather than create a service-specific standard. Consequently, PAL licensees must comply with § 1.949 of the Commission's rules. Under that section, each PAL licensee, in order to qualify for renewal, must demonstrate that over the course of its license term, the licensee either: (1) Provided and continues to provide service to the public, or (2) operated and continues to operate the license to meet the licensee's private, internal communications needs. Like other WRS licensees, Priority Access Licensees may avail themselves of appropriate safe harbors contained in § 1.949(e) or make a Renewal Showing consistent with § 1.949(f). Including PALs in the unified WRS renewal framework is consistent with the Commission's determination in the *WRS Renewals Second Report and Order* (82 FR 41531, Sept. 1, 2017) that ''uniform renewal rules [across different Wireless Radio Services] will promote the efficient use of spectrum resources, serve the public interest by providing licensees certainty regarding their license renewal requirements, encourage licensees to invest in new facilities and services, and facilitate their business and network planning.'' In this band, such an approach ''will provide incentives for licensees to continue to provide service'' over their license terms.

45. Some commenters have argued that, instead of renewability, the licenses should be reauctioned at the end of the license term. For example, one economist describes an auction format under which an incumbent would be required to bid for a renewal of its license at the end of the license term, but it would be given a bidding credit so that, if it won, it would have to pay only a fraction of the auction-determined price. Moreover, if the incumbent loses, it would be compensated with a transferable bidding credit to apply to the purchase of other licenses. The economist argues that this format would mitigate the risk that the incumbent licensee's investments may become stranded. This proposal gained little support in the record, however. Moreover, several commenters, opposing this proposal, argue that a ''foothold'' auction system will lower license valuations and initial investments in the band due to its complex approach within the setting of three-year terms and unknown subsidy rates. The Commission therefore declines to adopt this proposal in place of the time-tested approach of providing for renewability.

3. Performance Requirements

46. *Background.* In the *2015 Report and Order,* the Commission determined that, in light of the three-year license term and non-renewability of PALs, the rules permitting opportunistic GAA use, and the relatively inexpensive deployment costs, ''winning bidders for PAL licenses at auction will have sufficient incentive to deliver service so as to avoid the need for prescribing any further performance requirements.'' In the *2017 NPRM,* the Commission sought comment on whether to adopt performance requirements for PALs, and if so, which type, if they are licensed with a longer term and renewability.

47. *Discussion.* The Commission finds that, given the changes to PALs adopted

in the *Report and Order* (*i.e.,* longer license terms, larger license areas, and renewability), it is in the public interest to revise its rules to adopt new end-of-term performance requirements for PALs. Specifically, Priority Access Licensees will be required to provide a bona fide communications service that meets a ''substantial service'' standard of performance, and the Commission adopts two specific safe harbors to meet this standard, one for mobile or point-to-multipoint services and a second for point-to-point services. A licensee providing a mobile service or point-to-multipoint service may demonstrate substantial service by showing that it provides reliable signal coverage and offers service over at least 50 percent of the population in the license area. A licensee deploying a point-to-point service may demonstrate substantial service by showing that it has constructed and operates, using Category B CBSDs, at least four links in license areas with 134,000 population or less, and at least one link per 33,500 population (rounded up) in license areas with greater population. Licensees may fulfill their performance requirements by showing that they meet at least one of these safe harbors, or they may make an individualized showing of substantial service by relying, for example, on a combination of different services for which there is a safe harbor or on services for which there is no defined safe harbor.

48. New performance requirements are warranted given the other changes to the PALs that adopted in this *Report and Order.* Performance requirements promote the productive use of spectrum, encourage licensees to provide service in a timely manner, and promote the provision of innovative services and technologies in unserved areas, particularly rural ones. Further, Section 309(j)(4)(B) of the Act requires that the Commission, in establishing rules for auctioned licenses, must ''include performance requirements, such as appropriate deadlines and penalties for performance failures . . . .'' These considerations have led the Commission to require licensees to meet a particular standard or metric for performance in numerous other bands. The Commission found in 2015 that Priority Access Licensees had sufficient incentive to use their licensed spectrum that similar requirements were not necessary, in part due to the short license term and non-renewability. Given that the revised PALs will have a longer license term and renewability, as well as larger license areas, the Commission finds that the revised PALs are comparable to licenses in the other bands for which it has adopted a standard or metric for performance. Consistent with these past Commission actions, the Commission adopts such a performance requirement for the revised PALs to meet its obligations under Section 309(j)(4)(B), to reduce warehousing, and to promote timely and efficient use of spectrum, including in rural areas.

49. The Commission also find that, given the revised PAL parameters adopted herein, the potential for opportunistic GAA use of unused PAL spectrum does not obviate the need for performance requirements. Under the current rules, GAA users can operate in unused 3.5 GHz band spectrum on an opportunistic basis. GAA users will be excluded from operating only to the extent that the Priority Access Licensee actually operates over a given channel within its license area (*i.e.,* only from the PAL Protection Area surrounding a deployed CBSD). Given the other changes to PALs (*e.g.,* 10-year license terms, renewability, larger license areas), the Commission does not believe that opportunistic GAA use is, in itself, sufficient to prevent warehousing and encourage robust spectrum use. Absent performance requirements, the revisions to PALs likely will increase incentives for parties to seek PALs for speculative investment or warehousing. Such conduct could prevent intensive use of the band and reduce overall investment notwithstanding the option of GAA use. Notably, a lack of PAL performance would increase the uncertainty for GAA users surrounding long term spectrum availability. Potential GAA users would have little idea regarding when, where, and with what technology Priority Access Licensees may ultimately choose to deploy, which could reduce the incentive for GAA users to invest and innovate in the band. Further, the record indicates that there is significant demand for 3.5 GHz spectrum that is contingent on the ability to obtain interference protection, and while an unused PAL will not foreclose GAA use, it can preclude others from deploying in that area with the benefit of priority access. Adopting performance requirements in the 3.5 GHz band will encourage Priority Access Licensees to make timely and productive use of their licenses, and to the extent they choose not to do so, will incentivize them to make priority access to spectrum available to others through secondary market transactions. Accordingly, the Commission finds that adopting performance requirements in this band is in the public interest.

50. After review of the record, and the various alternatives for performance requirements discussed therein, the Commission concludes that an end-of-term performance requirement of substantial service, with certain specific safe harbors, is the appropriate requirement for the revised PALs. Many commenters emphasize the importance of ensuring that performance requirements do not inhibit the innovation anticipated in this band. The substantial service requirement, with appropriate safe harbors for different types of network deployments, will provide licensees with the flexibility to deploy new and innovative technologies while ensuring that the spectrum is used in a productive manner by the end of the license term.

51. In particular, the Commission finds that specific safe harbors for different types of network deployments will provide additional regulatory certainty that will promote investment and encourage robust deployment in the band. Priority Access Licensees will have the option of satisfying their end-of-term performance requirement by demonstrating that they have provided service that meets or exceeds one of the safe harbors or making an individualized showing of substantial service in the license area. This approach will incentivize licensees to provide service throughout their license areas while retaining the flexibility to deploy new and innovative services. In addition, the Commission anticipates that the option of opportunistic GAA use, while not eliminating the need for new performance requirements, will complement such requirements and provide a low-cost entry point in the band. This should promote additional use of spectrum assigned to PALs and thereby help ensure efficient and productive use of the band. For these reasons, the Commission finds that a substantial service standard, with appropriate specific safe harbors, adequately safeguards effective use of spectrum in the 3.5 GHz band and satisfies its obligations under section 309(j)(4)(B).

52. In selecting an appropriate safe harbor for mobile and point-to-multipoint services, the Commission notes that a wide range of metrics are proposed in the record. In addition, the Commission has adopted a range of performance standards for similar services in other spectrum bands. Several considerations in this band weigh in favor of a safe harbor that provides licensees with relatively greater flexibility. First, such flexibility is appropriate given the power limits for deployments in the 3.5 GHz band. The Commission adopted significantly lower limits in this band than it has typically

imposed in other bands in order to reduce coexistence challenges and with the expectation that deployment in the 3.5 GHz band would often focus on innovative low-power technologies. The adopted power limits and the technologies that the Commission anticipates will be appropriate for them may bring significant localized benefits such as increased network capacity, but they may be less suitable for wide-area coverage as compared to other bands. A more flexible safe harbor will therefore better accommodate these technologies and promote the innovation anticipated in the band. In addition, the Commission's rules incorporate several other measures to facilitate coexistence that may introduce some uncertainty in the timing, cost, interference management, or technical specifics of deployment, such as limitations on commercial operations to protect incumbent users, the SAS authority to require, in specific cases, power reduction below the rule limits (and potentially other technical restrictions), and the potential for dynamic spectrum re-assignments or even cessation of operations to which licensees will be subject to protect incumbent operations. These unique aspects of the licensing and authorization regime in the 3.5 GHz band generally supports providing licensees with greater flexibility in deployment than the Commission has provided in some other bands.

53. In addition, a flexible performance requirement for mobile and point-to-multipoint may provide particular benefits to WISPs and other small providers in the 3.5 GHz band. The record supports the conclusion that many small providers seek to overlay existing service areas that may incompletely cover a PAL license area, such as those who have deployed networks targeting unserved or underserved rural populations under the Commission's prior 3650–3700 MHz service rules. A flexible requirement that allows these providers to implement such overlay or incremental strategies will thus benefit small entities and help to foster a diversity of users in the band. Further, the Commission anticipates that opportunistic GAA use, although not eliminating the need for performance requirements, will complement such requirements and help to ensure that spectrum is used productively, including in rural areas. Accordingly, the Commission does not need to rely as heavily on performance requirements to ensure intensive and productive use in the 3.5 GHz band as in other bands.

54. After considering these factors and the arguments and proposals in the record, the Commission concludes that a 50 percent population coverage safe harbor strikes an appropriate balance between, on the one hand, ensuring spectrum is used efficiently and productively in rural and non-rural areas, including through secondary market access, and, on the other, providing licensees the flexibility to invest in and deploy innovative network technologies that may be more suitable for smaller coverage areas and the co-existence regime that governs the 3.5 GHz band. The Commission finds, consistent with the analysis above, that a 50 percent requirement, rather than the higher coverage requirements adopted in certain other bands, is appropriate in the context of the low power limits and other unique aspects of the licensing and authorization regime in the 3.5 GHz band. Further, this safe harbor for substantial service, together with secondary market mechanisms and the potential for opportunistic GAA use, will foster efficient and innovative use of the band, including in rural areas.

55. As the Commission indicated in 2015, it contemplates that the band may also be used for fixed point-to-point services. Commenters responding to the inquiry in the *2017 NPRM* concerning the possible performance metrics provide little discussion of a metric or approach for fixed point-to-point services. The Commission has adopted a link-based metric for fixed point-to-point services in many other bands, however. In the absence of commenter proposals, the Commission draws on the link-based metric adopted for fixed point-to-point services in the 2.3 GHz Band. Specifically, in the *WCS Report and Order* (75 FR 45058, Aug. 2, 2010), the Commission required 2.3 GHz licensees using the spectrum for point-to-point service to construct and operate a minimum number of links within each license area equal to the population of the license area divided by 33,500 and rounded up to the nearest whole number. The Commission found that this metric was ''achievable'' and would ''further our goal of ensuring meaningful wireless deployment.'' A similar metric is generally a reasonable safe harbor for such services in the 3.5 GHz band. However, for license areas with 134,000 population or less, licensees must construct and operate a minimum of four links to meet the safe harbor, which will be an achievable minimum given the geographic license areas adopted. Further, the Commission limits the safe harbor to links that operate using registered Category B CBSDs. Category B CBSDs must be deployed outdoors and have higher maximum power limits in comparison with Category A CBSDs. Links using Category B CBSDs are therefore likely to be more consistent with the traditional point-to-point services the Commission intends for this safe harbor, and they will avoid the possibility that a licensee could satisfy its performance requirement for an entire license area with a single in-building IoT deployment such as a sensor network.

56. The Commission recognizes that Priority Access Licensees may seek to deploy innovative services, including low-power IoT-type services, for which the safe harbors discussed above may not be suitable. Given the lack of any comment on a metric or safe harbor for such services, and the uncertainty regarding what type of services will be deployed and what safe harbor would be appropriate in the context of the 3.5 GHz band's multi-tiered sharing regime, power limits, and other band-specific rules, the Commission declines to adopt a specific safe harbor for such services at this time. Priority Access Licensees providing such services may file individualized showings to demonstrate that they provided a bona fide communications service, either for unaffiliated customers or for private, internal use, that meets the standard of substantial service.

57. Priority Access Licensees also may provide a mix of services covered by more than one safe harbor. With respect to such mixed deployments, the Commission declines to establish a specific formula for applying the safe harbors. Instead, licensees whose deployments contain a mix of services covered by more than one safe harbor may either demonstrate that at least one of these safe harbors is met, or they may make an individualized showing that the services in combination meet a standard of substantial service. The Commission clarifies, however, that in its assessment of individualized substantial service showings, the safe harbors established above will generally be important factors in cases involving, in whole or in part, services that fall within the scope of such safe harbors. Absent justifications such as those discussed above, and given the flexibility already incorporated into the safe harbors, its expects that, in cases of a service addressed by a safe harbor, substantial service will meet or exceed the relevant safe harbor standard.

58. The Commission declines to adopt interim performance requirements for PALs. Adopting specific coverage requirements as an interim requirement would be inconsistent with the flexible substantial service showings allowed at

the end of the license term, and that requiring licensees to provide ''substantial service'' by both the end-of-term and some earlier interim point would create significant regulatory uncertainty as to the difference between the interim and end-of-term requirements, raise the risk of arbitrary and inconsistent results between licensees, and be unlikely to incentivize more rapid or extensive deployment in the band. Indeed, there is little support in the record for either of these approaches. In addition, the still-nascent status of 5G and other innovative wireless technologies anticipated for this band and the unique aspects of the 3.5 GHz sharing regime support providing Priority Access Licensees with additional flexibility in the timeframe provided to develop and deploy services in the band.

59. In order to confirm that the spectrum is being utilized consistent with the performance requirements, the Commission adopts performance verification procedures largely consistent with those for other bands. Parties must comply with the procedures under § 1.946 of the Commission's rules in making their compliance demonstration. That section provides, in part, that licensees must notify the Commission of compliance with the performance requirement within 15 days of the relevant deadline by filing FCC Form 601. As part of this notification, licensees will be required to submit and certify to a description of the service and documentation of the extent of the service, including electronic coverage maps accurately depicting the boundaries of each license area and where in the license area the licensee provides service that meets the performance requirement (*e.g.,* for mobile services, where in the license area the licensee offers the service at a reliable signal level), supporting technical documentation, population-related assumptions if relevant, and any other information as the Wireless Telecommunications Bureau may prescribe by public notice. The Commission further concludes that licensees, in demonstrating service coverage, may rely on the PAL Protection Areas of the relevant CBSDs they use to provide the service. They must, however, specify the CBSDs and certify that they actually are being used to provide service, either to customers or for internal use. In any case, licensees may not claim service coverage outside of these PAL Protection Areas or deployments that are not reflected in SAS records of CBSD registrations. This approach appropriately leverages the SASs to help ensure consistency and accuracy in performance demonstrations, reduce administrative burdens on licensees and the Commission, and speed compliance and renewal review. The Commission delegates authority to the Wireless Telecommunications Bureau to specify the format of submissions, consistent with these determinations.

60. Consistent with the approach in many other bands, if a licensee fails to meet the substantial service requirement, its authorization under the relevant license will terminate automatically without Commission action. The Commission declines to adopt a ''use-or-lose'' regime, as suggested by some commenters, under which a licensee would lose only those areas or census tracts within a license area that are not developed. Such an approach, which has been adopted rarely for other bands, would complicate coordination with the PAL tier and between PAL and GAA users, may reduce incentives for licensees to build out to the less populated areas covered by their license, and is unnecessary to ensure effective use of the spectrum.

61. The Commission clarifies that operations pursuant to lease arrangements, other than short-term *de facto* transfer leasing arrangements, may be counted toward meeting the performance requirement, either under the safe harbors or as part of an individualized showing of substantial service. Doing so is consistent with the general rules for spectrum leasing, and the Commission finds that it will encourage parties to enter into secondary market transactions while ensuring that performance requirements will be met for the license overall. Consistent with the general short term *de facto* transfer leasing rule (covering *de facto* transfer leasing arrangements of one year or less), a licensee in such an arrangement will not be permitted to attribute to itself the activities of its spectrum lessee when seeking to establish that performance or build-out requirements applicable to the licensee have been met. The Commission rejects proposals that it credit licensees for merely making spectrum available for leasing on a spectrum exchange or otherwise, which would undermine the purposes of the performance requirement discussed above.

B. Competitive Bidding Procedures

1. Applicability of Part 1 Competitive Bidding Rules

62. *PAL Applications Subject to Competitive Bidding.* Consistent with its proposals to lengthen the term of a PAL, to make a PAL renewable, and to increase the size of a PAL's geographic area, the Commission proposed in the *2017 NPRM* to employ its standard practice for finding mutual exclusivity among accepted applications. It also proposed to eliminate the rule that made available one less PAL than the total number of PALs in a license area for which all applicants had applied. The Commission further proposed to assign a PAL even when only one applicant has applied for a PAL in a specific license area, subject to the applicant's being otherwise qualified, rather than to adhere to its decision in the *2015 Report and Order* not to assign any PAL for such a license area.

63. Given the other modifications the Commission adopts for PALs in this *Report and Order*, it eliminates the rule that made available one less PAL than the total number of PALs for which all applicants had applied in a given geographic license area. By making a PAL renewable, increasing the size of its geographic area, and lengthening its license term to 10 years, the Commission anticipates that the rights conferred by a PAL will be more beneficial to a wider range of potential users. The previous rule, which was adopted to limit the number of PALs available in a given license area, was premised on the view that GAA use should be easy to access and sufficient for many applications in the 3.5 GHz band, but that PALs should be available for those limited applications that required greater certainty as to interference protection because they would suffer in a congested use environment. The changes adopted in this *Report and Order* ensure that PALs will support all technologies and foster additional investment from a wide variety of users in the 3.5 GHz band, thereby expanding the potential use cases by Priority Access Licensees, and based on the record, the Commission agrees with the argument that GAA use is less likely to provide sufficient access for many application in the 3.5 GHz band. Therefore, it can no longer conclude that the similar use cases for PALs and the GAA that existed under the prior rules provide a reasoned basis on which to limit the number of PALs available in a given geographic area. The Commission therefore agrees with commenters that the public interest will not be served by limiting the availability of PALs within a given geographic area in the 3.5 GHz band. Rather, by eliminating this rule, the Commission can better achieve a licensing process that will promote the ''efficient and

intensive use'' of this spectrum and the ''development and rapid deployment of new technologies, products, and services for the benefit of the public, including those residing in rural areas,'' that ''recover[s] for the public . . . a portion of the value of the public spectrum resource made available for commercial use, and achieves the other goals of Section 309(j).''

64. Instead, the Commission will use its standard approach to determine whether accepted applications with respect to initial geographic area licenses are mutually exclusive applications subject to competitive bidding, which takes into consideration the Commission's need to ''effectively implement'' the public interest considerations underlying the licensing of the spectrum. Here, determining mutual exclusivity based on applicant interest in a given geographic area serves the public interest objective of assigning these licenses to the applicant that values them most highly and therefore is most likely to make effective use of them. Making the determination based on interest in geographic areas without respect to particular frequencies or bandwidth is necessary to provide applicants with maximum flexibility to pursue back-up strategies to aggregate blocks to meet their licensing needs as the auction progresses and the value of and opportunities in the band become better known. Applicants here will have an opportunity to identify on their short-form application each geographic area(s) in which they are interested in bidding for PALs. An applicant will only be permitted to bid for PALs in the particular geographic area or areas that it initially selects on its short-form application, subject to the 40-megahertz PAL aggregation cap. The record supports following this approach for identifying an applicant's interest in a particular geographic area. If the Commission accepts more than one application to bid on the generic PALs available in any particular geographic area, those PALs will be assigned by competitive bidding. As in other Commission auctions, the Commission will proceed to competitive bidding even if other applicants ultimately do not pursue licenses in that area or pursue fewer than all the licenses available.

65. The Commission also adopts the proposal to assign PAL(s) even when there is only one application in a given geographic area, assuming the applicant is otherwise qualified. In the absence of accepting mutually exclusive applications, the Commission cannot assign a license through the use of competitive bidding. Accordingly, consistent with its long-standing approach, if the Commission does not accept competing applications in a particular geographic area, it will cancel the auction for the PAL(s) in that area, and if the short form application is otherwise acceptable, it will establish a date for the filing of a long-form application by the applicant. The Commission also eliminates the single applicant exception in rural areas as the exception is no longer necessary under this approach. Adopting this licensing approach for PALs generally is also consistent with the Commission's earlier decision to do so on a limited basis. The fundamental benefit of a PAL is the right to prioritized, interference protected use of 10 megahertz of spectrum in a given geographic area. Commenters maintain that there are certain use cases that require the interference protected use of the spectrum that only a PAL can confer, making GAA access, with its lack of prioritized access, insufficient. Under the rules adopted in this *Report and Order*, if there is only one applicant seeking a PAL in an area, that applicant will be able to acquire a PAL outside of the auction process. Given that the decisions in this item make PALs similar in many ways to licenses in other services, the Commission concludes that it should follow this approach as it does in other services. In light of this decision and given the limited record received on the issue, the Commission further concludes that it need not address the issue of whether an application for a PAL in a given geographic area should be considered to be mutually exclusive with an application for GAA use in the same area.

66. The Commission reminds parties that it will conduct any auction of PALs in conformity with the general competitive bidding rules set forth in part 1, subpart Q of the Commission's rules, including any modifications that the Commission may adopt to its part 1 general competitive bidding rules in the future. As has been the Commission's practice in past spectrum auctions, the rules adopted in this *Report and Order* allow subsequent determination of specific final auction procedures. The pre-auction process will be initiated by the release of an auction Comment Public Notice, which will solicit public input on final auction procedures, and which will include specific proposals for auction components, such as minimum opening bids and bidding credit caps. Thereafter, an auction Procedures Public Notice will specify final procedures, including dates, deadlines, and other final details of the application and bidding processes. Accordingly, issues involving bidding procedures, like those raised by commenters, will be addressed at that time, and the Commission will seek public input on the competitive bidding procedures to be used for a particular auction of PALs. The Commission's practice of finalizing auction procedures in the pre-auction process provides time for interested participants both to comment on the final procedures and to develop business plans in advance of the auction.

67. *Bidding on Specific PAL License Blocks.* Under the current rules, Priority Access Licensees do not bid on specific spectrum blocks. Rather, the SAS assigns frequencies based on the amount of spectrum that a PAL licensee is authorized to use in a given license area. Licensees may request a particular channel or frequency range from the SAS, but they are not guaranteed a particular assignment. The SAS will ''assign geographically contiguous PALs held by the same Priority Access Licensee to the same channels in each geographic area'' and ''assign multiple channels held by the same Priority Access Licensee to contiguous frequencies within the same License Area'' when it is feasible to do so.

68. In the *2017 NPRM,* the Commission sought comment on the feasibility and desirability of allowing PAL licensees to bid on specific channel assignments. Specifically, the Commission sought comment on how it could allow bidding on specific license blocks given the constraints of the band and the need to protect incumbents. The Commission sought comment on whether the Incentive Auction could provide a model for a separate, voluntary channel assignment phase of the auction, and, if so, what changes to the Incentive Auction framework might be necessary to accommodate interference protection of federal incumbents by PALs. It also sought comment on possible alternative auction methodologies that might be appropriate.

69. The Commission affirms its decision that PALs will operate over 10 megahertz unpaired channels, wherein all channels will be assigned by the SAS. The exact frequencies of specific assigned channels may be changed by the SAS, if necessary, to facilitate sharing between the three tiers of authorized users. Accordingly, bidders will not be permitted to bid on specific channel assignments through competitive bidding. As the Commission previously explained, ''flexible band management is essential

to effective spectrum sharing between the three tiers of authorized users in the band.'' Coupled with the requirement that CBSDs be capable of operating across the entire 3.5 GHz band, SAS-controlled assignments will ensure that individual users are provided with flexible, stable access to the band. In assigning frequencies for Priority Access, the SAS must assign multiple channels held by the same Priority Access Licensee to contiguous channels in the same license area. Likewise, an SAS will be required to maintain consistent and contiguous frequency assignments for licensees with multiple PALs in the same or adjacent license areas whenever feasible. A wide variety of commenters support the current framework of SAS-assigned PAL channels.

70. While there may be some uncertainty for a Priority Access Licensee in receiving a channel assignment from an SAS rather than bidding on a specific PAL license block, it is precisely this flexibility that is needed in a tiered licensing approach to ensure that a Priority Access Licensee is not forced to shut down its operations indefinitely or even permanently. Under a static channel assignment framework proposed by certain commenters, a Priority Access Licensee could be required to move off of a frequency to protect an incumbent, thus losing access to the exclusive channel until incumbent operations were no longer affected. In contrast, under the approach the Commission affirms in the *Report and Order,* the SAS will be able to reassign the Priority Access Licensee dynamically, ensuring prioritized access to 10 megahertz of spectrum. A flexible channel assignment plan where the SAS can reassign a PAL dynamically when an incumbent is using a specific channel, will lead to better coordination and co-existence between PAL holders and incumbents. For this reason, the Commission rejects the argument that a predictable, static spectral environment provides the certainty needed for network deployments, and concludes that the approach the Commission adopted in 2015 supports a wide variety of use cases in the 3.5 GHz band. As the Commission previously explained, by having the SAS assign all channels, its rules aim to create a flexible, responsive spectral environment while retaining much of the stability of traditional static channel assignments. As the Commission has previously observed, modern networks typically have control features that allow for automated or managed channel selection. On balance, the flexibility afforded by the assignment of channels by the SAS allows the Commission to ensure protection to the Incumbent tier, including federal users, exclusivity to the Priority Access tier, and access to GAA users.

2. Bidding Credits for PALs

71. In the *2017 NPRM,* the Commission revisited its decision not to offer bidding credits in the 3.5 GHz band and sought comment on whether it should consider adopting such provisions for certain bidders or areas if it increased the size of a PAL's license area. Specifically, the Commission sought comment on whether it should adopt the bidding credits it used in the 600 MHz Band auction (Incentive Auction).

72. *Small Business Bidding Credit.* Based on the significant changes adopted for PALs in the *Report and Order,* as well as the Commission's experience with the use of bidding credits in recent spectrum auctions, the Commission concludes that utilizing bidding credits in competitive bidding for the 3.5 GHz band will provide it with an effective tool to achieve its statutory objective of promoting the participation of designated entities in the provision of spectrum-based service. Section 309(j)(4) of the Communications Act requires that when the Commission prescribes regulations to establish a methodology for the grant of licenses through the use of competitive bidding, it must ''ensure that small businesses, rural telephone companies, and businesses owned by members of minority groups and women are given the opportunity to participate in the provision of spectrum-based services, and, for such purposes, consider the use of . . . bidding preferences.'' In addition, Section 309(j)(3)(B) provides that in establishing eligibility criteria and bidding methodologies, the Commission shall promote ''economic opportunity and competition . . . by avoiding excessive concentration of licenses and by disseminating licenses among a wide variety of applicants, including small businesses, rural telephone companies, and businesses owned by members of minority groups and women.'' Historically, one of the principal means by which the Commission fulfills this mandate is through ''bidding preferences'' in the form of bidding credits to small businesses.

73. Because the Commission has modified the characteristics of PALs to more closely resemble those of other wireless licenses, it concludes that designated entities might have less opportunity to obtain spectrum in the 3.5 GHz band without small business size standards and bidding credits. Thus, by modifying its rules to include bidding credits, the Commission can address the concerns that some commenters have raised that the decision to adopt counties as the geographic area size for PAL licensing and a longer, renewal license term will impede small businesses' ability to effectively compete in the auction. Commenters generally support implementing a system of bidding credits for the 3.5 GHz band and recognize the related pro-competitive benefits for smaller carriers. Accordingly, the Commission is persuaded by commenters that maintain offering bidding credits here should improve the ability of small businesses to attract the capital necessary to meaningfully participate in a PAL auction.

74. In the *2017 NPRM*, the Commission sought comment on using the same small business size standards and bidding credits for the 3.5 GHz band as the Commission offered in the 600 MHz Band. In adopting competitive bidding rules for the 600 MHz Band, and more recently in the UMFUS bands, the Commission offered bidding credits to promote opportunities for small businesses, rural telephone companies, and businesses owned by members of minority groups and women to participate in the provision of spectrum-based services. Specifically, for the 600 MHz and UMFUS band auctions, the Commission adopted two small business definitions, the highest two of the three thresholds included in the Commission's part 1 standardized schedule of bidding credits.

75. As a general matter, the Commission defines eligibility requirements for small businesses benefits on a service-specific basis, taking into account the capital requirements and other characteristics of each particular service in establishing the appropriate threshold. While the capital requirements of the services to be deployed in the 3.5 GHz band are not yet known, based on the record and on the its most recent actions in other similar wireless spectrum bands, the Commission concludes that using the same small business size standards and bidding credits adopted in the 600 MHz and UMFUS bands should enhance the ability of small businesses to acquire and retain capital and thereby compete more meaningfully at auction in the 3.5 GHz band. Use of these small business definitions and associated bidding credits should provide consistency and predictability for small businesses

participating in competitive bidding in the 3.5 GHz band.

76. Accordingly, for the 3.5 GHz band, an entity with average annual gross revenues for the preceding three years not exceeding $55 million will be eligible to qualify as a ''small business'' for a bidding credit of 15 percent, while an entity with average annual gross revenues for the preceding three years not exceeding $20 million will be eligible to qualify as a ''very small business'' for a bidding credit of 25 percent, consistent with the standardized schedule in part 1 of the Commission's rules.

77. *Rural Service Provider Bidding Credit.* In the auction of 600 MHz Band licenses, the Commission also offered, for the first time, a rural service provider (RSP) bidding credit to counter the fact that rural service providers have often faced ''challenges in their efforts to obtain financing because the rural areas they seek to serve are not as profitable as more densely-populated markets.'' The RSP bidding credit provides a 15 percent bidding credit to eligible entities that predominantly serve rural areas and have fewer than 250,000 combined wireless, wireline, broadband and cable subscribers. Here too, the record supports the conclusion that an RSP bidding credit should provide an adequate tool to enable rural service providers to compete for 3.5 GHz band spectrum licenses at auction and in doing so, will support the statutory objectives to disseminate licenses among a wide variety of applicants, ensure that rural telephone companies have an opportunity to participate in the provision of spectrum-based services, and promote the availability of innovative services to rural America.

78. *Tribal Lands Bidding Credit.* The Commission also made tribal lands bidding credits available to winning bidders of licenses in the 600 MHz auction. In light of the record support for having similar bidding credits here as the Commission offered in the 600 MHz Band auction, and the modifications adopted for PALs that, as explained above, may cause designated entities to have less opportunity to obtain spectrum in this band, the Commission concludes that it should revise its earlier determination not to offer tribal lands bidding credits in competitive bidding for the 3.5 GHz band. The Commission generally has determined that such a credit should be available where wireless licenses are subject to the Commission's part 1 competitive bidding rules, and wireless providers are willing to offer service to qualifying tribal lands. Accordingly, a winning bidder for a market will be eligible to receive a credit for serving qualifying Tribal lands within that market, provided it complies with the applicable competitive bidding rules.

79. Finally, the Commission rejects a proposal from some commenters to provide a bidding preference for applicants that indicate their intention to use a PAL to meet Connect America Fund (CAF) obligations. Insofar as providers participating in CAF would be receiving CAF support already, additional bidding preferences should not be necessary, and are likely to distort participation in and the results of both the CAF–II and 3.5 GHz auctions. It also rejects other proposals from commenters asking the Commission to offer bidding credits to entities based upon standards other than the ones discussed above. The record lacks support to justify a departure from the Commission's approach to promoting the participation of designated entities in the provision of spectrum-based service, and it believes that the small business and rural service bidding credits should help sufficiently to address the challenges that such groups face.

C. Partitioning and Disaggregation of PALs on the Secondary Market

80. *Background.* In the *2016 Report and Order*, the Commission prohibited Priority Access Licensees from partitioning or disaggregating their licenses because the Commission found that the typical reasons for permitting partitioning and disaggregation in more traditionally licensed bands were not present in the 3.5 GHz band. The Commission noted that the licensing rules that it adopted in the *2015 Report and Order* did not have the same characteristics as other bands where partitioning and disaggregation were permitted, such as longer license terms, larger license areas, and construction obligations. In other bands, partitioning and disaggregation were needed to promote key policy goals such as access to spectrum and flexibility of use, which in turn could result in greater service to consumers.

81. In the *2016 Report and Order,* the Commission also determined that a light-touch leasing process could achieve the goal of making PAL spectrum use rights available in secondary markets—on a targeted, flexible basis—without the need for the Commission oversight required for partitioning and disaggregation. The Commission modified its streamlined part 1 spectrum manager lease rules to create a process tailored to the 3.5 GHz band. Under this streamlined process, parties contemplating spectrum manager lease arrangements with Priority Access Licensees may submit the required, non-lease specific certifications, including ownership information, to the Commission at any time prior to reaching a spectrum manger lease agreement with a Priority Access Licensee. The Commission will expeditiously process these certifications and provide SASs with confirmation that the putative lessee meets the corresponding eligibility criteria for a spectrum manager lease. Once the lessee notifies the SAS of a spectrum manager leasing agreement with a Priority Access Licensee, the SAS may then quickly complete the spectrum manager lease notification process for that lease, and provide confirmation to the parties. The lessee may then immediately begin operating under the lease.

82. In the *2017 NPRM,* the Commission proposed to allow partitioning and disaggregation of PALs in secondary market transactions. It noted that such a modification would be consistent with proposals to lengthen the license term and enlarge the geographic area of PALs, and that it also would be consistent with the licensing paradigm for other similarly licensed services. The Commission anticipated that, when coupled with a longer license term or larger license area for PALs, the ability to partition and disaggregate a PAL would be an effective way to improve spectral efficiency and facilitate targeted network deployments.

83. *Discussion.* The Commission adopts the proposal in the *2017 NPRM* to allow partitioning and disaggregation of PALs in the 3.5 GHz band, because it will promote investment, encourage robust use of the band by a wide variety of stakeholders, and help to ensure that spectrum is used efficiently. The Commission consistently has found that the flexibility afforded by partitioning and disaggregation facilitates the efficient use of spectrum by enabling licensees to make offerings directly responsive to market demands for particular types of services, increasing competition by allowing new entrants to enter markets, and expediting provision of services that might not otherwise be provided in the near term. Particularly here, where the Commission has decided to license the 3.5 GHz band in larger geographic areas for longer, renewable license terms, allowing secondary market transactions will allow licensees and the marketplace to determine the correct size of licenses on a market-specific and needs-based basis. These licensing changes also bring the

3.5 GHz band in line with other bands where partitioning and disaggregation are allowed. Thus, the unique features of PALs that had previously militated against allowing partitioning and disaggregation in the band—small census tract licenses with three-year, non-renewable terms—are no longer present. Partitioning and disaggregation of licenses in the 3.5 GHz band must comply with § 1.950 of the Commission's rules. Accordingly, each party to a partitioning or disaggregation agreement must have a clear construction and operation requirement and each party will face license termination, in the event of failure to meet these requirements. Allowing partitioning and disaggregation will not alter the light-touch leasing rules adopted in the *2016 Report and Order.*

84. Many commenters support allowing partitioning and disaggregation of PALs, particularly when coupled with the larger geographic area license size, longer license term, and license renewability that the Commission adopts in this *Report and Order.* These entities maintain that the flexibility afforded by partitioning and disaggregation will encourage a thriving secondary market, facilitate ''right sizing'' PALs for any local market, and increase the likelihood that a greater percentage of the whole PEA ultimately will receive service.'' These rationales all support the Commission's decision to allow PAL partitioning and disaggregation in the 3.5 GHz band.

85. Some commenters maintain that partitioning and disaggregation are not substitutes for initially licensing smaller license areas. Their positions, however, relate to disagreements over license size rather than opposition to these secondary market transactions *per se.* Some commenters that oppose increased license sizes in the band contend that partitioning and disaggregation offer some benefits, particularly in rural areas where even census tract-sized licenses can be very large. For the reasons discussed above, the Commission determines that licensing PALs on a county basis serves the public interest. It agrees, however, that partitioning and disaggregation are important tools which will help it fulfill its statutory mandate to make spectrum available across the United States, in all markets from urban to rural.

86. Other commenters contend that simply allowing secondary market transactions in the band will not necessarily result in such transactions. These commenters maintain that large wireless providers generally are unwilling to make licensed spectrum available on the secondary market. Some assert that secondary market transactions operate far more frequently and efficiently in the opposite direction, allowing large carriers to aggregate spectrum that initially was acquired by smaller operators. Other commenters argue that high transaction costs inhibit a robust secondary market.

87. The Commission is unpersuaded by commenters' claims that small entities will be unable to participate in secondary market transactions. Commission records reflect that there is an active secondary market for partitioned and disaggregated licenses. The Commission has received about 1,000 assignment applications involving partitioned or disaggregated licenses over the last 10 years. Further, the unique characteristics of the 3.5 GHz band are particularly conducive to secondary market transactions. First, the SAS can be leveraged to facilitate secondary market transactions. In addition, the use-or-share rule greatly diminishes the concerns of potential hoarding or incomplete deployment over a license area. Priority Access Licensees will be incentivized to sell on the secondary market spectrum within their license area that may lie outside of their current network build or that they otherwise do not need access to for their future deployments. The availability of up to seven PALs in each market combined with a 40 megahertz spectrum aggregation limit also decrease the likelihood of excessive or even prohibitive transaction costs.

88. The Commission rejects the suggestion of some commenters that, if it determines to license PALs in larger geographic areas, it should impose an affirmative obligation on larger providers to engage in secondary market transactions with smaller providers and new entrants. The Commission typically relies upon market forces and economic incentives to drive spectrum to its most beneficial use. This remains the correct approach in this band.

89. One commenter questions whether this approach fulfills the Commission's statutory and public responsibilities under section 309(j) of the Act to promote ''economic opportunity for a wide variety of applicants.'' It maintains that the Commission would be relying solely on private commercial interests' use of partitioning, disaggregation, and secondary market transactions to provide such economic opportunities. The Commission disagrees. By developing a new framework to license PALs by counties, the Commission creates opportunities for a variety of applicants both large and small to participate in this innovative band. Further, by making a variety of secondary market opportunities available to all licensees, it creates economic opportunities for all types of entrants to the band. The decision to permit partitioning and disaggregation in the band furthers, rather than undermines, efforts to fulfill the Commission's statutory responsibilities under section 309(j). This change, along with the others adopted in this *Report and Order,* will best balance the statutory objectives to promote competition, the efficient use of spectrum, and the deployment of innovative services to consumers—including those in rural areas. The Commission's decision to adopt performance requirements for PALs also advances its efforts to fulfill the statutory obligations under section 309(j) by helping to ensure that spectrum won't lie fallow.

90. For these reasons, the Commission finds that it is in the public interest to permit partitioning and disaggregation in the 3.5 GHz band, subject to the requirements in § 1.950 of the rules. The Commission's spectrum manager and *de facto* leasing rules remain in effect for PALs, thus affording potential entrants to the band a variety of options for accessing this spectrum.

D. PAL Spectrum Aggregation Limit

91. *Background.* In the *2015 Report and Order,* the Commission adopted an in-band spectrum aggregation limit of 40 megahertz (*i.e.,* four PALs) of the possible 70 megahertz per license area at any given point in time. The Commission concluded that the benefits of facilitating competition, innovation, and the efficient use of the 3.5 GHz band outweighed any harms of imposing such an aggregation limit. In the *2017 NPRM,* the Commission asked whether it should modify or eliminate the PAL aggregation limit, in the event it determined to change the geographic license area or make other changes to the PAL licensing scheme.

92. *Discussion.* The record largely supports retaining the PAL aggregation limit. For the reasons articulated in the *2015 Report and Order,* the Commission finds that the current framework for auction, assignment, and operation of the 3.5 GHz band is sufficient to incentivize investment and participation by a broader range of participants. The other changes made to the PAL licensing regime do not alter the Commission's underlying rationale that the 40 megahertz PAL aggregation limit will provide a minimum degree of diversity among users that likely will be operating in this band, and foster competition and innovation in both PAL

and GAA uses. Accordingly, the Commission maintains the PAL aggregation limit for both licensees and lessees.

E. Confidentiality of CBSD Registration Information

93. *Background.* In the *2015 Report and Order*, the Commission required that all CBSDs register with and be authorized by an SAS prior to initial service transmission. The SAS ensures spectral efficiency, non-discriminatory coexistence, and the minimalization of interference among GAA users, by such means as managing the frequencies in a manner to avoid assignment of the same frequency to multiple GAA users at the same location to the extent possible. CBSD registration must include detailed information specifying the location and characteristics of the CBSD. In addition, the CBSD must send an update to the SAS within 60 seconds of any change in the registration information. The Commission required SAS Administrators to disclose CBSD registration information in three circumstances. First, SAS Administrators must immediately respond to requests from Commission personnel for information stored or maintained by the SAS. Second, SAS Administrators must make available to other SAS Administrators all information necessary to effectively coordinate operations between and among CBSDs. Third, SAS Administrators must make CBSD registration information available to the general public. However, due to concerns raised by commenters about the potential for public disclosure of confidential business information that could compromise personal privacy or affect competitive interests, the Commission required SAS Administrators to ''obfuscate the identities of the licensees providing the information for any public disclosures.''

94. Noting that some parties had asserted that public disclosure of the registration information, even with licensee identities obfuscated, would raise both competitive and security concerns, the Commission proposed in the *2017 NPRM* to amend the rules to prohibit an SAS from disclosing publicly any CBSD registration information that may compromise the security of critical network deployments or be considered competitively sensitive. The Commission noted that it was not proposing any change in SAS-to-SAS information sharing requirements. The Commission sought comment, inter alia, on the potential risks presented by the public disclosure requirement, how to balance these potential risks against potential users' need for information to plan future GAA and/or PAL deployments, and whether there was a mechanism short of public disclosure for potential users to plan future GAA and/or PAL deployments, such as by communicating with an SAS on a confidential basis. It further sought comment on whether there was certain information an SAS could publicly provide while balancing data sensitivity and security concerns.

95. *Discussion.* After careful consideration of the record, the Commission finds that it is in the public interest to protect CBSD registration information from public disclosure while still ensuring that aggregated data on spectrum use is made available to the public. Specifically, the Commission prohibits SAS Administrators from disclosing disaggregated CBSD registration data to the public except where such disclosure is authorized by the registrant. However, it also requires SAS Administrators to make aggregated spectrum usage data for any particular area of interest available to the public, including the extent of usage and available spectrum in the 3.5 GHz band throughout that area and the maximum available contiguous spectrum, using graphical ''heat maps'' or other appropriate formats. This approach will effectively balance the interests in protecting sensitive network information and the legitimate needs that parties—including potential GAA operators—may have for information on the local spectrum environment. The Commission is not modifying the current requirements governing SAS-to-SAS information exchange.

96. Although the current requirement provides that licensees' identities must be obfuscated, numerous commenters argue that public disclosure of CBSD registration information would still allow competitors or other parties to identify the licensee—using a combination of publicly available data—and obtain competitively sensitive information about the licensee's network. Some commenters also argue that such information could compromise the security of network infrastructure. Due to the concerns raised by commenters, the Commission finds that, on balance, the current requirement to publicly disclose CBSD registration information does not adequately protect sensitive information about licensees' network deployments.

97. The Commission continues to find, however, that the success of the shared spectrum model adopted for the 3.5 GHz band requires providing potential users of the band with enough information to accurately assess the overall spectrum environment in an area in order to make investment and deployment decisions. It further finds substantial support in the record for the conclusion that revising the public disclosure requirement to require the disclosure of aggregated spectrum usage data will enable potential users of the 3.5 GHz band to make investment and deployment decisions, while significantly reducing the concerns from the disclosure of disaggregated device registration data. Several commenters support disclosure of a heat map based on aggregate data showing the level of spectrum use in a given area and the amount of spectrum available, arguing that such an approach would permit current and prospective users to better plan for future deployments while withholding potentially commercially sensitive or security-related, licensee-specific information. Accordingly, the Commission finds that it will serve the public interest to require SAS Administrators to make publicly available up-to-date aggregated spectrum usage data for any desired area of interest, including the extent of usage and available spectrum in the 3.5 GHz band throughout that area and the maximum available contiguous spectrum, using graphical ''heat maps'' or other appropriate formats that provide this information.

98. This approach strikes a better balance between protecting sensitive network information and the legitimate needs that parties have for information on the local spectrum environment than a prohibition on any public disclosures. Some commenters, while not disputing that potential users will need information on the spectrum environment to plan their deployments, argue that any public disclosure is nevertheless unnecessary because, under a Wireless Innovation Forum working document, SAS Administrators must publish certain information to assist operators in assessing whether there is available spectrum. The suggestion that no Commission requirement is needed in the light of the working document requirements is unpersuasive, particularly given that the working document requirements were only adopted pursuant to the existing Commission disclosure requirement. Some commenters argue that disclosure is unnecessary because potential users can obtain information from SAS Administrators on a confidential basis to make such decisions. But these commenters do not provide details regarding how such an option would operate, who would be authorized to access CBSD registration information,

and under what circumstances access would or would not be provided. The Commission finds that, on the record before it, the revised public disclosure requirement it adopts in this *Report and Order* is the best choice because it will ensure that all potential users have certain and convenient access to aggregate data on the spectrum environment for the area of interest while substantially reducing any legitimate concerns regarding the sensitivity of network data. The Commission acknowledges that aggregate spectrum usage data might in some circumstances implicitly reveal some provider- or CBSD-specific information (such as in cases where a 3.5 GHz Priority Access Licensee has deployed CBSDs in a particular geographic area with no other deployments in the band). It finds, however, that the benefits of the revised public disclosure requirement and its importance to the success of the shared model in the 3.5 GHz band far outweigh any remaining concerns from the potential for such inferred disclosures.

99. Some proponents of the current requirement assert that the harms of disclosure should be discounted because the deployment information will in any case become available through other means. The Commission disagrees that the possibility that, in the future, there may be independent methods to obtain data about some licensees' networks is an appropriate justification for us to disregard concerns over the commercial sensitivity of that data and to allow today the public disclosure of commercially sensitive data about all licensees' networks. Further, there is no evident source currently that would reproduce the CBSD registration information and find it unlikely that any third-party public source will provide 3.5 GHz band network infrastructure data of the same character, in terms of information covered, specificity, comprehensiveness, timeliness, and accuracy. As evidence that CBSD registration data will likely be available from providers' own voluntary disclosures, some commenters cite several cable provider websites disclosing the location of their commercially offered Wi-Fi hotspots. However, the Commission finds these disclosures of the locations of Wi-Fi hotspots reflect that such Wi-Fi services are typically provided only at discrete locations. Such disclosures do not support the conclusion that mobile broadband providers would similarly disclose the location of individual antenna sites that are subsumed within the broad coverage of a cellular service. The Commission also rejects the argument that concerns regarding the disclosure of the network data should be discounted because access points will cover very limited areas. While the anticipated deployment of 5G services in the band will likely often involve small cell technologies, that does not reduce the sensitive nature of the deployment information.

100. Some commenters also argue that the Commission typically has disclosed site information in historic site-based licensing regimes and that there is no reason to provide any greater protection here. Their assessment of Commission practice disregards other Commission or Bureau actions, however, that have found that comparable disclosures of network infrastructure information encompass sensitive information that warranted some degree of protection. These latter precedents, as well as the record in this proceeding, support a determination that parties have legitimate concerns regarding the sensitivity of CBSD registration data that may impact their investment and deployment decisions.

101. Arguments in the record that a disclosure of aggregate data would be insufficient are similarly unpersuasive. Some commenters argue that a GAA user will need to know how many contiguous channels are available throughout its service area in order to predict the speeds it can offer its subscribers; however, the modified requirement directly addresses that concern because the Commission requires publicly disclosed information to include aggregate information on the maximum number of contiguous channels available. While one commenter argues that a heat map is inadequate because it does not necessarily provide sufficient information for the aiming of directional antennas, aggregate data should enable potential users to identify geographic areas with sufficient available spectrum to support a range of directional orientations for deployments within that area. Some commenters argue that licensees need information on specific channel availability. However, specific channel availability will be far less relevant to 3.5 GHz band network planning than aggregate spectrum availability, given that all 3.5 GHz band equipment must be operable across the entire band, and that the SASs will be making the frequency assignments, which will be subject to change during the operation of the equipment.

102. One commenter proposes that if the Commission determines that the current public disclosure requirement raises security or competitive concerns, it should require SAS Administrators, in their public disclosure of disaggregated data, to obscure or randomize the location of individual CBSDs within a triangle of points 50 linear feet apart or another defined area. The Commission finds this proposal does not differ significantly from the current requirement, which does not adequately protect competitively sensitive information. The modified requirement is a better approach to address the concern, as it will directly provide current and potential users with information on the availability of spectrum in a geographic area without requiring public disclosure of disaggregated CBSD data.

103. Other purposes that commenters identify for the public disclosure of disaggregated registration data are likely to be able to be achieved without the public disclosure of such data. For example, while some argue that disclosure will help users identify sources of interference, that is a core function of the SAS itself and therefore does not require public disclosure of disaggregated SAS registration data. The role of the SASs further distinguishes the 3.5 GHz band from the prior 3650–3700 MHz Band service rules, where the Commission adopted public disclosure of site registrations to enable non-exclusive licensees to coordinate to avoid harmful interference. Under that regime, there was no license administrator to facilitate coordination.

104. The Commission does not find that disclosure would enable the public to detect and hold operators accountable for erroneous or obsolete information, as some commenters argue. The Commission acknowledges that, for the white space database, it did adopt public disclosure for some registrations in part to ''permit public examination of protected entity registration information to allow the detection and correction of errors.'' However, it finds the 3.5 GHz band is not analogous to the white space service in this regard, as the Commission discussed extensively in the *2016 Order on Reconsideration* (81 FR 49038, July 26, 2016). Among other distinctions in the case of 3.5 GHz, the Commission noted that ''[t]he licensed nature of the service coupled with industry certification requirements for professional installers provides a higher degree of accountability for Citizens Broadband Radio Service users and SAS Administrators, ensuring that CBSD locations are accurately reported and verified.'' It further noted that SASs ''will have capabilities and responsibilities that exceed those of White Spaces database administrators,''

including rules that require authentication of CBSDs with an SAS and require that SAS Administrators maintain the accuracy of CBSD records, which ''places a duty on SAS Administrators to take reasonable steps to validate newly entered data and to purge obsolete data.'' Accordingly, the Commission finds there is not the same benefit from public disclosures in helping to ensure registration accuracy in this context as was present in the white space service.

105. The Commission also disagrees that Category B GAA users will need disaggregated registration data, and particularly relevant contact data, to fulfill their obligation to coordinate with other Category B GAA users under § 96.35(e) of the Commission's rules. Mandatory disclosure of disaggregated CBSD registration data, including contact data, is not necessary for Category B GAA coordination, and voluntary mechanisms and arrangements facilitated by an SAS, supplemented by the mandatory disclosure of aggregate spectrum usage data, can reasonably be expected to support and achieve the coordination contemplated in § 96.35(e), given that Category B GAA users will generally have mutual incentives to coordinate with one another and SASs are required to facilitate such coordination. For example, one multi-stakeholder standards document for Citizens Broadband Radio Service commercial operation, noted by several commenters, addresses the need for GAA coordination through a voluntary approach to be administered by the SASs. The Commission anticipates that the SAS Administrators will play an active role in facilitating GAA coordination, and bases its expectation that a voluntary mechanism will be successful in part on SAS involvement.

106. The Commission also anticipates that disclosure of aggregate information on spectrum availability will be sufficient in many cases to help interested parties identify potential secondary market opportunities, and that the SASs will help facilitate secondary market transactions in other ways that do not require disaggregated disclosure. Further, parties can directly contact the Priority Access Licensees in a particular license area (which will be a matter of public record) for that purpose. Indeed, even if the Commission continued to mandate disclosure of anonymized CBSD data, it would still generally be necessary to determine from the licensees in an area (either directly or through SAS facilitation) whether a particular licensee has unused PAL spectrum it is willing to make available through a secondary market transaction. To the extent that mandatory public disclosures of detailed, disaggregated CBSD registration data might in some circumstances provide some additional benefit over aggregate data, and the benefits are outweighed by the security and competitive concerns that such disclosures would raise. In sum, the Commission concludes that the revised requirement provides a reasonable balance for the services in the 3.5 GHz band, including emerging 5G and other innovative services anticipated in this band, and will thus promote its effective and efficient use.

F. Emissions Limits for CBSDs and End User Devices

107. *Background.* The Commission's rules include the following emissions limits for CBSDs and End User Devices operating in the 3.5 GHz band:

- −13 dBm/MHz from 0 to 10 megahertz from the assigned channel edge;
- −25 dBm/MHz beyond 10 megahertz from the assigned channel edge down to 3530 megahertz and up to 3720 megahertz;
- −40 dBm/MHz below 3530 megahertz and above 3720 megahertz.

108. The Commission adopted these limits to achieve a balance between the ability of CBSDs and End User Devices to protect out-of-band incumbent services, the ability of equipment vendors to meet reasonable standards of design performance, and the ability of CBSD and End User Devices to minimize the addition of in-band noise affecting other users of the band. The Commission denied petitions for reconsideration that sought changes to these limits in 2016.

109. In the *2017 NPRM,* the Commission sought comment on two alternative emission masks to address concerns about the need to reduce transmit power for channels wider than 10 megahertz under the emissions mask set forth in § 96.41(e) of the Commission's rules. Both alternative emission masks would extend the width of the −13 dBm/MHz transition step. Instead of the fixed 10 megahertz wide transition step in § 96.41(e)(1), each alternative emission mask would extend the total transition bandwidth to be the bandwidth (B) of the fundamental transmission in megahertz. The first alternative emission mask (the Qualcomm Mask) has a single transition step at a level of −13 dBm/MHz. The second alternative emission mask (the Graduated Mask) has two steps with a steeper reduction of adjacent emission power, −13 dBm/MHz from 0 to B/2 megahertz from the channel edge, and −20 dBm/MHz from B/2 to B megahertz from the channel edge. The Commission sought comment on these two alternative emission masks and specifically requested quantitative analysis of the tradeoffs between the use of wider channels and the risk of higher interference to users in adjacent channels.

110. Qualcomm submitted results of a simulation study of the additional maximum power reduction (A–MPR) that would be required for the Qualcomm Mask and the Graduated Mask. Qualcomm asserts that both masks require the same amount of (non-zero) power reduction (*e.g.,* 2.2 dB) for channels with high resource utilization, but the Graduated Mask requires 0.8 dB–2.5 dB additional power reduction than the Qualcomm Mask for channels with low resource utilization. Thus, Qualcomm argues that its mask will more effectively facilitate wider bandwidth operations with less impact on transmit power. In *ex parte* presentations on March 6, 12, and 14, 2018, Qualcomm further asserted that with its proposed mask, emission reduction is achieved by power reduction resulting from both the spectrum emission mask (SEM) and the 3GPP Adjacent Channel Leakage Ratio (ACLR) requirement of 30 dB for user devices. In some cases, the ACLR requirement (and not the SEM) determines the amount of emission reduction, and in other cases the SEM requirement (and not the ACLR) determines the amount of emission reduction.

111. *Discussion.* After review of the record, the Commission concludes, first, that it should make no changes to the OOBE limits outside the 3.5 GHz band, specifically at or beyond the 3550 and 3700 MHz band edges. Second, it is not convinced that any change is needed in the emissions mask for Category A and B CBSDs to facilitate next generation wireless deployments, including 5G channels up to 40 megahertz wide. Third, it finds that some relaxation in the emissions mask for uplinks from End User Devices is warranted to accommodate wider bandwidths. This change will help facilitate wide-network deployments, consistent with the other changes adopted herein.

112. There is little in the record to suggest that changes in the OOBE limits outside the 3.5 GHz band are necessary to accommodate signals having wide bandwidths. Indeed, many commenters argue that there should be no relaxation of the emissions limits outside the 3.5 GHz band. The existing OOBE limits outside the 3.5 GHz band were adopted

to ensure interference protection for fixed satellite services operating above the band and federal operations below the band. These important adjacent band coexistence issues have not changed since the rules were adopted and, as such, there is no need to reconsider the Commission's prior findings on this matter.

113. In addition, the Commission finds that no changes to the emission limits for CBSDs are needed. Qualcomm's proposal is focused solely on End User Devices and there were no other technical showings that would support relaxation of the emissions limits for CBSDs. Indeed, equipment vendors argue that no change to the emission limits are necessary because current technologies can meet the existing limits and the existing rules allow higher power with wider bandwidth, which helps counteract the need for a reduction in power. The Commission believes their comments were in the context of CBSDs (*i.e.,* base stations).

114. The Commission is aware that it is generally easier to employ linearization techniques and better filtering in CBSDs to achieve low out-of-channel emissions because they operate off external electrical power and are less constrained by space limitations in the device as compared to End User Devices. Accordingly, the Commission is maintaining the existing OOBE limits for CBSDs.

115. There is justification for relaxing the OOBE limits within the 3.5 GHz band for End User Devices to accommodate bandwidths wider than ten megahertz. The Commission adopts the Qualcomm Mask and an adjacent channel leakage requirement of −30 dBc for End User Devices, because Qualcomm's analysis showed that −30 dBc, a 3GPP standard, in addition to the Qualcomm Mask, would limit the total emission power that affects adjacent channels. While most commenters support the Qualcomm Mask rather than the Graduated Mask, the Commission is concerned that the Qualcomm Mask, by itself, may lead to a higher level of OOBE than necessary to accommodate wider bandwidths with little or no power reduction. The Commission also believes that much of the equipment that will be used in this band will be designed to meet 3GPP standards. The 3GPP standards are based on an adjacent channel leakage ratio (ACLR) of 30 dBc for End User Devices, as well as a spectrum emission mask. The value of ACLR is a measure of the total power in the adjacent channel, as opposed to an emission mask that specifies a (typically) flat (per-megahertz) limit over some frequency range, with reductions at particular points (*i.e.,* 10 megahertz outside the channel). In its March 14, 2018 filing, Qualcomm demonstrated that for End User Devices, neither the Qualcomm Mask nor the Graduated Mask is sufficient, in some cases, to ensure that adjacent channel leakage is at least 30 dB below the fundamental channel power (*i.e.,* 3GPP ACLR limit of 30 dB). This necessitates maximum power reduction based on an ACLR limit, to ensure that adjacent channel emission power is sufficiently minimized. Qualcomm performed software simulation of End User Device transmitter emission performance for many combinations of uplink sub-carrier assignments, for inner channels, for edge channels, and for different configurations of contiguous and non-contiguous spectrum assignments. Their analysis showed the power back-off required to meet 3GPP performance standards for edge channels and inner channels, for the current mask, the Qualcomm Mask, and the Graduated Mask. Based on this analysis, the Commission believes that adopting the two emission requirements assessed by Qualcomm—the Qualcomm emission mask and ACLR—would allow for wider transmission bandwidths, and ensure that in-band noise is appropriately limited for all End User Devices, not just 3GPP user equipment. Therefore, it adopts the Qualcomm Mask and an adjacent channel leakage requirement of −30 dBc for End User Devices.

116. Some commenters expressed concern that changes to the emission limits could make some channels in the band (*i.e.,* those furthest from the band edges) more desirable than others. While wider bandwidth operations using spectrum near the upper and lower edges of the 3.5 GHz band may need to make adjustments—including operating at lower power—to use those parts of the band, the Commission does not believe this makes these parts of the band any less usable. The 3.5 GHz band will likely be used by a variety of different operators, each with unique spectrum needs. These operators should have the flexibility to use the band at a variety of different bandwidths and operational power levels suited to their particular business. For example, parties seeking to use the lower 10 megahertz channel may also seek to use it together with adjacent channels for wider aggregated bandwidth. They can also choose to employ devices with better filtering, slightly reduce power, or aggregate non-contiguous individual channels. The Commission is also cognizant that there is apt to be wide variability in the ability of multiple contiguous channels at any given location because it will depend on factors such as which channels have different licensees and the extent of other deployments in the band.

117. Finally, the Commission corrects a typographic error in a paragraph reference in § 96.41(e)(2) of its rules, which should reference paragraph (e)(1) instead of (d)(1).

IV. Procedural Matters

118. *Paperwork Reduction Analysis.*—This *Report and Order* contains new and modified information collection requirements subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. It will be submitted to the Office of Management and Budget (OMB) for review under section 3507(d) of the PRA. OMB, the general public, and other Federal agencies will be invited to comment on the new and modified information collection requirements contained in the proceeding. In addition, the Commission notes that pursuant to the Small Business Paperwork Relief Act of 2002, it previously sought specific comment on how we might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.'' It has described impacts that might affect small businesses, which includes most businesses with fewer than 25 employees, in the Final Regulatory Flexibility Analysis (FRFA), in Appendix B of the *Report and Order.*

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

120. *Regulatory Flexibility Act.*—The Regulatory Flexibility Act of 1980, as amended (RFA), requires that an agency prepare a regulatory flexibility analysis for notice and comment rulemakings, unless the agency certifies that ''the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities.'' Accordingly, the Commission has prepared a FRFA, set forth in Appendix B of the *Report and Order,* concerning the possible impact of the rule changes.

V. Ordering Clauses

121. Accordingly, *it is ordered* that, pursuant to Sections 1, 2, 4(i), 4(j), 5(c), 302, 303, 304, 307(e), and 316 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 152, 154(i), 154(j), 155(c), 302, 303, 304, 307(e), and 316, this *Report and Order* in GN Docket No. 17–258 *is hereby adopted.*

122. *It is further ordered* that the amendments of the Commission's rules as set forth in the Final Rules section *are adopted*, effective thirty (30) days after publication in the **Federal Register**. Sections 96.23(a), 96.25(b)(4), and 96.32(b) contain new or modified information collection requirements that require review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. The Commission directs the Bureau to announce the effective date of those information collections in a document published in the **Federal Register** after the Commission receives OMB approval, and directs the Bureau to cause §§ 96.23(d), 96.25(b)(5), and 96.32(d) to be revised accordingly.

123. *It is further ordered* that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, *shall send* a copy of this *Report and Order,* including the Final Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

124. *It is further ordered* that this *Report and Order shall be* sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, see 5 U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR Parts 1 and 96

Telecommunications, Radio.

Federal Communications Commission.

Katura Jackson,

Federal Register Liaison Officer, Office of the Secretary.

Final Rules

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR parts 1 and part 96 as follows:

PART 1—PRACTICE AND PROCEDURE

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

Authority: 47 U.S.C. chs. 2, 5, 9, 13; Sec. 102(c), Div. P, Public Law 115–141, 132 Stat. 1084; 28 U.S.C. 2461, unless otherwise noted.

■ 2. Amend § 1.907 by revising the definition of ''Covered Geographic Licenses'' to read as follows:

§ 1.907 Definitions.

* * * * *

Covered Geographic Licenses. Covered Geographic Licenses consist of the following services: 1.4 GHz Service (part 27, subpart I, of this chapter); 1.6 GHz Service (part 27, subpart J); 24 GHz Service and Digital Electronic Message Services (part 101, subpart G, of this chapter); 218–219 MHz Service (part 95, subpart F, of this chapter); 220–222 MHz Service, excluding public safety licenses (part 90, subpart T, of this chapter); 600 MHz Service (part 27, subpart N); 700 MHz Commercial Services (part 27, subparts F and H); 700 MHz Guard Band Service (part 27, subpart G); 800 MHz Specialized Mobile Radio Service (part 90, subpart S); 900 MHz Specialized Mobile Radio Service (part 90, subpart S); Advanced Wireless Services (part 27, subparts K and L); Air-Ground Radiotelephone Service (Commercial Aviation) (part 22, subpart G, of this chapter); Broadband Personal Communications Service (part 24, subpart E, of this chapter); Broadband Radio Service (part 27, subpart M); Cellular Radiotelephone Service (part 22, subpart H); Citizens Broadband Radio Service (part 96, subpart C, of this chapter); Dedicated Short Range Communications Service, excluding public safety licenses (part 90, subpart M); H Block Service (part 27, subpart K); Local Multipoint Distribution Service (part 101, subpart L); Multichannel Video Distribution and Data Service (part 101, subpart P); Multilateration Location and Monitoring Service (part 90, subpart M); Multiple Address Systems (EAs) (part 101, subpart O); Narrowband Personal Communications Service (part 24, subpart D); Paging and Radiotelephone Service (part 22, subpart E; part 90, subpart P); VHF Public Coast Stations, including Automated Maritime Telecommunications Systems (part 80, subpart J, of this chapter); Upper Microwave Flexible Use Service (part 30 of this chapter); and Wireless Communications Service (part 27, subpart D).

* * * * *

■ 3. Amend § 1.949 by revising paragraph (c) to read as follows:

§ 1.949 Application for renewal of authorization.

* * * * *

(c) *Implementation.* Covered Site-based Licenses, except Common Carrier Fixed Point-to-Point Microwave Service (part 101, subpart I, of this chapter), and Covered Geographic Licenses in the 600 MHz Service (part 27, subpart N, of this chapter); 700 MHz Commercial Services (part 27, subpart F); Advanced Wireless Services (part 27, subpart L) (AWS–3 (1695–1710 MHz, 1755–1780 MHz, and 2155–2180 MHz) and AWS–4 (2000–2020 MHz and 2180–2200 MHz) only); Citizens Broadband Radio Service (part 96, subpart C, of this chapter); and H Block Service (part 27, subpart K) must comply with paragraphs (d) through (h) of this section. All other Covered Geographic Licenses must comply with paragraphs (d) through (h) of this section beginning on January 1, 2023. Common Carrier Fixed Point-to-Point Microwave Service (part 101, subpart I) must comply with paragraphs (d) through (h) of this section beginning on October 1, 2018.

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PART 96—CITIZENS BROADBAND RADIO SERVICE

■ 4. The authority citation for part 96 continues to read as follows:

Authority: 47 U.S.C. 154(i), 303, and 307.

■ 5. Amend § 96.3 by:

■ a. Adding the definitions of ''Adjacent Channel Leakage Ratio'' and ''Aggregated Channel Bandwidth'' in alphabetical order;

■ b. Removing the definition of ''Census tract'';

■ c. Adding the definitions of ''County'' in alphabetical order; and

■ d. Revising the definition of ''License area.''

The additions and revision read as follows:

§ 96.3 Definitions.

* * * * *

Adjacent Channel Leakage Ratio. The Adjacent Channel Leakage Ratio (ACLR) is the ratio of the filtered mean power over the assigned Aggregated Channel Bandwidth to the filtered mean power over the equivalent adjacent channel bandwidth. The power in the assigned Aggregated Channel Bandwidth and its equivalent adjacent channel bandwidth are measured with rectangular filters with measurement bandwidths equal to the Aggregated Channel Bandwidth.

Aggregated Channel Bandwidth. The Aggregated Channel Bandwidth is the bandwidth of a single channel, or in the case of multiple contiguous channels, the bandwidth between the upper and lower limits of the combined contiguous channels.

* * * * *

County. For purposes of this part, counties shall be defined using the United States Census Bureau's data reflecting county legal boundaries and names valid through January 1, 2017.

* * * * *

License area. The geographic component of a PAL. A License Area consists of one county.

* * * * *

■ 6. Amend § 96.23 by revising paragraph (a) introductory text and adding paragraph (d) to read as follows:

§ 96.23 Authorization.

(a) An applicant must file an application for an initial PAL. Applications for PALs must:

* * * * *

(d) Paragraph (a) of this section contains information-collection and recordkeeping requirements. Compliance will not be required until after approval by the Office of Management and Budget. The Commission will publish a document in the **Federal Register** announcing that compliance date and revising this paragraph (d) accordingly.

■ 7. Amend § 96.25 by revising paragraph (b)(3) and adding paragraphs (b)(4) and (5) to read as follows:

§ 96.25 Priority access licenses.

* * * * *

(b) * * *

(3) *License term.* Each PAL has a ten-year license term. Licensees must file a renewal application in accordance with the provisions of § 1.949 of this chapter.

(4) *Performance requirement.* Priority Access Licensees must provide substantial service in their license area by the end of the initial license term. ''Substantial'' service is defined as service which is sound, favorable, and substantially above the level of mediocre service which might minimally warrant renewal. Failure by any licensee to meet this requirement will result in forfeiture of the license without further Commission action, and the licensee will be ineligible to regain it. Licensees shall demonstrate compliance with the performance requirement by filing a construction notification with the Commission in accordance with the provisions set forth in § 1.946(d) of this chapter. The licensee must certify whether it has met the performance requirement, and file supporting documentation, including description and demonstration of the bona fide service provided, electronic maps accurately depicting the boundaries of the license area and where in the license area the licensee provides service that meets the performance requirement, supporting technical documentation, any population-related assumptions or data used in determining the population covered by a service to the extent any were relied upon, and any other information the Wireless Telecommunications Bureau may prescribe by public notice. A licensee's showing of substantial service may not rely on service coverage outside of the PAL Protection Areas of registered CBSDs or on deployments that are not reflected in SAS records of CBSD registrations.

(i) *Safe harbor for mobile or point-to-multipoint service.* A Priority Access Licensee providing a mobile service or point-to-multipoint service may demonstrate substantial service by showing that it provides signal coverage and offers service, either to customers or for internal use, over at least 50 percent of the population in the license area.

(ii) *Safe harbor for fixed point-to-point service.* A Priority Access Licensee providing a fixed point-to-point service may demonstrate substantial service by showing that it has constructed and operates at least four links, either to customers or for internal use, in license areas with 134,000 population or less and in license areas with greater population, a minimum number of links equal to the population of the license area divided by 33,500 and rounded up to the nearest whole number. To satisfy this provision, such links must operate using registered Category B CBSDs.

(5) *Compliance date.* Paragraph (b)(4) of this section contains information-collection and recordkeeping requirements. Compliance will not be required until after approval by the Office of Management and Budget. The Commission will publish a document in the **Federal Register** announcing that compliance date and revising this paragraph (b)(5) accordingly.

* * * * *

§ 96.27 [Removed and Reserved]

■ 8. Remove and reserve § 96.27.

■ 9. Section 96.29 is revised to read as follows:

§ 96.29 Competitive bidding procedures.

Mutually exclusive initial applications for PALs are subject to competitive bidding. The general competitive bidding procedures set forth in part 1, subpart Q, of this chapter will apply unless otherwise provided in this subpart.

■ 10. Section 96.30 is added to read as follows:

§ 96.30 Designated entities in the Citizens Broadband Radio Service.

(a) *Small business.* (1) A small business is an entity that, together with its affiliates, its controlling interests, and the affiliates of its controlling interests, has average gross revenues not exceeding $55 million for the preceding three (3) years.

(2) A very small business is an entity that, together with its affiliates, its controlling interests, and the affiliates of its controlling interests, has average gross revenues not exceeding $20 million for the preceding three (3) years.

(b) *Eligible rural service provider.* For purposes of this section, an eligible rural service provider is an entity that meets the criteria specified in § 1.2110(f)(4) of this chapter.

(c) *Bidding credits.* (1) A winning bidder that qualifies as a small business as defined in this section or a consortium of small businesses may use a bidding credit of 15 percent, as specified in § 1.2110(f)(2)(i)(C) of this chapter. A winning bidder that qualifies as a very small business as defined in this section or a consortium of very small businesses may use a bidding credit of 25 percent, as specified in § 1.2110(f)(2)(i)(B) of this chapter.

(2) An entity that qualifies as eligible rural service provider or a consortium of rural service providers who has not claimed a small business bidding credit may use a bidding credit of 15 percent, as specified in § 1.2110(f)(4) of this chapter.

■ 11. Amend § 96.32 by revising paragraph (b) and adding paragraph (d) to read as follows:

§ 96.32 Priority access assignments of authorization, transfer of control, and leasing arrangements.

* * * * *

(b) Priority Access Licensees may partition or disaggregate their licenses and partially assign or transfer their licenses pursuant to § 1.950 of this chapter and may enter into de facto transfer leasing arrangements for a portion of their licensed spectrum pursuant to part 1 of this chapter.

* * * * *

(d) Paragraph (b) of this section contains information-collection and recordkeeping requirements. Compliance will not be required until after approval by the Office of Management and Budget. The Commission will publish a document in the **Federal Register** announcing that compliance date and revising this paragraph (d) accordingly.

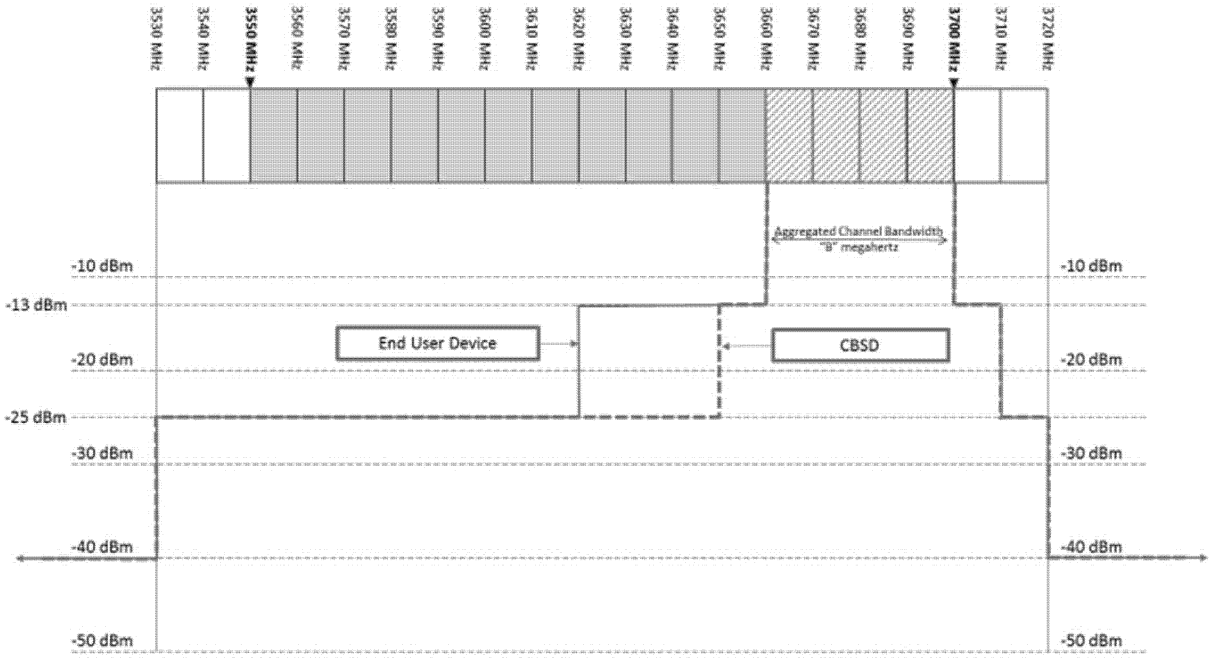
■ 12. Amend § 96.41 by revising paragraphs (e)(1) and (2) and (e)(3)(i) to read as follows:

§ 96.41 General radio requirements.

* * * * *

(e) *3.5 GHz Emissions and Interference Limits*—(1) *General protection levels.*

Figure 1 to paragraph (e) – Protection levels



(i) Except as otherwise specified in paragraph (e)(2) of this section, for channel and frequency assignments made by the SAS to CBSDs, the conducted power of any CBSD emission outside the fundamental emission bandwidth as specified in paragraph (e)(3) of this section (whether the emission is inside or outside of the authorized band) shall not exceed −13 dBm/MHz within 0–10 megahertz above the upper SAS-assigned channel edge and within 0–10 megahertz below the lower SAS-assigned channel edge. At all frequencies greater than 10 megahertz above the upper SAS assigned channel edge and less than 10 MHz below the lower SAS assigned channel edge, the conducted power of any CBSD emission shall not exceed −25 dBm/MHz. The upper and lower SAS assigned channel edges are the upper and lower limits of any channel assigned to a CBSD by an SAS, or in the case of multiple contiguous channels, the upper and lower limits of the combined contiguous channels.

(ii) Except as otherwise specified in paragraph (e)(2) of this section, for channel and frequency assignments made by a CBSD to End User Devices, the conducted power of any End User Device emission outside the fundamental emission (whether in or outside of the authorized band) shall not exceed −13 dBm/MHz within 0 to B megahertz (where B is the bandwidth in megahertz of the assigned channel or multiple contiguous channels of the End User Device) above the upper CBSD-assigned channel edge and within 0 to B megahertz below the lower CBSD-assigned channel edge. At all frequencies greater than B megahertz above the upper CBSD assigned channel edge and less than B megahertz below the lower CBSD-assigned channel edge, the conducted power of any End User Device emission shall not exceed −25 dBm/MHz. Notwithstanding the emission limits in this paragraph, the Adjacent Channel Leakage Ratio for End User Devices shall be at least 30 dB.

(2) *Additional protection levels.* Notwithstanding paragraph (e)(1) of this section, for CBSDs and End User Devices, the conducted power of emissions below 3540 MHz or above 3710 MHz shall not exceed −25 dBm/MHz, and the conducted power of emissions below 3530 MHz or above 3720 MHz shall not exceed −40dBm/MHz.

(3) *Measurement procedure.* (i) Compliance with this provision is based on the use of measurement instrumentation employing a resolution bandwidth of 1 megahertz or greater. However, in the 1 megahertz bands immediately outside and adjacent to the licensee's authorized frequency channel, a resolution bandwidth of no less than one percent of the fundamental emission bandwidth may be employed. A narrower resolution bandwidth is permitted in all cases to improve measurement accuracy provided the measured power is integrated over the full reference bandwidth (*i.e.,* 1 MHz or 1 percent of emission bandwidth, as specified). The fundamental emission bandwidth is defined as the width of the signal between two points, one below the carrier center frequency and one above the carrier center frequency, outside of which all emissions are attenuated at least 26 dB below the transmitter power.

* * * * *

■ 13. Amend § 96.55 by revising paragraph (a)(3) to read as follows:

§ 96.55 Information gathering and retention.

(a) * * *

(3) Upon request, SAS Administrators must make available to the general public aggregated spectrum usage data for any geographic area. Such information must include the total available spectrum and the maximum available contiguous spectrum in the requested area. SAS Administrators shall not disclose specific CBSD registration information to the general public except where such disclosure is authorized by the registrant.

* * * * *

[FR Doc. 2018–25795 Filed 12–6–18; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 20

[WT Docket No. 17–228; FCC 18–167]

Reporting Requirements Governing Hearing Aid-Compatible Mobile Handsets

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Federal Communications Commission (''Commission'' or ''FCC'') revises its rules to require service providers to post on their publicly accessible websites information regarding the hearing aid compatibility of their offered handsets. Service providers are also required to retain information regarding the hearing aid compatibility of handsets previously offered. Through this information, consumers will have access to the most recent data about hearing aid-compatible handsets and the Commission will be able to ensure compliance with the hearing aid compatibility rules and requirements. In addition, the Commission no longer requires providers to file FCC Form 655 on an annual basis. Instead, providers must file an annual certification indicating whether or not they are compliant with the hearing aid compatibility rules.

DATES: *Effective Date:* January 7, 2019.

Compliance Date: Compliance will not be required for § 20.19(e), (h), and (i), until after approval by the Office of Management and Budget. We will publish a document in the **Federal Register** announcing the compliance date.

FOR FURTHER INFORMATION CONTACT: Weiren Wang, Wireless Telecommunications Bureau, (202) 418–7275, email *Weiren.Wang@fcc.gov,* and Michael Rowan, Wireless Telecommunications Bureau, (202) 418–1883, email *Michael.Rowan@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order (Order), WT Docket No. 17–228; FCC 18–167, adopted November 15, 2018 and released November 16, 2018. The full text of this document is available for inspection and copying during business hours in the FCC Reference Information Center, Portals II, 445 12th Street SW, Room CY–A257, Washington, DC 20554. Also, it may be purchased from the Commission's duplicating contractor at Portals II, 445 12th Street SW, Room CY–B402, Washington, DC 20554; the contractor's website, *http://www.bcpiweb.com;* or by calling (800) 378–3160, facsimile (202) 488–5563, or email *FCC@BCPIWEB.com.* Copies of the Order also may be obtained via the Commission's Electronic Comment Filing System (ECFS) by entering the docket number WT Docket 17–228. Additionally, the complete item is available on the Federal Communications Commission's website at *http://www.fcc.gov.*

Synopsis

I. Report and order

1. The Commission has witnessed unprecedented growth in the degree to which service providers offer handsets that are hearing aid-compatible. In light of the growth in hearing aid-compatible handsets and decreasing public reliance on reports since they were first adopted by the Commission in 2003, the Commission takes two key steps to reform the hearing-aid compatibility reporting regime. First, the Commission revises its rules to require service providers to post on their websites the most critical information currently submitted on FCC Form 655. By requiring all service providers to post this information on publicly accessible websites that they control, the Commission can ensure that consumers have access to information about the increased numbers of hearing aid-compatible handset models with less burden for both service providers and consumers. This website information also will allow the Commission to continue to evaluate rule compliance without collecting information directly from service providers. Consumers will benefit from having access to the most up-to-date information about each handset model being offered by service providers.

2. Second, the Commission finds that many of the benefits of annual status reporting by service providers have become increasingly outweighed by the burdens that such information collection places on these entities. Instead of requiring providers to submit the FCC Form 655 on an annual basis, the Commission will require providers to submit annual certifications that require only a statement that a service provider is or is not in full compliance with the Commission's hearing aid compatibility rules, and if not, explain why. The action the Commission takes here streamlines the Commission's collection of information while continuing to fulfill the underlying purposes of the current reporting regime.

3. By using streamlined annual certifications combined with website reporting, the Commission ensures that it meets its objectives of monitoring industry and enforcing compliance with the relevant deployment benchmarks and other hearing aid compatibility provisions in the Commission's rules. This approach will ensure that consumers have better access to useful, current information about the hearing aid compatibility of the handset models being offered by service providers.

4. The Commission notes that in a separate docket, it is considering broader changes to the hearing aid compatibility rules that may be appropriate in the event the Commission requires 100% of covered handsets to be hearing aid-compatible. Per the schedule established in that proceeding, which the Commission has no current plan to deviate from, the process through which the Commission would make a determination whether a 100 percent requirement is achievable would conclude at the end of 2022. Revisions to the existing deployment benchmarks and other related rules are outside of the scope of this proceeding, and therefore these requirements will remain in place unless and until the Commission takes further action in that docket. To that end, the Commission's decision here is not predicated on further changes that might be under consideration, and thus, does not prejudge any further steps it may take to modify its reporting rules in that proceeding.

A. Improvements to Service Provider Website Requirements

5. The Commission amends its hearing aid compatibility website requirements for service providers to ensure that the objectives of the FCC Form 655 reporting requirement continue to be met. In doing so, the Commission adopts, in part, the proposal put forth by the Joint Consensus filers. Under the Commission's new rules, service providers will continue to comply with the existing website requirements supplemented with additional content that is useful to consumers. In addition, the Commission will carry over to the new website posting obligation limited content from the FCC Form 655 necessary to meet the Commission's information, monitoring, and enforcement goals.

6. In addition to the current website requirements, all service providers that operate publicly accessible websites (other than *de minimis* service providers, which remain exempt from website requirements) will now be required to post to their websites the following additional information:

(1) A list of all non-hearing aid-compatible handset models currently offered, including the level of functionality of those models;

(2) among other pieces of data, the marketing model name/number(s) and FCC ID number of each hearing aid-compatible and non-hearing aid-compatible handset model currently offered;

(3) a link to a third-party website as designated by the Commission or Wireless Telecommunications Bureau, with information regarding hearing aid-compatible and non-hearing aid-compatible devices OR, alternatively, a clearly marked list of hearing aid-compatible devices that have been offered in the past 24 months but are no longer offered by that provider. For purposes of initial implementation, the Commission designates the Global Accessibility Reporting Initiative (GARI) website as the third party website referred to in this portion of the rule;

(4) A link to the current FCC web page containing information about the wireless hearing aid compatibility rules and service providers' obligations; and

(5) A ''date stamp'' on any website page containing the above referenced information that indicates when the page was last updated.

7. Service providers must also retain internal records for discontinued models, to be made available upon Commission request of:

(1) Handset model information, including the month year/each hearing aid-compatible and non-hearing aid-compatible handset model was first offered; and

(2) the month/year each hearing aid-compatible handset model and non-hearing aid-compatible handset was last offered for all discontinued handset models until a period of 24 months has passed from that date.

8. Retaining a trailing list of all handsets offered over the past 24 months will ensure that the Commission can continue to monitor whether service providers meet numerical and percentage-based handset deployment obligations. The obligation to post a link to the GARI website, or alternatively, post a clearly marked list of hearing aid compatible devices that have been offered in the past 24 months (which at least one smaller provider has already voluntarily adopted) also permits consumers to locate information about a model they may have recently purchased that is no longer being offered. The Commission concludes that it can serve as a useful tool for consumers to obtain hearing aid compatibility information regarding past handsets offered. Past handset information is useful not only to consumers who purchase devices via re-sale, but also to consumers who, for instance, start using a hearing aid or change hearing aids and want to check on whether their current device is compatible. So that service providers have flexibility, the Commission will not prescribe a standard template for posting and retaining this information. In addition, service providers can rely on the information from device manufacturers' FCC Form 655 as a safe harbor, similar to the Commission's policy in the past for service providers' FCC Form 655 filings.

9. The Commission does not anticipate that it will be difficult or burdensome for service providers to gather and post this additional information on their websites or to retain it. Service providers must continue to meet applicable deployment benchmarks and maintain compliance with all other hearing aid compatibility requirements. Therefore, service providers would likely need to track the information outlined above, some of which service providers need in order to run their businesses independent of the Commission's requirements (*e.g.,* when a handset is first offered and no longer offered). Posting this information to their websites and/or retaining it for their records should impose on providers only a minimal additional burden. This conclusion is confirmed by the record in this proceeding showing that service providers already post some of this newly required information and the willingness of the Joint Consensus filers to endorse a similar approach.

10. The Commission finds that its new website and record retention requirements should better serve the Commission's objectives because the information on websites will be more up-to-date than the data submitted on FCC Form 655. The current website rules require providers to update the website information within 30 days of any relevant changes. As the Commission stated when it adopted the website posting requirement, ''updated website postings are necessary . . . so that consumers can obtain up-to-date hearing aid compatibility information from their service providers.'' To ensure that providers are aware that their websites need to be kept up to date, the Commission codifies this requirement.

11. The Commission will be able to use the information on a service provider's website to ensure that it is in compliance with the appropriate deployment benchmarks on a month-by-month basis. The Commission believes this is a better approach than other options, such as, for example, relying on informal complaints. The Commission also can use the posted information to monitor the state of the provision of hearing aid-compatible handsets by the wireless industry and the effectiveness of its hearing aid compatibility requirements. The Commission also believes that the proceeding in which the Commission is considering whether to require 100% of handsets to be hearing aid-compatible allows the Commission to monitor industry progress without requiring individual hearing aid compatibility status data from service providers. These revisions to the Commission's website posting requirements will allow consumers better access to more current information about the hearing aid compatibility features of current handset models offered by their service providers, and the information will be in a clearer format than is currently possible on FCC Form 655.

12. The website and record retention requirements the Commission adopts here differ slightly from the approach outlined in the Joint Consensus Letter and the separate request of HLAA–RERC. The requirement to post information about non-hearing aid-compatible handsets, for instance, is not addressed by the Joint Consensus filers. Nevertheless, the Commission concludes that requiring the posting of this information, along with information regarding currently offered hearing aid-compatible handsets on providers' websites, provides an easy means for the Commission and interested third parties to quickly derive a percentage of hearing aid-compatible handsets to determine whether the provider is meeting the relevant benchmarks. The Commission would not have to wait for the annual certification or make a request for internal data from the provider to determine whether the provider is currently compliant. Because the majority of handsets are hearing aid-compatible, this requirement imposes a limited burden compared to the compliance benefit.

B. Adoption of Service Provider Certification Requirement To Replace Annual Reporting Requirements

13. The Commission adopts a requirement that all service providers certify whether they are in compliance with all of the Commission's wireless hearing aid compatibility requirements. Service providers should affirmatively state their compliance with the hearing aid compatibility rules through an annual certification. The Commission adopts the Joint Consensus proposal with some modifications. This new annual certification requirement applies

to all service providers including *de minimis* service providers. It will assure the public and the Commission that service providers have a strong incentive to comply fully with all of the Commission's hearing aid compatibility requirements, including deployment, website, labeling, and disclosure requirements, among others. Under this new rule, service providers will be required to file a certification by January 15 of each calendar year using the existing electronic interface for the FCC Form 655 and stating as follows:

I am a knowledgeable executive [of company x] regarding compliance with the Federal Communications Commission's wireless hearing aid compatibility requirements at a wireless service provider covered by those requirements.

I certify that the provider was [(in full compliance/not in full compliance)] [choose one] at all times during the applicable time period with the Commission's wireless hearing aid compatibility deployment benchmarks and all other relevant wireless hearing aid compatibility requirements.

The company represents and warrants, and I certify by this declaration under penalty of perjury pursuant to 47 CFR 1.16 that the above certification is consistent with 47 CFR 1.17, which requires truthful and accurate statements to the Commission. The company also acknowledges that false statements and misrepresentations to the Commission are punishable under Title 18 of the U.S. Code and may subject it to enforcement action pursuant to sections 501 and 503 of the Act.

14. If the certification states that the provider is ''not in full compliance,'' it must include an explanation of which wireless hearing aid compatibility requirements the wireless service provider was not in full compliance with, and when non-compliance began and (if applicable) ended with respect to each requirement. In addition, as part of the certification, the service provider must submit the name of the signing executive, his or her contact information, the website address (if applicable) of pages(s) containing hearing aid compatibility information required by section 20.19(h), and the FCC FRN and the name of the company(ies) covered by the certification. The Commission expects to rely on this affirmative statement of compliance in any enforcement action.

15. The service provider must also indicate on the certification form the percentage of hearing aid compatible wireless handsets it made available that year. Providers will derive this percentage by determining the number of hearing aid-compatible handsets offered across all air interfaces during the year divided by the total number of handsets offered during the year. This requirement, while not directly related to service providers' compliance, will help the Commission and consumers quickly determine the state of the hearing aid compatibility marketplace. The Commission will rely on website postings of current handsets and the document retention requirements it adopts here to monitor carrier compliance with the deployment benchmarks by air interface.

16. The Commission does not adopt one element of the Joint Consensus Letter regarding the certification. Specifically, it does not adopt the Joint Consensus Letter request to state in the rules that providers may request confidentiality when submitting records to the Commission because providers already have the right to make such a request and such requests are typically ruled upon subsequent to the information submission. The Commission also adopts the requirement proposed by CTIA, CCA and TIA that a ''knowledgeable executive,'' rather than an officer, sign the certification in order to increase service providers' flexibility and consistency with the language of the Form FCC 655 certification. The Commission does not however, adopt their proposal that the knowledgeable executive certify only that the company has procedures in place to ensure compliance with the rules. Requiring the executive to certify that the company is in fact in compliance increases service providers' accountability and is necessary to provide the Commission and the public with a clear picture of each company's compliance as well as industry-wide compliance levels.

17. Given the Commission's improved website posting obligations, the new, streamlined certification requirements, and manufacturers' continued submission of FCC Form 655s, it is no longer necessary to require service providers to file FCC Form 655. The revised website and certification requirements the Commission adopts in this Order fulfill the objectives underlying the filing requirement with increased consumer benefits and less burden. For example, service providers will no longer be required to list the air interface(s) and frequency band(s) over which an offered model operates, information that they say is particularly burdensome to gather and list in their filings. Moreover, this information duplicates what manufacturers are filing for the same handsets. As long as service providers correctly and clearly identify on their websites the models that they currently offer and retain historical handset information, the Commission will be able to use this information to compare the handsets offered to Commission databases and derive the relevant information for enforcement purposes, and consumers will have much simpler access to this data.

18. Further, the Commission will be able to determine benchmark compliance by air interface by examining the data on service providers' websites by cross referencing that information on manufacturers' FCC Form 655. Service providers will not need to answer or provide a description in response to the several questions on the status of product labeling and outreach efforts. Service providers will no longer have the burden of identifying the total number of hearing aid-compatible and non-hearing aid-compatible models they offer to customers for each air interface over which the service provider offers service by month, or answer company information questions regarding their status as it relates to the *de minimis* exception.

19. Based on the record, the Commission therefore modifies its rules to eliminate the FCC Form 655 reporting requirement for all service providers. The Joint Consensus filers support eliminating the FCC Form 655 if other safeguards are put in place, and with minor deviations, the Commission is adopting the safeguards they propose. Moreover, small service providers, such as members of RWA, agree that the burden of reporting is not justified and that the costs saved by eliminating the requirement will allow them to maintain and improve their websites and other outreach materials that are more readily accessible to consumers. And CTIA/CCA state that a certification approach would not harm consumers' ability to obtain information about hearing aid-compatible handsets from other publicly available sources of information.

20. For small, rural, and regional service providers, especially, the burden of reporting is substantial. The record indicates that such service providers must devote substantial time and resources to tracking and collecting the information necessary to fill out the form. These efforts are a strain on these providers' limited resources. The financial cost of the reporting requirement is disproportionate to the number of customers served by these providers. For example, in January

2018, compared to the reports from the four largest carriers (which serve more than 98% of wireless subscribers), 209 smaller providers filed annual Form 655 status reports. Even for nationwide carriers, the costs of reporting are no longer justified given their high level of compliance with deployment benchmarks and the information the Commission already collects from device manufacturers.

21. The Commission expects that service providers' percentages of hearing aid-compatible handset models being offered, as well as their compliance levels with deployment benchmarks, are unlikely to decline for the foreseeable future because nearly all handsets offered by manufacturers are hearing aid-compatible, reducing the need for up-front detailed information in FCC Form 655. The Commission recognizes that the implementation of new, unforeseen technologies could affect handset manufacturers' and providers' ability to offer hearing aid-compatible handsets in the future. The Commission will therefore continue to monitor the wireless handset marketplace to assess the need for further amendments to its rules.

22. The Commission notes that it is eliminating certain reporting requirements, such as reporting on the status of outreach efforts and product labelling, because they are no longer useful for the Commission or consumers, and the burden of these requirements outweighs the benefits.

23. Finally, the Commission makes clear that its decision today does not affect its wireless hearing aid compatibility rules outside of its reporting and website requirements, including those designed to facilitate consumer access to hearing aid-compatible devices. Although service providers will no longer be required to complete the FCC Form 655, the Commission's hearing aid compatibility rules still require service providers to comply with all labeling, disclosure, in-store testing, and level of functionality requirements. The Commission continues to encourage providers to continue engaging in outreach efforts to educate the public, audiologists, hearing aid dispensers, and retail personnel concerning the use of digital wireless phones with hearing aids.

C. Transition and Implementation Issues

24. In order that service providers focus future efforts toward an orderly transition to the new website and annual certification requirements that the Commission adopted in this Report and Order, it waived, on its own motion, the requirement that service providers file the hearing aid status report currently due by January 15, 2019. This waiver will last from public release of the Report and Order until its effective date whereupon this reporting requirement will be deleted from the rules. The first annual certification will cover calendar year 2018, the same period that would be covered by the FCC Form 655 for which the Commission is providing a waiver. Subsequent annual certifications starting in 2020 will be due by January 15 each year.

25. The Commission finds good cause to grant a waiver under the circumstances presented. The Commission intends to relieve providers of the current reporting burden as soon as possible and a limited waiver both effectuates this purpose as efficiently as possible and avoids duplicate collections of the same 2018 calendar-year handset information. The certification that would substitute for the January 2019 report fully satisfies the Commission's goals. And although the certification will occur somewhat later than January in order to obtain the necessary OMB approval, this minor delay will not significantly undercut the purpose underlying the certification in part because the revisions the Commission adopts here require posting and retention of data for the 2018 calendar year, not just data from approval of the information collection requirements onward. Service providers will still have an affirmative obligation to confirm compliance with all of the Commission's hearing aid-compatibility requirements, including the handset deployment benchmarks, and the Commission and public will have an opportunity to evaluate that statement against the Commission's revised website deployment obligations. In addition, because manufacturers will continue to file even more detailed handset information on their Form 655 to which consumers may refer, the Commission believes that any harm from this limited waiver would be minimal. Finally, while the Commission does not choose to eliminate the existing reporting rule immediately upon publication of this Report and Order in the **Federal Register**, it observes that the exception to the Administrative Procedure Act to adopt a ''substantive rule which . . . relieves a restriction'' supports its recognition of the public interest served by its grant of this waiver. The Commission therefore finds it in the public interest to waive the annual reporting requirements for service providers.

26. The Commission also provides for a transition for the revised website and data retention obligations. Thirty days following publication in the **Federal Register** of a notice that OMB has approved the information collection requirements related to the new website posting rule, service providers will be required to post and retain the prescribed handset model information. This information will include posting information on all handsets currently offered, retaining information on handsets previously offered starting January 1, 2018 and thereafter, as well as either posting information on handsets previously offered starting on January 1, 2018 *or* providing a link to the GARI website with previously offered handset information.

27. Per the new 24-month handset history rule, the number of months of historical handset information providers must post to the website and retain will increase until it reaches 24 months in January 2020, at which time providers will no longer have an obligation to retain or post data from January 2018. Until the revised rule takes effect, providers must still meet current website requirements and post an ongoing list of all hearing aid-compatible models that they currently offer, the ratings of those models, and an explanation of the rating system, as well as other information about handset functionality levels, and update the website information within thirty days of any relevant change.

28. The Commission finds that this website and data retention transition period and the FCC Form 655 waiver affords service providers time to compile the requisite information and make the necessary changes to their websites and internal compliance processes. This schedule appropriately balances service providers' need for time to collect the information that will be required with the public's interest in maintaining a steady flow of handset information. By having the revised certification and website rule become effective at the same time, they work in tandem to ensure compliance with the Commission's wireless hearing aid compatibility rules in 2018 and subsequent years.

29. Amendments to § 20.19(e), § 20.19(h), and § 20.19(i) contain new or modified information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13, that are not effective until approved by the Office of Management and Budget (OMB). The Commission will publish a document in the **Federal Register** announcing the effective date once OMB approves.

II. Procedural Matters

A. Final Regulatory Flexibility Analysis

30. As required by the Regulatory Flexibility Act of 1980, as amended (RFA), an Initial Regulatory Flexibility Analysis (IRFA) was incorporated in the Notice of Proposed Rulemaking (NPRM), released in September 2017. The Commission sought written public comment on the proposals in the NPRM, including comment on the IRFA. The comments received are addressed below in section 2. This present Final Regulatory Flexibility Analysis (FRFA) conforms to the RFA.

1. Need for, and Objectives of, the Proposed Rules

31. In the Report and Order, the Commission modifies its wireless hearing aid compatibility rules, eliminates unnecessary and outdated reporting requirements, and improves its collection of information regarding the status of hearing aid-compatible handsets. The Commission finds that many of the benefits of annual status reporting by service providers have been realized and increasingly have become outweighed by the burdens that such information collection places on these entities. The Commission's new streamlined approach will continue to serve the underlying purposes of the Commission's annual reporting requirements without the burdens associated with that filing.

32. Specifically, the Commission waives the requirement for service provides to file the FCC Form 655 annual filing by January 15, 2019 and eliminates the requirement in subsequent years. Under the Commission's new approach, only wireless device manufacturers will continue to be obligated to file FCC Form 655 by July 15 of each calendar year. Next, the Commission amends its existing website requirements to ensure that consumers have access to the most up-to-date and useful information about the hearing aid compatibility of the handset models offered by service providers, and the Commission has sufficient information to verify compliance with the benchmark requirements. Only the most critical pieces of information currently submitted as part of the FCC Form 655 must continue to be made available on service providers' websites. The Commission will also require the service providers to file a simple, new, annual certification to enhance the ability of the Commission to enforce the hearing aid compatibility rules. The Commission also requires service providers to retain data regarding handsets no longer offered to verify compliance with its rules.

33. This new light-touch regulatory approach will enable the Commission to fulfill its responsibilities and objectives for wireless hearing aid compatibility. By requiring all service providers to post consistent content and information on their publicly available websites, the Commission ensures that consumers can access the information they need about the hearing aid compatibility of the handsets being offered. This website information will also allow the Commission to evaluate compliance with the relevant benchmarks and other hearing aid compatibility provisions in its rules. In addition to being able to verify compliance with its rules when necessary, the Commission will also be able to monitor the overall status of access to hearing aid-compatible handsets. The Commission's ability to verify and enforce compliance and monitor industry developments will also be served by requiring all service providers to annually file a certification stating whether or not they are in compliance with the Commission's hearing aid compatibility provisions.

2. Summary of Significant Issues Raised by Public Comments in Response to the IRFA

34. There were no comments filed that specifically addressed the rules and policies proposed in the IRFA.

3. Response to Comments by the Chief Counsel for Advocacy of the Small Business Administration

35. Pursuant to the Small Business Jobs Act of 2010, which amended the RFA, the Commission is required to respond to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration (SBA), and to provide a detailed statement of any change made to the proposed rules as a result of those comments.

36. The Chief Counsel did not file any comments in response to the proposed rules in this proceeding.

4. Description and Estimate of the Number of Small Entities to Which the Rules Will Apply

37. The RFA directs agencies to provide a description of, and where feasible, an estimate of the number of small entities that may be affected by the rules adopted herein. The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act. A ''small business concern'' is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA.

38. *Small Businesses, Small Organizations, Small Governmental Jurisdictions.* The Commission's actions, over time, may affect small entities that are not easily categorized at present. The Commission therefore describe here, at the outset, three broad groups of small entities that could be directly affected herein. First, while there are industry specific size standards for small businesses that are used in the regulatory flexibility analysis, according to data from the SBA's Office of Advocacy, in general a small business is an independent business having fewer than 500 employees. These types of small businesses represent 99.9% of all businesses in the United States which translates to 28.8 million businesses.

39. Next, the type of small entity described as a ''small organization'' is generally ''any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.'' Nationwide, as of August 2016, there were approximately 356,494 small organizations based on registration and tax data filed by nonprofits with the Internal Revenue Service (IRS).

40. Finally, the small entity described as a ''small governmental jurisdiction'' is defined generally as ''governments of cities, counties, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand.'' U.S. Census Bureau data from the 2012 Census of Governments indicate that there were 90,056 local governmental jurisdictions consisting of general purpose governments and special purpose governments in the United States. Of this number there were 37,132 General purpose governments (county, municipal and town or township) with populations of less than 50,000 and 12,184 Special purpose governments (independent school districts and special districts) with populations of less than 50,000. The 2012 U.S. Census Bureau data for most types of governments in the local government category show that the majority of these governments have populations of less than 50,000. Based on this data the Commission estimates that at least 49,316 local government jurisdictions fall in the category of ''small governmental jurisdictions.''

41. *Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing.* This industry comprises

establishments primarily engaged in manufacturing radio and television broadcast and wireless communications equipment, including unlicensed devices. Examples of products made by these establishments are: Transmitting and receiving antennas, cable television equipment, GPS equipment, pagers, cellular phones, mobile communications equipment, radio and television studio and broadcasting equipment. The Small Business Administration has established a size standard for this industry of 750 employees or less. U.S. Census data for 2012, shows that 841 establishments operated in this industry in that year. Of that number, 828 establishments operated with fewer than 1,000 employees, 7 establishments operated with between 1,000 and 2,499 employees and 6 establishments operated with 2,500 or more employees. Based on this data, the Commission concludes that a majority of manufacturers in this industry is small.

42. *Part 15 Handset Manufacturers.* The Commission has not developed a definition of small entities applicable to unlicensed communications handset manufacturers. The SBA category of Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing is the closest NAICS code category for Part 15 Handset Manufacturers. The Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing industry is comprised of establishments primarily engaged in manufacturing radio and television broadcast and wireless communications equipment. Examples of products made by these establishments are: Transmitting and receiving antennas, cable television equipment, GPS equipment, pagers, cellular phones, mobile communications equipment, and radio and television studio and broadcasting equipment.'' The SBA has developed a small business size standard for Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing, as firms having 750 or fewer employees. U.S. Census data for 2012, shows that 841 establishments operated in this industry in that year. Of that number, 828 establishments operated with fewer than 1,000 employees, 7 establishments operated with between 1,000 and 2,499 employees and 6 establishments operated with 2,500 or more employees. Thus, under this size standard, the majority of firms can be considered small.

43. *Wireless Telecommunications Carriers (except Satellite).* This industry comprises establishments engaged in operating and maintaining switching and transmission facilities to provide communications via the airwaves. Establishments in this industry have spectrum licenses and provide services using that spectrum, such as cellular phone services, paging services, wireless internet access, and wireless video services.'' The appropriate size standard under SBA rules is for the category Wireless Telecommunications Carriers (except Satellite) is that a business is small if it has 1,500 or fewer employees. For this industry, U.S. Census data for 2012 shows that there were 967 firms that operated for the entire year. Of this total, 955 firms had employment of 999 or fewer employees and 12 had employment of 1000 employees or more. Thus, under this category and the associated size standard, the Commission estimates that the majority of wireless telecommunications carriers (except satellite) are small entities.

44. The Commission's own data—available in its Universal Licensing System—indicate that, as of October 25, 2016, there are 280 Cellular licensees that will be affected by the Commission's actions here. The Commission does not know how many of these licensees are small, as the Commission does not collect that information for these types of entities. Similarly, according to Commission data, 413 carriers reported that they were engaged in the provision of wireless telephony, including cellular service, Personal Communications Service (PCS), and Specialized Mobile Radio (SMR) Telephony services. Of these, an estimated 261 have 1,500 or fewer employees and 152 have more than 1,500 employees. Thus, using available data, the Commission estimates that the majority of wireless firms can be considered small.

45. Also included in this classification is Personal Radio Services, which provide short-range, low power radio for personal communications, radio signaling, and business communications not provided for in other services. The Personal Radio Services include spectrum licensed under part 95 of the Commission's rules. These services include Citizen Band Radio Service (''CB''), General Mobile Radio Service (''GMRS''), Radio Control Radio Service (''R/C''), Family Radio Service (''FRS''), Wireless Medical Telemetry Service (''WMTS''), Medical Implant Communications Service (''MICS''), Low Power Radio Service (''LPRS''), and Multi-Use Radio Service (''MURS''). The Commission notes that many of the licensees in these services are individuals, and thus are not small entities. In addition, due to the mostly unlicensed and shared nature of the spectrum utilized in many of these services, the Commission lacks direct information upon which to base a more specific estimation of the number of small entities under an SBA definition that might be directly affected by its action.

46. *Wireless Resellers.* The SBA has not developed a small business size standard specifically for Wireless Resellers. The SBA category of Telecommunications Resellers is the closest NAICS code category for wireless resellers. The Telecommunications Resellers industry comprises establishments engaged in purchasing access and network capacity from owners and operators of telecommunications networks and reselling wired and wireless telecommunications services (except satellite) to businesses and households. Establishments in this industry resell telecommunications; they do not operate transmission facilities and infrastructure. Mobile virtual network operators (MVNOs) are included in this industry. Under the SBA's size standard, such a business is small if it has 1,500 or fewer employees. U.S. Census data for 2012 shows that 1,341 firms provided resale services during that year. Of that number, all operated with fewer than 1,000 employees. Thus, under this category and the associated small business size standard, the majority of these resellers can be considered small entities.

5. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements for Small Entities

47. In the Report and Order, the Commission is eliminating a substantial reporting requirement that all service providers—large and small—argue is burdensome and unnecessary. The Commission finds that as the percentage of hearing aid-compatible handsets offered by service providers increases, the burden of the annual reporting requirement outweighs its usefulness as a monitoring and compliance tool. The Commission has determined that annual hearing aid compatibility status reports show a near universal compliance with the Commission's hearing aid compatibility requirements. Further, the Commission finds that the information that service providers submit as part of their FCC Form 655 filing requirement is duplicative of information that wireless device manufacturers are already providing and will continue to provide to the Commission in their annual filings. By eliminating the FCC

Form 655 filing requirement for all service providers, the Commission eliminates an unnecessary and outdated reporting requirement and streamlines its collection of information regarding the status of hearing aid-compatible handsets. In addition, the Commission finds that the elimination of the reporting requirement will allow service providers to utilize the cost savings in time and money to maintain and improve their websites and other outreach materials that are more readily accessible to consumers.

48. While the Commission is eliminating a reporting requirement that all service providers argue should be eliminated, the Commission's new light-touch regulatory approach will continue to allow it to fulfill its responsibilities and objectives for wireless hearing aid compatibility. Service providers will continue to have to meet relevant hearing aid compatibility handset benchmarks and comply with product labeling and disclosure requirements. Further, service providers will have to continue to post certain information about their handsets on their publicly accessible websites along with certain information that they previously included as part of their FCC Form 655 annual reporting requirement. The Commission is not prescribing a standard template for posting this information on their websites and the Commission finds that service providers may rely on information that device manufacturers included in their FCC Form 655 filings as a safe harbor. The record in this proceeding shows that some service providers already post some of this information to their websites and both large and small service providers support the use of web posting as an alternative to the FCC Form 655 filing requirement. Service providers will also be required to retain information regarding past handsets offered.

49. In addition to web posting and data retention requirements, the Commission is requiring all service providers to certify whether or not the provider is in full compliance with the Commission's hearing aid compatibility provisions and if they are not, a requirement to explain why. This requirement includes a short statement and information about who is making the certification. Commenters in the proceeding supported replacing the annual filing requirement with a certification requirement. The Commission does not anticipate that it will be difficult or burdensome for service providers to gather and post information on their website or to make the required certification. While the Commission is eliminating FCC Form 655 reporting requirements for all service providers, the Commission is not eliminating the requirement that they continue to meet applicable deployment benchmarks and maintain compliance with all other hearing aid compatibility provisions. Therefore, all service providers would likely need to maintain information demonstrating compliance with the rules in the normal course of business and posting this information to their websites and making the required certification should only impose a minimal additional incremental burden and, and, be substantially less than the burden associated with filing FCC Form 655 each year.

6. Steps Proposed To Minimize Significant Economic Impact on Small Entities, and Significant Alternatives Considered

50. The RFA requires an agency to describe any significant alternatives that it has considered in reaching its approach, which may include the following four alternatives (among others): ''(1) the establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities; (3) the use of performance rather than design standards; and (4) an exemption from coverage of the rule, or any part thereof, for such small entities.''

51. The Commission considered but rejected more burdensome compliance requirements. For instance, the Commission considered retaining but streamlining the information that is collected in the FCC Form 655. The Commission found that this approach would only result in a minimal reduction of regulatory burdens for service providers. Given the passage of time and the current state of availability of information about handset hearing aid compatibility, the burden of collecting the information necessary to fill out the form and file it, the Commission found that even in a streamlined format the benefit of filing the form was not outweighed by any benefit to consumers or the Commission. The Commission determined that streamlining the form will only result in a minimal reduction of regulatory burden with no corresponding benefit to the public interest. As a result, the Commission rejected the solution of streamlining the form and continuing the requirement that service providers file the form on an annual basis.

52. The Commission also chose to make the elimination of the FCC Form 655 reporting requirement for service providers effective 30 days after publication of the rule in the **Federal Register**. Therefore, service providers will benefit from the Commission's new rules almost immediately while the new website posting, and certification requirements will be effective 30 days following notice of OMB approval of the relevant information collection requirements. This approach affords service providers sufficient time to make any necessary preparations required by the new certification approach.

7. Report to Congress

53. The Commission will send a copy of the Report and Order, including this FRFA, in a report to Congress pursuant to the Congressional Review Act. In addition, the Commission will send a copy of the Report and Order, including this FRFA, to the Chief Counsel for Advocacy of the SBA. A copy of the Report and Order and FRFA (or summaries thereof) also will be published in the **Federal Register**.

B. Paperwork Reduction Act

54. The requirements in revised section 20.19(e), (h) and (i) constitute new or modified collections subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. They will be submitted to the Office of Management and Budget (OMB) for review under section 3507(d) of the PRA. OMB, the general public, and other Federal agencies are invited to comment on the new information collection requirements contained in this proceeding. This document will be submitted to OMB for review under section 3507(d) of the PRA. In addition, the Commission notes that, pursuant to the Small Business Paperwork Relief Act of 2002, it previously sought, but did not receive, specific comment on how the Commission might further reduce the information collection burden for small business concerns with fewer than 25 employees. The Commission describes impacts that might affect small businesses, which includes more businesses with fewer than 25 employees, in the Final Regulatory Flexibility Analysis in Appendix C.

C. Congressional Review Act

55. The Commission will include a copy of this Report and Order in a report to be sent to Congress and the Government Accountability Office

pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

III. Ordering Clauses

56. Accordingly, *it is ordered*, pursuant to sections 4(i), 303(r), and 710 of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 303(r), and 610, this Report and Order *is hereby adopted*.

57. *It is further ordered* that Part 20 of the Commission's rules *is amended* as set forth in Appendix B.

58. *It is further ordered* that the amendments of the Commission's rules as set forth in Appendix B *are adopted*, effective thirty days from the date of publication in the **Federal Register**. Section 20.19, paragraphs (e), (h) and (i) contain new or modified information collection requirements that require review by the OMB under the PRA. The Commission directs the Bureau to announce the compliance date for those information collections in a document published in the **Federal Register** after the Commission receives OMB approval and directs the Bureau to cause section 20.19(m) to be revised accordingly.

59. *It is further ordered* that, pursuant to the authority of section 4(i) of the Communications Act, as amended, 47 U.S.C. 154(i), and section 1.3 of the Commission's rules, 47 CFR 1.3, the requirements of section 20.19(i) of the Commission's rules, 47 CFR 20.19(i), *are waived* to the extent described herein.

60. *It is further ordered* that the Commission's Consumer & Governmental Affairs Bureau, Reference Information Center, *shall send* a copy of this Report and Order, including the Final Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the SBA.

List of Subjects in 47 CFR Part 20

Communications common carriers, Communications equipment, Radio.

Federal Communications Commission.

Katura Jackson,

Federal Register Liaison, Office of the Secretary.

Final Rules

For the reasons set forth in the preamble, part 20 of title 47 of the Code of Federal Regulations is amended as follows:

PART 20—COMMERCIAL MOBILE RADIO SERVICES

■ 1. The authority citation for part 20 continues to read as follows:

Authority: 47 U.S.C. 151, 152(a), 154(i), 157, 160, 201, 214, 222, 251(e) 301, 302, 303, 303(b), 303(r), 307, 307(a), 309, 309(j)(3), 316, 316(a), 332, 610, 615, 615a, 615b, 615c, unless otherwise noted.

■ 2. Section 20.19 is amended by revising paragraphs (c)(4)(ii), (d)(4)(ii), (e)(1)(i), (h), (i)(1), (i)(3), and (i)(4), and adding paragraph (m) to read as follows:

§ 20.19 Hearing aid-compatible mobile handsets.

* * * * *

(c) * * *

(4) * * *

(ii) *Offering models with differing levels of functionality.* Each service provider must offer its customers a range of hearing aid-compatible models with differing levels of functionality (*e.g.,* operating capabilities, features offered, prices). Each provider may determine the criteria for determining these differing levels of functionality.

(d) * * *

(4) * * *

(ii) *Offering models with differing levels of functionality.* Each service provider must offer its customers a range of hearing aid-compatible models with differing levels of functionality (*e.g.,* operating capabilities, features offered, prices). Each provider may determine the criteria for determining these differing levels of functionality.

(e) *De minimis exception.* (1)(i) Manufacturers or service providers that offer two or fewer digital wireless handsets in an air interface in the United States are exempt from the requirements of this section in connection with that air interface, except with regard to the reporting and certification requirements in paragraph (i) of this section. Service providers that obtain handsets only from manufacturers that offer two or fewer digital wireless handset models in an air interface in the United States are likewise exempt from the requirements of this section other than paragraph (i) of this section in connection with that air interface.

* * * * *

(h) *Website and record retention requirements*—(1) Each manufacturer and service provider that operates a publicly-accessible website must make available on its website a list of all hearing aid-compatible models currently offered, the ratings of those models, and an explanation of the rating system. Each service provider must also specify on its website, based on the levels of functionality and rating that the service provider has defined, the level that each hearing aid-compatible model falls under, as well as an explanation of how the functionality of the handsets varies at the different levels. Each service provider must also include on its website: A list of all non-hearing aid-compatible models currently offered, including the level of functionality that each of those models falls under, an explanation of how the functionality of the handsets varies at the different levels as well as a link to the current FCC web page containing information about the wireless hearing aid compatibility rules and service providers' obligations. Each service provider must also include the marketing model name/number(s) and FCC ID number of each hearing aid-compatible and non-hearing aid-compatible model currently offered.

(2) Service providers must maintain on their website either:

(i) A link to a third-party website as designated by the Commission or Wireless Telecommunications Bureau with information regarding hearing aid-compatible and non-hearing aid-compatible handset models; or

(ii) A clearly marked list of hearing aid-compatible handset models that are no longer offered if the calendar month/year that model was last offered is within 24 months of the current calendar month/year and was last offered in January 2018 or later along with the information listed in paragraph (h)(1) of this section for each hearing aid-compatible handset.

(3) If the Wireless Telecommunications Bureau determines that the third-party website has been eliminated or is not updated in a timely manner, it may select another website or require service providers to comply with paragraph (h)(2)(ii) of this section.

(4) The information on the website must be updated within 30 days of any relevant changes, and any website pages containing information so updated must indicate the day on which the update occurred.

(5) Service providers must maintain internal records including the ratings, if applicable, of all hearing aid-compatible and non-hearing aid-compatible models no longer offered (if the calendar month/year that model was last offered is within 24 months of the current calendar month/year and was last offered in January 2018 or later); for models no longer offered (if the calendar month/year that model was last offered is within 24 months of the current calendar month/year), the calendar months and years each hearing aid-compatible and non-hearing aid-compatible model was first and last offered; and the marketing model name/number(s) and FCC ID number of each hearing aid-compatible and non-hearing aid-compatible model no longer offered (if the calendar month/year that model was last offered is within 24 months of

the current calendar month/year and was last offered in January 2018 or later).

(i) *Reporting and certification requirements*—(1) *Reporting and certification dates.* Manufacturers shall submit reports on efforts toward compliance with the requirements of this section on an annual basis on July 15. Service providers shall submit certifications on their compliance with the requirements of this section by January 15 of each year. Information in each report and certification must be up-to-date as of the last day of the calendar month preceding the due date of each report and certification.

* * * * *

(3) *Content of service provider certifications.* Certifications filed by service providers must include:

(i) The name of the signing executive and contact information;

(ii) The company(ies) covered by the certification;

(iii) The FCC Registration Number (FRN);

(iv) If the service provider is subject to paragraph (h) of this section, the website address of the page(s) containing the required information regarding handset models;

(v) The percentage of handsets offered that are hearing aid-compatible (providers will derive this percentage by determining the number of hearing aid-compatible handsets offered across all air interfaces during the year divided by the total number of handsets offered during the year); and

(vi) The following language:

I am a knowledgeable executive [of company x] regarding compliance with the Federal Communications Commission's wireless hearing aid compatibility requirements at a wireless service provider covered by those requirements.

I certify that the provider was [(in full compliance/not in full compliance)] [choose one] at all times during the applicable time period with the Commission's wireless hearing aid compatibility deployment benchmarks and all other relevant wireless hearing aid compatibility requirements.

The company represents and warrants, and I certify by this declaration under penalty of perjury pursuant to 47 CFR 1.16 that the above certification is consistent with 47 CFR 1.17, which requires truthful and accurate statements to the Commission. The company also acknowledges that false statements and misrepresentations to the Commission are punishable under Title 18 of the U.S. Code and may subject it to enforcement action pursuant to Sections 501 and 503 of the Act.

(vii) If the company selected that it was not in full compliance, an explanation of which wireless hearing aid compatibility requirements it was not in compliance with, when the non-compliance began and (if applicable) ended with respect to each requirement.

(4) *Format.* The Wireless Telecommunications Bureau is delegated authority to approve or prescribe formats and methods for submission of the reports and certifications required by this section. Any format that the Bureau may approve or prescribe shall be made available on the Bureau's website.

* * * * *

(m) *Compliance date.* Paragraphs (e), (h), and (i) of this section contain new or modified information-collection and recordkeeping requirements adopted in FCC 18–167. Compliance with these information-collection and recordkeeping requirements will not be required until after approval by the Office of Management and Budget. The Commission will publish a document in the **Federal Register** announcing that compliance date and revising this paragraph accordingly.

[FR Doc. 2018–26037 Filed 12–6–18; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

49 CFR Part 270

[Docket No. FRA–2011–0060, Notice No. 9]

RIN 2130–AC79

System Safety Program

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Final rule; stay of regulations.

SUMMARY: On August 12, 2016, FRA published a final rule requiring commuter and intercity passenger railroads to develop and implement a system safety program (SSP) to improve the safety of their operations. FRA has stayed the SSP final rule's requirements until December 4, 2018. FRA is issuing this final rule to extend that stay until September 4, 2019.

DATES: Effective December 4, 2018, the stay of 49 CFR part 270 is extended until September 4, 2019.

ADDRESSES: *Docket:* For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and follow the online instructions for accessing the docket.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Gross, Attorney, U.S. Department of Transportation, Federal Railroad Administration, Office of Chief Counsel; telephone: 202–493–1342; email: *Elizabeth.Gross@dot.gov.*

SUPPLEMENTARY INFORMATION: On August 12, 2016, FRA published a final rule requiring commuter and intercity passenger railroads to develop and implement an SSP to improve the safety of their operations. *See* 81 FR 53850. On February 10, 2017, FRA stayed the SSP final rule's requirements until March 21, 2017, consistent with the new Administration's guidance issued January 20, 2017, intended to provide the Administration an adequate opportunity to review new and pending regulations. *See* 82 FR 10443 (Feb. 13, 2017). To provide additional time for that review, FRA extended the stay until May 22, 2017, June 5, 2017, December 4, 2017, and then December 4, 2018. *See* 82 FR 14476 (Mar. 21, 2017); 82 FR 23150 (May 22, 2017); 82 FR 26359 (June 7, 2017); and 82 FR 56744 (Nov. 30, 2017).[1] In that November 2017 document, FRA stated that the stays of the rule's requirements did not affect the SSP final rule's information protection provisions in 49 CFR 270.105, which took effect on August 14, 2017, for information a railroad compiles or collects after that date solely for SSP purposes.

FRA's review included petitions for reconsideration of the SSP final rule (Petitions). Various rail labor organizations (Labor Organizations) filed a single joint petition.[2] State and local transportation departments and authorities (States) filed the three other petitions, one of which was a joint petition (State Joint Petition).[3] The State Joint Petition requested that FRA stay the SSP final rule, and NCDOT specifically requested that FRA stay the rule while FRA was considering the

[1] FRA notes it inadvertently published two notifications in the **Federal Register** identified as Notice No. 6 for this docket. *See* 82 FR 23150 (May 22, 2017), Docket No. FRA–2011–0060–0043; and 82 FR 26359 (June 7, 2017), Docket No. FRA–2011–0060–0044. Before identifying the duplication, FRA published a subsequent Notice No. 7. *See* 82 FR 56744 (Nov. 30, 2017), Docket No. FRA–2011–0060–0047. FRA is numbering this document as Notice No. 9, to reflect that it is actually the ninth notification published for this docket.

[2] The labor organizations that filed the joint petition are: The American Train Dispatchers Association (ATDA), Brotherhood of Locomotive Engineers and Trainmen (BLET), Brotherhood of Maintenance of Way Employes Division (BMWED), the Brotherhood of Railroad Signalmen (BRS), Brotherhood Railway Carmen Division (TCU/IAM), and Transport Workers Union of America (TWU).

[3] The Capitol Corridor Joint Powers Authority (CCJPA), Indiana Department of Transportation (INDOT), Northern New England Passenger Rail Authority (NNEPRA), and San Joaquin Joint Powers Authority (SJJPA) filed a joint petition (Joint Petition). The North Carolina Department of Transportation (NCDOT) and State of Vermont Agency of Transportations (VTrans) each filed separate petitions.

petitions. All Petitions were available for public comment in the docket for the SSP rulemaking. On November 15, 2016, the Massachusetts Department of Transportation submitted a comment supporting the State Joint Petition, also asking FRA to stay the SSP final rule. FRA did not receive any public comments opposing the States' requests for a stay.

On October 30, 2017, FRA met with the Passenger Safety Working Group and the System Safety Task Group of the Railroad Safety Advisory Committee (RSAC) to discuss the Petitions and comments received in response to the Petitions.[4] FRA specifically invited its state partners to this meeting, which was also open to the public. This meeting was necessary for FRA to receive input from industry and the public, and to discuss potential paths forward to respond to the Petitions prior to FRA taking final action. During the meeting, a representative from the Oregon Department of Transportation asked whether the SSP final rule would be further stayed pending FRA's development of a response to the Petitions and public input received at the meeting. An FRA representative indicated that he anticipated a further stay of the rule to provide time to resolve the issues raised by the petitions. None of the meeting participants expressed opposition to a further stay. *See generally* FRA–2011–0060–0046.

In response to draft rule text FRA presented for discussion during the RSAC meeting, the States indicated they would need an extended caucus to discuss. On March 16, 2018, the Executive Committee of the States for Passenger Rail Coalition (SPRC)[5] provided, and FRA uploaded to the rulemaking docket, proposed revisions to the draft rule text. *See* FRA–2011–0060–0050. FRA is reviewing and considering these suggested revisions in formulating its response to the petitions for reconsideration.

Given the request for a continued stay of the rule, the comment received supporting a stay, the lack of opposition to a stay in either the comments or at the public RSAC meeting, and FRA's interest in addressing the issues raised in the State petitions through notice and comment rulemaking prior to requiring full compliance with the SSP final rule, FRA finds notice and comment for this stay to be impracticable and incompatible with the forthcoming NPRM.

Regulatory Impact and Notices

Executive Orders 12866 and 13771, and DOT Regulatory Policies and Procedures

This final rule is a non-significant deregulatory action within the meaning of Executive Order 12866 and DOT policies and procedures. *See* 44 FR 11034 (Feb. 26, 1979. The final rule is considered an E.O. 13771 deregulatory action. Details on the estimated cost savings are below.

In August 2016, FRA issued the System Safety Program final rule (2016 Final Rule) as part of its efforts to continuously improve rail safety and to satisfy the statutory mandate in sections 103 and 109 of the Rail Safety Improvement Act of 2008. The 2016 Final Rule requires passenger railroads to establish a program that systematically evaluates railroad safety risks and manages those risks with the goal of reducing the number and rates of railroad accidents, incidents, injuries, and fatalities. Paperwork requirements are the largest burden of the 2016 Final Rule.

FRA believes that this final rule, which will stay the requirements of the 2016 Final Rule until September 4, 2019, will reduce regulatory burden on the railroad industry. By staying the requirements of the 2016 Final Rule, railroads will realize a cost savings as railroads will not sustain any costs during the first nine months of this analysis. In addition, because this analysis discounts future costs and this final rule will move forward all costs by nine months, the present value costs of this stay will lower the present value cost of the SSP rulemaking. FRA estimates this cost savings to be approximately $255,928, at a 3-percent discount rate, and $246,360, at a 7-percent discount rate. The following table shows the 2016 Final Rule's total cost, delayed an additional nine months past the 2017 stay extension, the implementation date total costs, and the cost savings from the additional nine-month implementation date delay.

	Present value (7%)	Present value (3%)
2016 Final Rule, total cost	$2,327,223	$3,412,649
Cost savings from nine-month delay	246,360	255,928
2016 Final Rule, total cost with cost savings from nine-month delay	2,080,863	3,156,721

Regulatory Flexibility Act and Executive Order 13272

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601 *et seq.,* and Executive Order 13272, 67 FR 53461 (Aug. 16, 2002), require agency review of proposed and final rules to assess their impact on small entities. An agency must prepare an Initial Regulatory Flexibility Analysis unless it determines and certifies that a rule, if promulgated, would not have a significant impact on a substantial number of small entities. Pursuant to the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the FRA Administrator certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

This final rule will affect passenger railroads, but will have a beneficial effect, lessening the burden on any small railroad.

''Small entity'' is defined in 5 U.S.C. 601 as including a small business concern that is independently owned and operated, and is not dominant in its field of operation. The U.S. Small Business Administration (SBA) has authority to regulate issues related to small businesses, and stipulates in its size standards that a ''small entity'' in the railroad industry is a for profit ''linehaul railroad'' that has fewer than 1,500 employees, a ''short line railroad'' with fewer than 1,500 employees, or a ''commuter rail system'' with annual receipts of less than $15.0 million dollars. *See* ''Size Eligibility Provisions and Standards,'' 13 CFR part 121, subpart A. Additionally, 5 U.S.C. 601(5) defines as ''small entities'' governments of cities, counties, towns, townships, villages, school districts, or special districts with populations less than 50,000. Federal agencies may adopt their own size standards for small entities, in consultation with SBA and in conjunction with public comment. Pursuant to that authority, FRA has published a final statement of agency policy that formally establishes ''small entities'' or ''small businesses'' as being railroads, contractors, and hazardous

[4] Attendees at the October 30, 2017, meeting included representatives from the following organizations: ADS System Safety Consulting, LLC; American Association of State Highway and Transportation Officials (AASHTO); American Public Transportation Association (APTA); American Short Line and Regional Railroad Association (ASLRRA); ATDA; Association of American Railroads (AAR); BLET; BMWED; BRS; CCJPA; The Fertilizer Institute; Gannett Fleming Transit and Rail Systems; International Brotherhood of Electrical Workers; Metropolitan Transportation Authority (MTA); National Railroad Passenger Corporation (Amtrak); National Transportation Safety Board (NTSB); NCDOT; NNEPRA; San Joaquin Regional Rail Commission/Altamont Corridor Express; Sheet Metal, Air, Rail, and Transportation Workers (SMART); and United States Department of Transportation—Transportation Safety Institute. During the meeting, an attorney from Kaplan Kirsch & Rockwell, LLP representing AASHTO indicated he was authorized to speak on behalf of all the State petitioners.

[5] SPRC's website indicates it is an ''alliance of State and Regional Transportation Officials,'' and each state petitioner appears to be an SPRC member. *See https://www.s4prc.org/state-programs.*

materials shippers that meet the revenue requirements of a Class III railroad as set forth in 49 CFR 1201.1–1, which is $20 million or less in inflation-adjusted annual revenues, and commuter railroads or small governmental jurisdictions that serve populations of 50,000 or less. *See* 68 FR 24891 (May 9, 2003), codified at appendix C to 49 CFR part 209. The $20-million limit is based on the Surface Transportation Board's revenue threshold for a Class III railroad. Railroad revenue is adjusted for inflation by applying a revenue deflator formula in accordance with 49 CFR 1201.1–1. FRA is using this definition for this rulemaking.

For purposes of this analysis, this final rule will apply to 30 commuter or other short-haul passenger railroads and two intercity passenger railroads, the National Railroad Passenger Corporation (Amtrak) and the Alaska Railroad Corporation (ARC). Neither is considered a small entity. Amtrak serves populations well in excess of 50,000, and the ARC is owned by the State of Alaska, which has a population well in excess of 50,000.

Based on the definition of ''small entity,'' only one passenger railroad is considered a small entity: The Hawkeye Express (operated by the Iowa Northern Railway Company). As the final rule is not significant, this final rule will merely provide this entity with additional compliance time without introducing any additional burden.

Pursuant to the Regulatory Flexibility Act, 5 U.S.C. 601(b), the FRA Administrator hereby certifies that this final rule will not have a significant impact on a substantial number of small entities. A substantial number of small entities may be impacted by this regulation; however, any impact will be minimal and positive.

Paperwork Reduction Act

There are no new collection of information requirements contained in this final rule and, in accordance with the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.,* an information collection submission to the Office of Management and Budget (OMB) is not required. The record keeping and reporting requirements already contained in the SSP final rule were approved by OMB on October 5, 2016. The information collection requirements thereby became effective when they were approved by OMB. The OMB approval number is OMB No. 2130–0599, and OMB approval expires on October 31, 2019.

Federalism Implications

Executive Order 13132, ''Federalism'' (64 FR 43255, Aug. 10, 1999), requires FRA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' are defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' Under Executive Order 13132, the agency may not issue a regulation with federalism implications that imposes substantial direct compliance costs and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments or the agency consults with State and local government officials early in the process of developing the regulation. Where a regulation has federalism implications and preempts State law, the agency seeks to consult with State and local officials in the process of developing the regulation.

This final rule has been analyzed in accordance with the principles and criteria contained in Executive Order 13132. FRA has determined that this rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. In addition, FRA has determined that this rule does not impose substantial direct compliance costs on State and local governments. Therefore, the consultation and funding requirements of Executive Order 13132 do not apply.

Environmental Assessment

FRA has evaluated this rule in accordance with its ''Procedures for Considering Environmental Impacts'' (FRA's Procedures) (64 FR 28545, May 26, 1999) as required by the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*), other environmental statutes, Executive Orders, and related regulatory requirements. FRA has determined that this rule is not a major FRA action (requiring the preparation of an environmental impact statement or environmental assessment) because it is categorically excluded from detailed environmental review pursuant to section 4(c)(20) of FRA's Procedures. *See* 64 FR 28547, May 26, 1999.

In accordance with section 4(c) and (e) of FRA's Procedures, the agency has further concluded that no extraordinary circumstances exist with respect to this regulation that might trigger the need for a more detailed environmental review. As a result, FRA finds that this rule is not a major Federal action significantly affecting the quality of the human environment.

Unfunded Mandates Reform Act of 1995

Pursuant to section 201 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4, 2 U.S.C. 1531), each Federal agency shall, unless otherwise prohibited by law, assess the effects of Federal regulatory actions on State, local, and tribal governments, and the private sector (other than to the extent that such regulations incorporate requirements specifically set forth in law). Section 202 of the Act (2 U.S.C. 1532) further requires that before promulgating any general notice of proposed rulemaking that is likely to result in the promulgation of any rule that includes any Federal mandate that may result in expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year, and before promulgating any final rule for which a general notice of proposed rulemaking was published, the agency shall prepare a written statement detailing the effect on State, local, and tribal governments and the private sector. This final rule will not result in such an expenditure, and thus preparation of such a statement is not required.

Energy Impact

Executive Order 13211 requires Federal agencies to prepare a Statement of Energy Effects for any ''significant energy action.'' 66 FR 28355 (May 22, 2001). FRA has evaluated this rule in accordance with Executive Order 13211 and has determined that this regulatory action is not a ''significant energy action'' within the meaning of Executive Order 13211.

Executive Order 13783, ''Promoting Energy Independence and Economic Growth,'' requires Federal agencies to review regulations to determine whether they potentially burden the development or use of domestically produced energy resources, with particular attention to oil, natural gas, coal, and nuclear energy resources. *See* 82 FR 16093 (Mar. 31, 2017). FRA determined this regulatory action will not burden the development or use of

domestically produced energy resources.

List of Subjects in 49 CFR Part 270

Penalties, Railroad safety, Reporting and recordkeeping requirements, System safety.

Authority: 49 U.S.C. 20103, 20106–20107, 20118–20119, 20156, 21301, 21304, 21311; 28 U.S.C. 2461, note; and 49 CFR 1.89.

Issued in Washington, DC.

Mathew M. Sturges,

Deputy Administrator.

The Rule

■ In consideration of the foregoing, FRA extends the stay of the SSP final rule published August 12, 2016 (81 FR 53850) until September 4, 2019.

[FR Doc. 2018–26447 Filed 12–4–18; 8:45 am]

BILLING CODE 4910–06–P

Proposed Rules

Federal Register

Vol. 83, No. 235

Friday, December 7, 2018

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 THE TREASURY

Office of the Comptroller of the Currency

12 CFR Part 34

[Docket No. OCC–2018–0038]

RIN 1557–AE57

FEDERAL RESERVE SYSTEM

12 CFR Part 225

[Docket No. R–1639]

RIN 7100–AF30

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Part 323

RIN 3064–AE87

Real Estate Appraisals

AGENCY: Office of the Comptroller of the Currency, Treasury (OCC); Board of Governors of the Federal Reserve System (Board); and Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice of proposed rulemaking and request for comment.

SUMMARY: The OCC, Board, and FDIC (collectively, the agencies) are inviting comment on a proposed rule to amend the agencies' regulations requiring appraisals for certain real estate-related transactions. The proposed rule would increase the threshold level at or below which appraisals would not be required for residential real estate-related transactions from $250,000 to $400,000. Consistent with the requirement for other transactions that fall below applicable thresholds, regulated institutions would be required to obtain an evaluation of the real property collateral that is consistent with safe and sound banking practices. The proposed rule would make conforming changes to add transactions secured by residential property in rural areas that have been exempted from the agencies' appraisal requirement pursuant to the Economic Growth, Regulatory Relief and Consumer Protection Act to the list of exempt transactions. The proposed rule would require evaluations for these exempt transactions. Pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act, the proposed rule would amend the agencies' appraisal regulations to require regulated institutions to subject appraisals for federally related transactions to appropriate review for compliance with the Uniform Standards of Professional Appraisal Practice.

DATES: Comments must be received by February 5, 2019.

ADDRESSES: Interested parties are encouraged to submit written comments jointly to all of the agencies. Commenters should use the title ''Real Estate Appraisals'' to facilitate the organization and distribution of comments among the agencies. Interested parties are invited to submit written comments to:

Office of the Comptroller of the Currency: You may submit comments to the OCC by any of the methods set forth below. Commenters are encouraged to submit comments through the Federal eRulemaking Portal or email, if possible. Please use the title ''Real Estate Appraisals'' to facilitate the organization and distribution of the comments. You may submit comments by any of the following methods:

- *Federal eRulemaking Portal—''Regulations.gov'':* Go to *www.regulations.gov.* Enter ''Docket ID OCC–2018–0038'' in the Search Box and click ''Search.'' Click on ''Comment Now'' to submit public comments.
- Click on the ''Help'' tab on the *Regulations.gov* home page to get information on using *Regulations.gov,* including instructions for submitting public comments.
- *Email: regs.comments@occ.treas.gov.*
- *Mail:* Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Hand Delivery/Courier:* 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Fax:* (571) 465–4326.

Instructions: You must include ''OCC'' as the agency name and ''Docket ID OCC–2018–0038'' in your comment. In general, the OCC will enter all comments received into the docket and publish the comments on the *Regulations.gov* website without change, including any business or personal information that you provide such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

You may review comments and other related materials that pertain to this rulemaking action by any of the following methods:

- *Viewing Comments Electronically:* Go to *www.regulations.gov.* Enter ''Docket ID OCC–2018–0038'' in the Search box and click ''Search.'' Click on ''Open Docket Folder'' on the right side of the screen. Comments and supporting materials can be viewed and filtered by clicking on ''View all documents and comments in this docket'' and then using the filtering tools on the left side of the screen.
- Click on the ''Help'' tab on the *Regulations.gov* home page to get information on using *Regulations.gov.* The docket may be viewed after the close of the comment period in the same manner as during the comment period.
- *Viewing Comments Personally:* You may personally inspect comments at the OCC, 400 7th Street SW, Washington, DC 20219. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 649–6700 or, for persons who are deaf or hearing impaired, TTY, (202) 649–5597. Upon arrival, visitors will be required to present valid government-issued photo identification and submit to security screening in order to inspect comments.

Board of Governors of the Federal Reserve System: You may submit comments, identified by Docket No. R–1639 and RIN 7100–AF30, by any of the following methods:

- *Agency Website: http://www.federalreserve.gov.* Follow the instructions for submitting comments at *http://www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm.*

• *Email: regs.comments@federalreserve.gov.* Include the docket number and RIN number in the subject line of the message.

• *Fax:* (202) 452–3819 or (202) 452–3102.

• *Mail:* Address to Ann E. Misback, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.

All public comments will be made available on the Board's website at *http://www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm* as submitted, unless modified for technical reasons or to remove personally identifiable information at the commenter's request. Accordingly, comments will not be edited to remove any identifying or contact information. Public comments may also be viewed electronically or in paper in Room 3515, 1801 K Street NW (between 18th and 19th Streets NW), between 9:00 a.m. and 5:00 p.m. on weekdays.

Federal Deposit Insurance Corporation: You may submit comments, identified by RIN 3064–AE87, by any of the following methods:

• *Agency Website: https://www.FDIC.gov/regulations/laws/federal.*

• *Mail:* Robert E. Feldman, Executive Secretary, Attention: Comments/Legal ESS, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

• *Hand Delivery/Courier:* The guard station at the rear of the 550 17th Street NW, building (located on F Street) on business days between 7:00 a.m. and 5:00 p.m.

• *Email: Comments@FDIC.gov.* Comments submitted must include ''FDIC'' and ''RIN 3064–AE87—Real Estate Appraisals.'' Comments received will be posted without change to *https://www.FDIC.gov/regulations/laws/federal,* including any personal information provided.

FOR FURTHER INFORMATION CONTACT:

OCC: G. Kevin Lawton, Appraiser and Real Estate Specialist, (202) 649–6670, or Mitchell E. Plave, Special Counsel, (202) 649–5490, for persons who are deaf or hearing impaired, TTY, (202) 649–5597, or Joanne Phillips, Counsel, (202) 649–5500, Office of the Comptroller of the Currency, 400 7th Street SW, Washington, DC 20219.

Board: Anna Lee Hewko, Associate Director, (202) 530–6260, or Peter Clifford, Manager Risk Policy Section, (202) 785–6057, or Carmen Holly, Senior Supervisory Financial Analyst, (202) 973–6122, Division of Supervision and Regulation; or Laurie Schaffer, Associate General Counsel, (202) 452–2272, Gillian Burgess, Senior Counsel, (202) 736–5564, Matthew Suntag, Counsel, (202) 452–3694, or Kirin Walsh, Attorney, (202) 452–3058, Legal Division, Board of Governors of the Federal Reserve System, 20th and C Streets NW, Washington, DC 20551. For the hearing impaired only, Telecommunications Device for the Deaf (TDD) users may contact (202) 263–4869.

FDIC: Beverlea S. Gardner, Senior Examination Specialist, Division of Risk Management and Supervision, (202) 898–3640, *BGardner@FDIC.gov;* Benjamin K. Gibbs, Counsel, (202) 898–6726; Lauren Whitaker, Senior Attorney, (202) 898–3872; or Ryan M. Goodstein, Senior Financial Economist, (202) 898–6863, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429. For the hearing impaired only, TDD users may contact (202) 925–4618.

SUPPLEMENTARY INFORMATION:

I. Introduction

The agencies are inviting comment on a proposal to increase the threshold level at or below which appraisals would not be required for residential real estate-related transactions from $250,000 to $400,000. The proposal would continue to require evaluations that are consistent with safe and sound business practices for transactions exempted by the increased threshold. Additionally, the proposal would require regulated institutions to obtain evaluations for transactions secured by residential property in rural areas that have been exempted from the agencies' appraisal requirement pursuant to the Economic Growth, Regulatory Relief and Consumer Protection Act [1] (rural residential appraisal exemption), and would fulfill the requirement to add appraisal review to the minimum standards for an appraisal, pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act).[2]

The proposal to raise the residential threshold is based on consideration of available information on real estate transactions secured by a single 1-to-4 family residential property (residential real estate transactions), supervisory experience, and comments received from the public in connection with the Economic Growth and Regulatory Paperwork Reduction Act (EGRPRA) [3] process, and the rulemaking to increase the appraisal threshold for commercial real estate appraisals (CRE Final Rule). The agencies believe that the proposed increase to the appraisal threshold for residential real estate transactions would reduce burden in a manner that is consistent with federal public policy interests in real estate-related transactions and the safety and soundness of regulated institutions.

The agencies have long recognized that the valuation information provided by appraisals and evaluations assists financial institutions in making informed lending decisions and mitigating risk. The agencies also recognize and support the role that appraisers play in helping to ensure a safe and sound real estate lending process. The agencies acknowledge as well that appraisals can provide protection to consumers by facilitating the informed use of credit and helping to ensure that the estimated value of the property supports the mortgage amount. However, the agencies also are aware that the cost and time of obtaining an appraisal can, in some cases, result in delays and higher expenses for both regulated institutions and consumers.

In addition, the agencies are proposing several conforming and technical amendments to their appraisal regulations. The agencies are also proposing to define a residential real estate transaction as a real estate transaction secured by a single 1-to-4 family residential property, which is consistent with current references to appraisals for residential real estate in the agencies' appraisal regulations and in Title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989 (Title XI).[4] Adding this

[1] Public Law 115–174, Title I, section 103, codified at 12 U.S.C. 3356. Effective May 24, 2018, section 103 provides that a Title XI appraisal is not required if the real property or interest in real property is located in a rural area, as described in 12 CFR 1026.35(b)(2)(iv)(A), and if the transaction value is $400,000 or less. In addition, the mortgage originator or its agent, directly or indirectly must have contacted not fewer than three state certified or state licensed appraisers, as applicable, on the mortgage originator's approved appraiser list in the market area, in accordance with 12 CFR part 226, not later than three days after the date on which the Closing Disclosure was provided to the consumer and documented that no state certified or state licensed appraiser, as applicable, was available within five business days beyond customary and reasonable fee and timeliness standards for comparable appraisal assignments.

[2] *See* Dodd-Frank Act, § 1473(e), Public Law 111–203, 124 Stat. 1376, 2191.

[3] Public Law 104–208, Div. A, Title II, section 2222, 110 Stat. 3009–414, (1996) (codified at 12 U.S.C. 3311). EGRPRA requires that, not less than once every 10 years, the Federal Financial Institutions Examination Council (FFIEC), Board, OCC, and FDIC conduct a review of their regulations to identify outdated or otherwise unnecessary regulatory requirements imposed on insured depository institutions.

[4] 12 U.S.C. 3331 *et seq.*

definition would not change any substantive requirement, but would provide clarity to the regulation. The agencies are also proposing to add the rural residential appraisal exemption [5] to the list of transactions that do not require appraisals. The proposed rule would require evaluations for transactions exempted from the agencies' appraisal requirement by this exemption, which is consistent with the requirement for regulated institutions to obtain an evaluation for certain other exempt residential real estate transactions (which in practice are generally retained in their portfolios). This proposed requirement reflects the agencies' judgment that valuation information concerning the real estate collateral for these transactions assists financial institutions in making informed lending decisions and is consistent with safe and sound banking practices.[6]

Further, the agencies are proposing to implement the appraisal review provision in Section 1473(e) of the Dodd-Frank Act,[7] which amended Title XI to require that the agencies' appraisal regulations include a requirement for institutions to subject appraisals for federally related transactions to appropriate review for compliance with the Uniform Standards of Professional Appraisal Practice (USPAP).[8] The proposed rule would implement this statutory requirement, which is consistent with the agencies' long-standing recognition of the importance of appropriate appraisal reviews for safety and soundness.[9]

Under Title XI, the agencies must receive BCFP concurrence that the proposed threshold level provides reasonable protection for consumers who purchase 1-to-4 unit single-family residences.[10] Accordingly, the agencies are consulting with the BCFP regarding the proposed threshold increase and will continue this consultation in developing the final rule.

A. Background

Title XI directs each Federal financial institutions regulatory agency [11] to require regulated institutions to obtain appraisals meeting minimum standards (Title XI appraisals) for certain real estate-related transactions. The purpose of Title XI is to protect federal financial and public policy interests [12] in real estate-related transactions [13] by requiring that Title XI appraisals be performed in accordance with uniform standards by individuals whose competency has been demonstrated and whose professional conduct will be subject to effective supervision.[14]

Title XI directs the agencies to prescribe appropriate standards for Title XI appraisals under the agencies' respective jurisdictions.[15] At a minimum, Title XI appraisals must be: (1) Performed in accordance with USPAP; (2) written appraisals, as defined by the statute; and (3) subject to appropriate review for compliance with USPAP.

A federally related transaction [16] is a real estate-related financial transaction that the agencies or a financial institution regulated by the agencies engages in or contracts for, for which the agencies require a Title XI appraisal. The agencies have authority to determine those real estate-related financial transactions that do not require Title XI appraisals. Real estate-related financial transactions that are exempt from the agencies' appraisal requirement are not federally related transactions under the agencies' appraisal regulations. The agencies have exercised this authority by exempting several categories of real estate-related financial transactions from the agencies' appraisal requirement, including transactions at or below certain designated thresholds.[17] Other significant exemptions include exemptions for loans that are wholly or partially insured or guaranteed by, or eligible for sale to, a U.S. government agency or U.S. government-sponsored agency.[18]

Title XI expressly authorizes the agencies to establish thresholds at or below which Title XI appraisals are not required if: (1) The agencies determine in writing that the threshold does not represent a threat to the safety and soundness of financial institutions; and (2) the agencies receive concurrence from the BCFP that such threshold level provides reasonable protection for consumers who purchase 1-to-4 unit single-family residences.[19] Under the current thresholds, residential real estate transactions [20] with a transaction value [21] of $250,000 or less, certain real estate-secured business loans (qualifying business loans) [22] with a

[5] *See supra* note 1.

[6] *See* 59 FR 29482 (June 7, 1994) (adopting the $250,000 threshold and the requirement for evaluations for certain exempt transactions).

[7] Dodd-Frank Act, § 1473(e).

[8] USPAP is written and interpreted by the Appraisal Standards Board of the Appraisal Foundation. USPAP contains generally recognized ethical and performance standards for the appraisal profession in the United States, including real estate, personal property, and business appraisals. *See http://www.appraisalfoundation.org/imis/TAF/Standards/Appraisal_Standards/Uniform_Standards_of_Professional_Appraisal_Practice/TAF/USPAP.aspx?hkey=a6420a67-dbfa-41b3-9878-fac35923d2af.*

[9] *See Interagency Appraisal and Evaluation Guidelines* (Guidelines), at Section XV, 75 FR 77450 (December 10, 2010) (addressing appraisal review).

[10] Dodd-Frank Act, § 1473(a), Public Law 111–203, 124 Stat. 2190 (amending 12 U.S.C. 3341(b)).

[11] The term ''Federal financial institutions regulatory agencies'' means the Board, the FDIC, the OCC, the National Credit Union Administration (NCUA), and, formerly, the Office of Thrift Supervision. 12 U.S.C. 3350(6).

[12] These interests include those stemming from the federal government's roles as regulator and deposit insurer of financial institutions that engage in real estate lending and investment, guarantor or lender on mortgage loans, and as a direct party in real-estate related financial transactions. These federal financial and public policy interests have been described in predecessor legislation and accompanying Congressional reports. *See* Real Estate Appraisal Reform Act of 1988, H.R. Rep. No. 100–1001, pt. 1, at 19 (1988); 133 Cong. Rec. 33047–33048 (1987).

[13] A real estate-related financial transaction is defined as any transaction that involves: (i) The sale, lease, purchase, investment in or exchange of real property, including interests in property, or financing thereof; (ii) the refinancing of real property or interests in real property; and (iii) the use of real property or interests in real property as security for a loan or investment, including mortgage-backed securities. 12 U.S.C. 3350(5).

[14] 12 U.S.C. 3331.

[15] 12 U.S.C. 3339. The agencies' Title XI appraisal regulations apply to transactions entered into by the agencies or by institutions regulated by the agencies that are depository institutions or bank holding companies or subsidiaries of depository institutions or bank holding companies. OCC: 12 CFR 34, subpart C; Board: 12 CFR 225.61(b); 12 CFR part 208, subpart E; FDIC: 12 CFR part 323.

[16] 12 U.S.C. 3350(4).

[17] *See* OCC: 12 CFR 34.43(a); Board: 12 CFR 225.63(a); FDIC: 12 CFR 323.3(a). The agencies have determined that these categories of transactions do not require appraisals by state certified or state licensed appraisers in order to protect federal financial and public policy interests or to satisfy principles of safe and sound banking.

[18] *See* OCC: 12 CFR 34.43(a)(9) and (10); Board: 12 CFR 225.63(a)(9) and (10); and FDIC: 12 CFR 323.3(a)(9) and (10). The NCUA also exempts these loans from its appraisal requirements. *See* 12 CFR 722.3(a)(7) and (8).

[19] 12 U.S.C. 3341(b).

[20] While the $250,000 threshold explicitly applies to all real estate-related financial transactions with transaction values of $250,000 or less, it effectively only applies to residential real estate transactions because all other real estate-related financial transactions are subject to higher thresholds.

[21] For loans and extensions of credit, the transaction value is the amount of the loan or extension of credit. For sales, leases, purchases, investments in or exchanges of real property, the transaction value is the market value of the real property. For the pooling of loans or interests in real property for resale or purchase, the transaction value is the amount of each loan or the market value of each real property, respectively. *See* OCC: 12 CFR 34.42(m); Board: 12 CFR 225.62(m); and FDIC: 12 CFR 323.2(m).

[22] Qualifying business loans are business loans that are real estate-related financial transactions and that are not dependent on the sale of, or rental income derived from, real estate as the primary source of repayment. The Title XI appraisal regulations define ''business loan'' to mean a loan or extension of credit to any corporation, general or limited partnership, business trust, joint venture, pool, syndicate, sole proprietorship, or other business entity. *See* OCC: 12 CFR 34.42(d); Board: 12 CFR 225.62(d); and FDIC: 12 CFR 323.2(d).

transaction value of $1 million or less, and commercial real estate (CRE) transactions with a transaction value of $500,000 or less do not require Title XI appraisals.[23] The appraisal threshold applicable to residential real estate transactions has not been changed since 1994.[24]

For real estate-related financial transactions at or below the applicable thresholds and for certain existing extensions of credit exempt from the agencies' appraisal requirement,[25] the Title XI appraisal regulations require regulated institutions to obtain an appropriate evaluation of the real property collateral that is consistent with safe and sound banking practices.[26] An evaluation should contain sufficient information and analysis to support the financial institution's decision to engage in the transaction.[27]

In preparing the proposed rule, the agencies conducted analyses using 2017 data reported under the Home Mortgage Disclosure Act (HMDA),[28] which requires a variety of financial institutions to maintain, report, and publicly disclose loan-level information about residential mortgage originations.[29] Information reported under HMDA includes various data points relevant to the agencies' analyses, including loan size, loan type, property type, property location, and secondary market purchaser. While the HMDA data has limitations, including that certain low-volume originators and originators located in rural areas are not required to report,[30] the agencies believe it provides a reasonably representative sample of the universe of mortgage originations, including transactions subject to the agencies' appraisal requirement. In addition, the agencies are not aware of any other data source that would better inform these analyses.

As described in further detail below, the agencies used the 2017 HMDA data [31] to estimate the coverage of the proposed threshold increase in terms of number of transactions and dollar volume of transactions that would be affected relative to: (1) Total HMDA originations [32] and (2) only those transactions originated by FDIC-insured institutions and affiliated institutions [33] that were not sold to the government-sponsored enterprises (GSEs) or otherwise insured or guaranteed by a U.S. government agency [34] (regulated transactions).[35] The agencies compared these coverage estimates with the coverage of the current threshold both now and when the current threshold was adopted in 1994. The agencies used these analyses to estimate the number and dollar volume of loans that could be affected by the threshold increase, including the expected number and dollar volume of loans in rural areas, and to assess the potential impact of the threshold increase on burden reduction and on the safety and soundness of financial institutions.

B. Reducing Burden Associated With Appraisals

The agencies are proposing to increase the appraisal threshold for residential real estate transactions in an effort to reduce regulatory burden, while maintaining federal public policy interests in real estate-related transactions and the safety and soundness of regulated institutions. The agencies' appraisal regulations were identified as an opportunity to reduce regulatory burden by commenters to the EGRPRA process that concluded in early 2017. The agencies concluded in the joint EGRPRA report to Congress (EGRPRA Report) [36] that a change to the current $250,000 appraisal threshold for residential real estate transactions would not be appropriate at that time, citing three reasons: A limited impact on burden reduction due to appraisals still being required for the vast majority of these transactions pursuant to the rules of other federal government agencies and the GSEs; safety and soundness concerns; and consumer protection concerns.[37] However, the EGRPRA Report stated that the agencies would continue to consider possibilities for relieving burden related to appraisals for residential mortgage loans.[38]

In response to comments received during the EGRPRA process, the agencies published a Notice of Proposed Rulemaking to increase the CRE appraisal threshold (CRE NPR).[39] In connection with the CRE NPR, the agencies restated the reasons set forth in the EGRPRA Report for declining to propose an increase to the residential threshold, and invited comment on other factors that should be considered in evaluating the appraisal threshold for residential real estate transactions and on whether the threshold can and should be raised, consistent with consumer protection, safety and

[23] *See* OCC: 12 CFR 34.43(a)(1), (5), and (13); Board: 12 CFR 225.63(a)(1), (5), and (14); and FDIC: 12 CFR 323.3(a)(1), (5), and (13).

[24] *See* 59 FR 29482 (June 7, 1994). The NCUA promulgated a similar rule with similar thresholds in 1995. 60 FR 51889 (October 4, 1995). The OCC, Board, and FDIC had previously raised the appraisal threshold to $100,000. OCC: 57 FR 12190–02 (April 9, 1992); Board: 55 FR 27762 (July 5, 1990); FDIC: 57 FR 9043–02 (March 16, 1992).

[25] Transactions that involve an existing extension of credit at the lending institution are exempt from the agencies' appraisal requirement, but are required to have evaluations, provided that there has been no obvious and material change in market conditions or physical aspects of the property that threatens the adequacy of the institution's real estate collateral protection after the transaction, even with the advancement of new monies; or there is no advancement of new monies, other than funds necessary to cover reasonable closing costs. *See* OCC: 12 CFR 34.43(a)(7) and (b); Board: 12 CFR 225.63(a)(7) and (b); and FDIC: 12 CFR 323.3(a)(7) and (b).

[26] *See* OCC: 12 CFR 34.43(b); Board: 12 CFR 225.63(b); and FDIC: 12 CFR 323.3(b). An evaluation is not required when real estate-related financial transactions meet the threshold criteria and also qualify for another exemption from the agencies' appraisal requirement where no evaluation is required by the regulation.

[27] Evaluations are not required to be performed in accordance with USPAP or by state certified or state licensed appraisers by federal law. The agencies have provided supervisory guidance for conducting evaluations in a safe and sound manner in the Guidelines and the *Interagency Advisory on the Use of Evaluations in Real Estate-Related Financial Transactions* (Evaluations Advisory). *See* 75 FR 77450 (December 10, 2010); OCC Bulletin 2016–8 (March 4, 2016); Board SR Letter 16–5 (March 4, 2016); and *Supervisory Expectations for Evaluations,* FDIC FIL–16–2016 (March 4, 2016).

[28] 12 U.S.C. 2801 *et seq.*

[29] *See* FFIEC, *Home Mortgage Disclosure Act, www.ffiec.gov/hmda/.*

[30] Although originators located in rural areas are not required to report HMDA information, originators not located in rural areas that make loans in rural areas are required to report.

[31] The HMDA analyses described in this document are limited to first-lien originations secured by single-family residential mortgage properties. Originations with loan amounts greater than $20 million are excluded.

[32] The total number of first-lien, single-family originations reported under HMDA in 2017 is approximately 6.9 million.

[33] FDIC-insured institutions and affiliated institutions include those that report under HMDA to the OCC, the Board, the FDIC, or the BCFP (excluding institutions that are not supervised by the OCC, Board, or FDIC).

[34] Some loans sold to the GSEs may not be observable in HMDA, for example if the sale occurred after calendar year 2017, or if the loan was sold to another entity that in turn sold the loan to a GSE.

[35] Regulated transactions are the only residential real estate transactions subject to the appraisal threshold, because transactions originated by regulated institutions but sold to the GSEs or otherwise insured or guaranteed by a U.S. government agency are separately exempted from the agencies' appraisal requirement and transactions originated by non-regulated institutions are not subject to the agencies' appraisal regulations.

[36] *See* EGRPRA Report, *available at https://www.ffiec.gov/pdf/2017_FFIEC_EGRPRA_Joint-Report_to_Congress.pdf.* The NCUA is also named on the EGRPRA Report, though it was not required to participate in the review process. NCUA elected to participate in the EGRPRA review, conducted its own parallel review of its regulations, and included its own report in a separate part of the EGRPRA Report. The NCUA is not a participant in this rulemaking.

[37] *Id.*

[38] *Id.*

[39] 82 FR 35478 (July 31, 2017).

soundness, and reduction of unnecessary regulatory burden.[40]

The comments received in the EGRPRA process and in response to the CRE NPR reflect different perspectives on the appraisal threshold for residential real estate transactions.[41] Some of the commenters supported the agencies' decision not to propose an increase in the appraisal threshold for residential real estate transactions. Other commenters supported increasing the appraisal threshold for residential real estate transactions to reduce regulatory burden.

To consider the probable effect on burden reduction, the agencies assessed the potential impact of the proposed threshold increase on the entire mortgage market and on regulated transactions.[42] The agencies estimate that increasing the appraisal threshold from $250,000 to $400,000 would have exempted an additional 214,000 residential real estate originations[43] at regulated institutions from the agencies' appraisal requirement, which represent only three percent of total HMDA originations (first-lien, single-family) in 2017. However, they represent 16 percent of regulated transactions. This increase in the number of loans that would no longer require appraisals would provide meaningful burden reduction for regulated institutions.

After considering all of the comments and further analysis by the agencies, the agencies are proposing an increase to the appraisal threshold for residential real estate transactions in order to reduce regulatory burden, particularly in rural areas, in a manner that is safe and sound and consistent with consumer protection.

Cost and Time Savings. Commenters to the EGRPRA process and in response to the CRE NPR that supported a residential threshold increase noted that obtaining an appraisal for a residential real estate transaction adds to the cost of the transaction, which is often passed on to the consumer, and can delay the closing of a transaction when an appraiser cannot complete the appraisal on the preferred schedule and increase the consumer's costs. Thus, reducing regulatory burden by increasing the appraisal threshold for residential real estate transactions may provide both transaction cost and time savings for both regulated institutions and consumers.

As described in the CRE NPR, available information suggests that evaluations for CRE properties typically cost significantly less than Title XI appraisals for the same properties.[44] Further, some of the comments to the CRE NPR indicated that evaluations in general cost substantially less than appraisals.[45]

The United States Department of Veterans Affairs' appraisal fee schedule[46] for a single-family residence reflects that the typical cost of an appraisal generally ranges from $375 to $900, depending on the location of the property. The limited information available on the cost of evaluations and appraisals suggests that there could be material cost savings in connection with the valuation of the property for regulated institutions and consumers where an evaluation, as opposed to an appraisal, is obtained.

Question 1. The agencies invite comment on the cost data for evaluations and appraisals detailed above. Should the agencies consider other data and data sources in assessing the costs of appraisals and evaluations to regulated institutions and consumers?

The agencies also considered the amount of time associated with performing and reviewing appraisals and evaluations. There may be less delay in finding appropriate personnel to perform an evaluation than to perform a Title XI appraisal, particularly in rural areas. As described in the Guidelines, financial institutions should also review the property valuation prior to entering into the transaction.[47] The agencies estimate that, on average, the review process for an evaluation would take substantially less time than the review process for an appraisal.[48] Thus, for affected transactions, the proposed rule could reduce the time required for employees to review transactions, potentially reducing delay and increasing cost savings of obtaining an evaluation instead of an appraisal.

Question 2. The agencies invite comment on the time associated with performing and reviewing appraisals versus evaluations. Should the agencies consider other data and data sources in assessing the time associated with performing and reviewing appraisals and evaluations?

In considering the aggregate effect of this proposed rule, the agencies considered the number of affected transactions. As discussed in the *Coverage of the Threshold* section below, the agencies estimate that under the proposed rule, the share of the number of regulated transactions exempted from the agencies' appraisal requirement would increase from 56 percent to 72 percent. Thus, while the precise number of affected transactions and the precise cost reduction per transaction is difficult to determine, the proposed rule is expected to lead to cost and time savings for regulated institutions and could benefit consumers.

Consumer Protection. Through the EGRPRA process and in response to the CRE NPR, the agencies received comments stating that appraisals provide some measure of consumer protection, and that increasing the appraisal threshold for residential real estate transactions could raise consumer protection issues. Indeed, the Dodd-Frank Act's amendment to Title XI adding the BCFP to the group of agencies assigned a role in the appraisal threshold-setting process indicates Congressional views that appraisals can play a role in providing protection to consumers who purchase 1-to-4 unit single-family residences.[49] The agencies recognize that appraisals can provide protection to consumers by helping to ensure that the estimated value of the property supports the purchase price and the mortgage amount. Consumer protection considerations contributed to the agencies' reluctance to propose increasing the appraisal threshold for residential real estate transactions

[40] 82 FR 35478, 35481–82, 35487 (July 31, 2017).

[41] *See, e.g.,* 83 FR 15019, 15029–30 (April 9, 2018).

[42] As noted earlier, for this **SUPPLEMENTARY INFORMATION** section, regulated transactions are residential mortgage originations by FDIC-insured institutions and affiliated institutions that were not sold to the GSEs or otherwise insured or guaranteed by a U.S. government agency.

[43] The 214,000 originations represent transactions originated by FDIC-insured institutions or affiliated institutions, excluding transactions that were sold to the GSEs or otherwise insured or guaranteed by a U.S. government agency; transactions for which the value was equal to or below the current $250,000 appraisal threshold; and transactions that exceeded the proposed $400,000 threshold.

[44] 82 FR at 35487 (July 31, 2017).

[45] 82 FR at 15028 (April 9, 2018).

[46] *See VA Appraisal Fee Schedules and Timeliness Requirements, available at https://www.benefits.va.gov/HOMELOANS/appraiser_fee_schedule.asp.*

[47] Guidelines, 75 FR at 77461.

[48] The agencies have heard from commenters that evaluations can, in some cases, require more time to review than appraisals due to the limited information contained in some evaluations.

[49] 12 U.S.C. 3341(b). The Dodd-Frank Act also required the BCFP to engage in rulemakings under amendments to Title XI, including standards for appraisal management companies (12 U.S.C. 3353) and automated valuation models (12 U.S.C. 3354). In addition, as discussed further in this **SUPPLEMENTARY INFORMATION**, the Dodd-Frank Act amended two consumer protection laws,—the Truth in Lending Act (TILA), 15 U.S.C. 1601 *et seq.,* and Equal Credit Opportunity Act (ECOA), 15 U.S.C. 1691 *et seq.*—to establish new requirements for appraisals and other valuation types. *See* 15 U.S.C. 1639e and 1639h (TILA) and 15 U.S.C. 1691e (ECOA).

immediately after the EGRPRA process.[50]

One consideration in assessing consumer protection issues related to this rulemaking is that the agencies have long required evaluations in lieu of appraisals for many transactions, including those transactions exempted by an appraisal threshold. An evaluation must be consistent with safe and sound banking practices [51] and should contain sufficient information and analysis to support the decision to engage in the transaction,[52] although it may be less structured than an appraisal. The agencies noted in the Guidelines [53] and the Evaluations Advisory that individuals preparing evaluations should be qualified, competent, and independent of the transaction and the loan production function of the institution. The agencies believe that evaluations prepared accordingly could provide a level of consumer protection for transactions at or below the proposed appraisal threshold.

Another consideration is the availability of property valuation information to consumers in residential real estate transactions. In this regard, the Dodd-Frank Act amended the Equal Credit Opportunity Act [54] (ECOA) to require creditors to provide applicants free copies of appraisals and other types of valuations prepared in connection with first-lien transactions secured by a dwelling, which include evaluations.[55] When obtained, evaluations must be provided to consumers and, thus, provide some consumer protection.[56]

The agencies also note that consumers have significantly more access to information relevant to residential real estate values than when the appraisal threshold was last increased in 1994. For example, property records are often available to the public through the internet. These records may include not only a particular property's tax assessed value, but also the property's historical sale activity.[57] Consumers also may voluntarily obtain an appraisal before engaging in the transaction. Consumers can use this valuation information to become better informed before entering into an agreement to purchase a specific property.

At the same time, the agencies recognize that these options might not be readily available to or used by some consumers, and that appraisals provide more property information to a consumer than an evaluation. Given that evaluations are not required to be in a standard form and specific content is not mandated, it is also possible that some evaluations might be more difficult for consumers to understand or lack information about the property typically included in an appraisal that could be useful to a consumer.

Question 3. What valuation information, if any, would consumers lose in practice if more evaluations are performed rather than appraisals? What additional comments, if any, are there relative to the presentation or content of evaluations for residential real estate transactions in practice? Please provide data or other evidence to support any comments.

Question 4. To what extent do appraisals or evaluations provide benefits or protections for consumers that are purchasing 1-to-4 unit single-family residences? What are the nature and magnitude of the differences, if any, in consumer protection, including any differences in credibility, arising from the use of evaluations rather than appraisals, especially with respect to residential real estate transactions of $400,000 or less? For example, are there any differences with respect to negotiating the price of a home or canceling a transaction when an evaluation rather than an appraisal is obtained? Please provide data or other evidence to support any comments.

Question 5. To what extent is useful property valuation information readily available to consumers through public sources?

Another consideration is that under federal law, individuals performing evaluations are not required to have professional credentials for valuing real estate. The agencies acknowledge that expanding the appraisal exemption for more residential transactions might therefore raise concerns about the accountability of individuals performing evaluations and could limit the options for recourse available to consumers. For example, the Dodd-Frank Act required establishment of a national hotline for complaints against state-certified and state-licensed appraisers,[58] and state appraisal regulatory agencies have authority to discipline appraisers that violate USPAP.[59]

A further consideration is that appraisal and valuation rules put into place to protect consumers would remain unchanged. As noted, under ECOA, creditors must provide to consumers in first-lien, dwelling-secured transactions free copies of valuations, including evaluations, in connection with their applications for credit.[60] In addition, appraisals would still be required, regardless of transaction amount, for certain HPMLs, pursuant to the HPML Appraisal Rule.[61]

Further, the interim final rule on valuation independence (IFR on Valuation Independence), also implementing TILA, applies to all types of valuations (other than valuations produced solely using an automated model or system) used in connection with a consumer-purpose transaction secured by a consumer's principal dwelling.[62] Creditors using evaluations for transactions covered by this rule must meet standards for independence that carry civil liability, regardless of transaction size. On this point, the agencies note that one of the benefits of

[50] *See* EGRPRA Report, *available at https://www.ffiec.gov/pdf/2017_FFIEC_EGRPRA_Joint-Report_to_Congress.pdf.*

[51] OCC: 12 CFR 34.43(b); Board: 12 CFR 225.63(b); and FDIC: 12 CFR 323.3(b).

[52] Guidelines, 75 FR at 77461.

[53] Guidelines, 75 FR at 77457–58.

[54] 15 U.S.C. 1691 *et seq.*

[55] *See* 15 U.S.C. 1691(e), implemented by the BCFP at 12 CFR 1002.14. The Dodd-Frank Act also amended TILA to require creditors to provide applicants free copies of appraisals prepared in connection with certain higher-priced mortgage loans (HPMLs). *See* 15 U.S.C. 1639h(c), implemented jointly by the OCC, Board, FDIC, NCUA, Federal Housing Finance Agency (FHFA), and BCFP at OCC: 12 CFR 34.203(f); Board: 12 CFR 226.43(f); BCFP: 12 CFR 1026.35(c)(6); NCUA: 12 CFR 722.3(f); FHFA: 12 CFR 1222, subpart A (HPML Appraisal Rule). The FDIC adopted the HPML Appraisal Rule as published in the BCFP's regulation. *See* 78 FR 78520, 10370, 10415 (December 26, 2013).

[56] 12 CFR 1002.14.

[57] Some states (or counties within states) do not publish sale amounts, but do provide estimates based on loan amounts or mortgage transfer taxes, which could be substantially different from the actual sale amount.

[58] The Dodd-Frank Act instituted a number of reforms to ensure the legitimacy, independence, and oversight of appraisals. *See* Dodd-Frank Act, Title XIV, Subtitle F—Appraisal Activities, Public Law 111–203, 124 Stat. 1376, 2185.

[59] USPAP is written and interpreted by the Appraisal Standards Board of the Appraisal Foundation. USPAP contains generally recognized ethical and performance standards for the appraisal profession in the United States, including real estate, personal property, and business appraisals. *See http://www.appraisalfoundation.org/imis/TAF/Standards/Appraisal_Standards/Uniform_Standards_of_Professional_Appraisal_Practice/TAF/USPAP.aspx?hkey=a6420a67-dbfa-41b3-9878-fac35923d2af.*

[60] *See* 15 U.S.C. 1691(e), implemented by the BCFP at 12 CFR 1002.14.

[61] *See supra* note 55. Transactions covered by the HPML Appraisal Rule are limited due to significant exemptions from the requirements, including an exemption for qualified mortgages. *See, e.g.,* 78 FR 10368, 10418–20 (February 13, 2013).

[62] The Board issued the IFR on Valuation Independence in 2010 (effective April 2011) establishing independence rules for consumer purpose residential mortgage loans secured by a consumer's primary dwelling. *See* 75 FR 66554 (October 28, 2010) and 75 FR 80675 (December 23, 2010) (implementing Dodd-Frank Act amendments to TILA at 15 U.S.C. 1639e); Board: 12 CFR 226.42; and BCFP: 12 CFR 1026.42. Under the Dodd-Frank Act, the IFR on Valuation Independence is deemed to have been prescribed jointly by the OCC, Board, FDIC, NCUA, BCFP and FHFA. *See* 15 U.S.C. 1639e(g)(2).

evaluations over appraisals that institutions have cited is that they can more readily be performed in-house. There are concerns, however, that ensuring the independence of financial institution staff performing evaluations from the loan production function might be difficult to achieve in practice, particularly in smaller institutions.

In the Evaluations Advisory, the agencies also observed that evaluations may be completed by a bank employee or by a third party.[63] The agencies further observed that, in smaller communities, bankers and third-party real estate professionals have access to local market information and may be qualified to prepare evaluations for an institution.[64] The evaluation preparer should be knowledgeable, competent, and independent of the transaction.

Question 6. How often do institutions use their own internal staff to prepare evaluations? What challenges, if any, to meeting requirements and standards for independence, particularly in smaller institutions, do internally-prepared evaluations present? Similarly, what challenges, if any, to meeting requirements and standards for independence are presented by evaluations prepared by third parties?

Finally, if the proportion of residential mortgage transactions subject to the Title XI appraisal requirements increases in the future, the proposed threshold increase could exempt a larger percentage of the overall market of residential mortgage originations, which may have an effect on consumer protection. As noted above, loans that are wholly or partially insured or guaranteed by, or eligible for sale to, a U.S. government agency or U.S. government-sponsored agency, are not subject to the agencies' appraisal requirement.[65] Other federal agencies, such as the U.S. Department of Housing and Urban Development, the U.S. Department of Veterans Affairs, and the Rural Housing Service of the U.S. Department of Agriculture, and the GSEs, which are regulated by the Federal Housing Finance Agency (FHFA), have their own authority to establish appraisal rules and standards, and generally require appraisals by a certified or licensed appraiser for residential real estate transactions that they originate, acquire, insure, or guarantee, regardless of the value of the loan. The percentage of the market comprising loans subject to the requirements of these other entities has fluctuated historically. Currently, these loans account for more than 6 in 10 of all first-lien, single-family mortgage originations in the United States, a level considerably higher than the share in the years prior to the most recent financial recession.[66]

Question 7. Are there any other consumer protection concerns raised by the proposal that the agencies should consider?

Burden Relief in Rural Areas. Many commenters in the EGRPRA process and to the CRE NPR noted that the requirement to obtain appraisals has increased costs and resulted in delays, particularly in rural areas. With the rural residential appraisal exemption, Congress added an exemption to the agencies' appraisal requirement for certain mortgage loans under $400,000 secured by property in rural areas, but the exemption is only available where regulated institutions can document that they are unable to obtain an appraisal at a reasonable cost and within a reasonable timeframe, among other requirements.[67] The proposed rule is broader in scope and would eliminate the agencies' appraisal requirement for all residential real estate transactions at or below $400,000. The proposed threshold would include all such transactions in rural areas without requiring regulated institutions to meet the other criteria of the rural residential appraisal exemption.

The 2017 HMDA data show that the proposed rule would provide significant burden relief in rural areas. The agencies estimate that increasing the appraisal threshold to $400,000 would potentially increase the share of exempt transactions from 82 percent to 91 percent of the number and from 43 percent to 58 percent of the dollar volume of regulated transactions that were secured by residential property located in a rural area.[68]

II. Revisions to the Title XI Appraisal Regulations

A. Threshold Increase for Residential Real Estate Transactions Level of Appraisal Threshold Increase

The agencies propose to increase the appraisal threshold from $250,000 to $400,000 for residential real estate transactions. In determining the level of the proposed increase, the agencies considered the comments received through the EGRPRA process and in response to the CRE NPR, as well as a variety of house price and inflation indices. In particular, the agencies analyzed the Standard & Poor's Case-Shiller Home Price Index (Case-Shiller Index)[69] and the FHFA Index,[70] as well as the Consumer Price Index (CPI).[71]

These house price indices reflect that prices for residential real estate have increased since 1994. Table 1 shows the expected sales price at about its highest amount in 2006, at about its lowest amount in 2011, and about its current amount in 2018 relative to a residential property that sold for $250,000 in 1994 for each index.

TABLE 1—INFLATION ADJUSTMENTS OF $250,000 AT JUNE 30, 1994, FOR THE CASE-SHILLER INDEX AND THE FHFA INDEX, AND JULY 1, 1994 FOR THE CPI INDEX

Table 1 year	Case-Shiller	FHFA	CPI
1994	250,000	250,000	250,000
2006	578,813	511,636	341,109

[63] Evaluations Advisory at 2.

[64] *See id.*

[65] *See supra* note 18.

[66] This figure is based on an analysis the agencies conducted using 2017 HMDA data. *See supra* note 29. *See also Housing Finance at a Glance,* Monthly Chartbook, The Urban Institute, October 2018, p.8. According to this source, between 2001 and 2017, the share of first-lien originations sold to the GSEs or guaranteed or insured by the FHA or VA ranged from about 35 percent in 2005 to nearly 90 percent in 2009. *See id.*

[67] *See supra* note 1.

[68] Estimates based on 2017 HMDA. For the purposes of the HMDA analysis, a property is considered to be located in a ''rural'' area if it is in a county that is neither in a metropolitan statistical area nor in a micropolitan statistical area that is adjacent to a metropolitan statistical area, based on 2013 Urban Influence Codes (UIC) published by the United States Department of Agriculture. Any loans from Census tracts that are missing geographical identifiers or undefined in the 2013 UIC have been excluded from the analysis of burden relief in rural areas.

[69] The Case-Shiller Index reflects changes in home prices from a base of $250,000 in June 1994, based on the Standard & Poor's Case-Shiller Home Price Index. *See* Standard & Poor's CoreLogic Case-Shiller Home Price Indices, *available at https://us.spindices.com/index-family/real-estate/sp-corelogic-case-shiller.*

[70] The FHFA Index reflects changes in home prices from a base of $250,000 in June 1994, based on the FHFA House Price Index. *See* FHFA House Price Index, *available at https://www.fhfa.gov/DataTools/Downloads/Pages/House-Price-Index.aspx.*

[71] The CPI, which is published by the Bureau of Labor Statistics, is a measure of the average change over time in the prices paid by urban consumers for a market basket of goods and services. *See https://www.bls.gov/cpi/.*

TABLE 1—INFLATION ADJUSTMENTS OF $250,000 AT JUNE 30, 1994, FOR THE CASE-SHILLER INDEX AND THE FHFA INDEX, AND JULY 1, 1994 FOR THE CPI INDEX—Continued

Table 1 year	Case-Shiller	FHFA	CPI
2011	445,152	414,629	379,997
2018	641,191	611,700	424,031

In proposing to raise the appraisal threshold for residential real estate transactions to $400,000, the agencies are approximating housing prices on an indexed basis at the low point of the most recent cycle, which generally occurred in 2011. For example, the Case-Shiller Index reflects that home prices fell from about $578,000 in December 2006 to their lowest point of about $445,000 in December 2011. The FHFA Index also reflects a similar decline in housing prices, which fell from about $512,000 to $415,000 during this same time period. This more conservative approach takes into consideration the potential risk exposure to institutions that engage in residential real estate lending. In addition, the increased appraisal threshold in the proposed rule is consistent with general measures of inflation across the economy reflected in the CPI since 1994, when the current appraisal threshold of $250,000 was set.

Question 8. Is the proposed level of $400,000 for the threshold at or below which regulated institutions would not be required to obtain appraisals for residential real estate transactions appropriate?

Safety and Soundness Considerations for Increasing the Appraisal Threshold for Residential Real Estate Transactions

Under Title XI, in setting a threshold at or below which an appraisal performed by a state certified or state licensed appraiser is not required, the agencies must determine in writing that such a threshold level does not pose a threat to the safety and soundness of financial institutions.[72] As noted in the Coverage of the Threshold section below, the agencies estimate that approximately 72 percent of regulated transactions in 2017 would have been exempt from the appraisal requirement under the proposal. However, analysis of supervisory experience and available data, taking into account the continuing evaluation requirement for transactions that would be exempted by the threshold, indicates that the proposed threshold level of $400,000 for residential real estate transactions is unlikely to pose a threat to the safety and soundness of financial institutions. Specifically, the agencies examined data reported on the Consolidated Reports of Condition and Income (Call Report)[73] to determine net charge-off rates[74] for residential real estate transactions. The agencies also examined the number and dollar volume of residential real estate transactions covered by the existing threshold and the increased threshold.

Supervisory Experience

Based on supervisory experience and analysis of material loss reviews,[75] the agencies observe that the substantial increase in losses on residential real estate transactions during the recent recession has been attributed to a number of factors, such as a weakening economy, declining home values, overstating the market value of homes in appraisal reports, increasing demand for residential mortgage backed securities, relaxing underwriting practices, and the expanded use of higher risk loan products. For example, prior to the onset of the most recent recession, the financial industry expanded its use of non-traditional mortgage products that did not consider borrowers' ability to repay on a fully indexed and fully amortizing basis. An FDIC study notes, ''Many of the banks that failed did so because management relaxed underwriting standards and did not implement adequate oversight and controls. For their part, many borrowers who engaged in commercial or residential lending arrangements did not always have the capacity to repay loans.''[76]

Similar concerns are detailed in the material loss review for Downey Savings and Loan,[77] which partly attributed its failure to management engaging in higher risk underwriting practices, such as offering option adjustable rate mortgages (which give borrowers the option of making monthly payments that do not cover the interest charges accrued), reducing or not requiring any documentation of borrowers' income or assets, accepting lower borrower credit scores, and layering two or more of these features in the same loan product. Likewise, the material loss review of IndyMac Bank, FSB[78] listed poor loan underwriting, such as offering nontraditional mortgage products, failing to verify borrowers' income or assets, and lending to borrowers with poor credit histories, among the core weaknesses that ultimately caused the thrift to fail. Both material loss reviews also noted some concerns with appraisals.

In its final report, the National Commission on the Causes of the Financial and Economic Crisis in the United States documents the pressure appraisers were under from mortgage lenders, brokers, and others with an interest in generating loan volume, to meet target values in order to complete loan transactions.[79] As noted earlier, among Congressional measures taken in response to the crisis, the Dodd-Frank Act instituted a number of reforms to ensure the legitimacy, independence,

[72] 12 U.S.C. 3341(b).

[73] The agencies used data reported on Schedule RC–C of the Call Report, which includes the dollar volume of all loans secured by real estate, including loans secured by residential properties with fewer than five dwelling units (RCFD 1797, 5367, and 5368). *See* FFIEC, *Consolidated Reports of Condition and Income for a Bank with Domestic and Foreign Offices—FFIEC 031, available at https://www.ffiec.gov/pdf/FFIEC_forms/FFIEC031_201703_f.pdf.*

[74] Net charge-offs are charge-offs minus recoveries. Net charge-offs represent losses to financial institutions, which, in the aggregate, can pose a threat to safety and soundness.

[75] Section 38(k) of the Federal Deposit Insurance Act, as amended, provides that if the Deposit Insurance Fund incurs a ''material loss'' with respect to an insured depository institution (IDI), the Inspector General of the appropriate regulator (which for the OCC is the Inspector General of the Department of the Treasury) shall prepare a report to that agency, identifying the cause of failure and reviewing the agency's supervision of the institution. 12 U.S.C. 1831o(k).

[76] *See* FDIC, Office of the Inspector General (OIG), EVAL–13–002, *Comprehensive Study on the Impact of the Failure of Insured Depository Institutions* 50, Table 6 (January 2013), *available at https://www.fdicoig.gov/sites/default/files/publications/13-002EV.pdf.*

[77] *See* Audit Report OIG–09–039, *Material Loss Review of Downey Savings and Loan, FA* (June 15, 2009), *available at https://www.treasury.gov/about/organizational-structure/ig/Documents/OIG09039.pdf* .

[78] *See* Audit Report OIG–09–032, *Material Loss Review of IndyMac Bank, FSB* (Feb. 26, 2009), *available at https://www.treasury.gov/about/organizational-structure/ig/Documents/oig09032.pdf.*

[79] Financial Crisis Inquiry Commission, The Financial Crisis Inquiry Report: *Final Report of the National Commission on the Causes of the Financial and Economic Crisis in the United States, available at https://www.gpo.gov/fdsys/pkg/GPO-FCIC/pdf/GPO-FCIC.pdf.*

and oversight of appraisals.[80] The federal financial institution regulatory agencies also issued the Interagency Guidance on Nontraditional Mortgage Product Risks [81] in response to concerns with the higher risk attributes of nontraditional mortgage products.

The agencies do not have data that show that raising the appraisal threshold would result in increased loss rates. The agencies note that loss rates did not increase in the 13 years after the threshold was raised from $100,000 to $250,000 in 1994 and returned to more historical levels in 2014 after the implementation of more prudent underwriting practices in 2009. The agencies also note that a majority of residential real estate transactions are sold to the GSEs or otherwise insured or guaranteed by a U.S. government agency, which reduces the impact of the agencies' appraisal requirement to an estimated three percent of all first-lien, single-family mortgage transactions in the United States, based on 2017 HMDA data.[82] Accordingly, the agencies' supervisory experience suggests that an increase in the threshold is unlikely to pose a safety and soundness risk to financial institutions.

Analysis of Charge-Off Rates

The agencies assessed trends in the loss rate experience of residential real estate transactions. While the agencies do not regularly collect data on rates of loss for residential real estate by the size of loans, they do collect net charge-off data for residential real estate loans on the Call Report. The agencies considered aggregate net charge-off rates for residential real estate loans in determining whether the threshold would pose a threat to the safety and soundness of financial institutions.

To evaluate the impact of residential real estate transactions on the safety and soundness of the banking system, the agencies compared the peak net charge-off rates from 1991 to 2018, which includes two recessionary periods. The net charge-off rate for residential real estate transactions did not increase after the increase in the appraisal threshold from $100,000 to $250,000 in June 1994, which indicates that the 1994 threshold increase did not have a negative impact on the safety and soundness of regulated institutions. As discussed above, housing prices have increased substantially since the last increase of this threshold, and the agencies are proposing an increase close to the lower bound of the estimate of current value of a residential property that sold for $250,000 in 1994.

The historical loss information in the Call Reports also reflects that the net charge-off rate for residential real estate transactions did not increase during and after the recession in 2001 through year-end 2007. During this timeframe, the net charge-off rate ranged from 8 basis points to 30 basis points. However, the net charge-off rate for residential real estate transactions increased significantly from 2008 through 2013, which was during and immediately after the recent recession, ranging from 63 basis points to 204 basis points. This data suggests that the loss experience associated with residential real estate loans generally stayed at a relatively consistent low rate except during the most recent crisis.

To evaluate whether the loss experience on residential real estate loans had an impact on the safety and soundness of regulated institutions of varying sizes, the agencies examined peak charge-off rates on such loans for all regulated institutions, as well as those with total assets under one billion dollars, total assets between one billion dollars and ten billion dollars, and total assets of more than ten billion dollars. The analysis showed that aggregate peak net charge-off rates for residential real estate loans over the most recent cycle were generally much worse than those recorded before the prior cycle, with larger regulated institutions experiencing a higher loan loss rate than regulated institutions with less than $1 billion in total assets. However, the loss rates declined to historical levels for all regulated institutions in 2014, indicating that the increase in the appraisal threshold in 1994 was not a significant contributing factor to the safety and soundness of regulated institutions, regardless of their size, during the recent recession.

Coverage of the Threshold

The agencies examined the 2017 HMDA data, as explained above, to estimate the number and dollar volume of residential real estate transactions covered by the existing and proposed residential appraisal thresholds. An analysis using the 2017 HMDA data shows that transactions subject to the agencies' current appraisal requirement continue to comprise only a small portion of all reported mortgage originations. The agencies estimate that approximately 91 percent of all mortgages originated in the United States are not subject to the agencies' appraisal requirement due to their not being originated by regulated institutions, being sold to the GSEs or otherwise insured or guaranteed by a U.S. government agency, or having transaction amounts at or below the current $250,000 threshold.

Table 2 shows the aggregate number and dollar volume of regulated transactions in 2017 for loans that would have been exempted under the current threshold, that would be newly exempted under the proposed threshold increase, the totals exempted under the proposed threshold increase, and the totals not exempted by the proposed threshold increase.

TABLE 2 [83]—REGULATED TRANSACTIONS BY TRANSACTION AMOUNT

	Exempted by current threshold of $250,000	Newly exempted by proposed increase to $400,000	Total exempted by proposed increase to $400,000	Total not exempted by proposed increase to $400,000
Number of Transactions				
Number of Transactions	750,000	214,000	965,000	379,000
% of Total	56%	16%	72%	28%
Dollar Volume				
Dollar Volume ($billions)	96	68	164	305

[80] Dodd-Frank Act, Title XIV, Subtitle F—Appraisal Activities, Public Law 111–203, 124 Stat. 1376, 2185.

[81] *See* 71 FR 58609 (October 4, 2006).

[82] Estimates based on first-lien, single-family mortgage transactions reported in 2017 HMDA data.

TABLE 2 [83]—REGULATED TRANSACTIONS BY TRANSACTION AMOUNT—Continued

	Exempted by current threshold of $250,000	Newly exempted by proposed increase to $400,000	Total exempted by proposed increase to $400,000	Total not exempted by proposed increase to $400,000
% of Total	20%	14%	35%	65%

As shown, the agencies estimate that increasing the residential appraisal threshold to $400,000 would raise the share of the number of regulated transactions that would be exempt from 56 percent to 72 percent and the share of the dollar volume of regulated transactions from 20 percent to 35 percent. Thus, the aggregate dollar volume of exempted transactions would remain a modest percentage of regulated transactions.

When the threshold was raised in 1994, the agencies estimated that the aggregate dollar volume of exempted transactions due to the threshold increase was 85 percent of all new home sales, and 82 percent of all existing home sales.[84] Thus, the agencies expect the proposed threshold level to have a much smaller impact on the dollar volume of transactions and, therefore would be less likely to pose a safety and soundness risk than the current threshold level did when it was introduced in 1994.

Question 9. Is the data used in this analysis appropriate? Are there alternative sources of data that would be appropriate for this analysis?

Evaluation Requirement

The agencies note that evaluations consistent with safe and sound banking practices would continue to be required for residential real estate transactions exempted by the increased threshold. Evaluations prepared by qualified, competent, and independent individuals who provide appropriate supporting information can provide an estimate of market value that regulated institutions and consumers can consider. The agencies have issued guidance to assist regulated institutions in obtaining evaluations.[85] Regulated institutions and consumers also may voluntarily obtain appraisals for exempt transactions when deemed appropriate such as higher risk transactions that may pose a threat to safety and soundness. The agencies also retain the ability to require an appraisal whenever ''necessary to address safety-and-soundness concerns.'' [86] The agencies expect regulated institutions to follow general guidelines for safety and soundness found in the Interagency Guidelines for Real Estate Lending Policies [87] and the Interagency Guidelines Establishing Standards for Safety and Soundness.[88]

B. Use of Evaluations

As discussed above, the Title XI appraisal regulations require regulated institutions to obtain evaluations for four categories of real estate-related financial transactions that the agencies have determined do not require a Title XI appraisal, including residential real estate transactions at or below the current $250,000 threshold. Under the proposal, residential real estate transactions exempted by the proposed increase to a $400,000 threshold would be required to obtain appropriate evaluations that are consistent with safe and sound banking practices.

The Guidelines describe the transactions for which financial institutions are required to obtain an evaluation and advise that institutions should develop policies and procedures for identifying when to obtain appraisals for such transactions.[89] An evaluation provides an estimate of the market value of real estate, but is not subject to the same requirements as a Title XI appraisal. An evaluation should provide appropriate information to enable the institution to make a prudent decision regarding the transaction. Through the Guidelines, the agencies have provided guidance to regulated institutions on their expectations regarding when and how evaluations should be used.

The Guidelines provide guidance on obtaining appropriate evaluations that are consistent with safe and sound banking practices.[90] As described in the Guidelines, evaluations should be performed by persons who are competent and have the relevant experience and knowledge of the market, location, and type of real property being valued.[91] Evaluations may be completed by an independent bank employee or by a third party, as explained by the Guidelines [92] and the Evaluations Advisory.[93] Guidance on achieving independence in the collateral valuation program can be found in the Guidelines, among other sources.[94] The Guidelines state that an evaluation should provide an estimate of the property's market value and have sufficient information and analysis to support the credit decision.[95] The Guidelines also describe the content that an evaluation should contain.[96]

Question 10. Will institutions expand their use of evaluations if the proposal to raise the residential threshold is finalized or continue to use appraisals for the additional residential real estate transactions of $400,000 or less that are eligible for this exemption? How frequently do lenders obtain evaluations for eligible residential real estate transactions in practice? For what types of eligible residential real estate transactions are lenders likely to obtain evaluations? Please provide data or other evidence to support any comments.

[83] Numbers and dollar volumes are based 2017 HMDA data, and include first lien, conventional originations on single-family residential properties by FDIC-insured institutions and affiliated institutions that are not sold to the GSEs or otherwise insured or guaranteed by a U.S. government agency. Originations with loan amounts greater than $20 million are excluded. Subtotals may not add to totals due to rounding.

[84] 59 FR at 29486 (June 7, 1994).

[85] *E.g.,* Guidelines, Evaluations Advisory and *Frequently Asked Questions on the Appraisal Regulations and the Interagency Appraisal and Evaluation Guidelines* (October 16, 2018), OCC Bulletin 2018–39; Board SR Letter 18–9; FDIC FIL–62–2018.

[86] *See,* OCC: 12 CFR 34.43(c); Board: 12 CFR 225.63(c); and FDIC: 12 CFR 323.3(c).

[87] OCC: 12 CFR part 34, subpart D; Board: 12 CFR part 208.51 and part 208, Appendix C; and FDIC: 12 CFR part 365, subpart A, Appendix A.

[88] OCC: 12 CFR part 30, Appendix A; Board: 12 CFR 208 subpart E and Appendix C and D–1; FDIC: 12 CFR part 364, Appendix A.

[89] Guidelines, 75 FR at 77460.

[90] *Id.,* at 77461.

[91] *Id.,* at 77458.

[92] *Id.*

[93] Evaluations Advisory at 2.

[94] Guidelines, 75 FR at 77457–58. *See also* Valuation Independence rules in Regulation Z, which apply to all creditors and cover extensions of consumer credit that are or will be secured by a consumer's principal dwelling: Board: 12 CFR 226.42; BCFP: 12 CFR 1026.42.

[95] Guidelines, 75 FR at 77457.

[96] *Id.,* at 77461.

C. Conforming and Technical Amendments

Definition of Residential Real Estate Transaction. In the CRE Final Rule, the agencies defined a CRE transaction as a real estate-related financial transaction that is not secured by a single 1-to-4 family residential property. The agencies are proposing to extend this definitional framework by defining ''residential real estate transaction'' as a real estate-related financial transaction that is secured by a single 1-to-4 family residential property. The agencies are also proposing to clarify in the regulatory text that the proposed $400,000 threshold applies to residential real estate transactions. The agencies are proposing this approach to provide regulatory clarity and believe that this change would not affect any substantive requirement.

Question 11. Is the proposed definition of a residential real estate transaction appropriate?

Increase in the threshold for the use of state certified appraisers for complex residential real estate transactions and other conforming changes. The agencies' appraisal regulations require that all complex 1-to-4 family residential property appraisals rendered in connection with federally related transactions shall have a state certified appraiser if the transaction value is $250,000 or more.[97] In order to make this paragraph consistent with the other proposed changes to the agencies' appraisal regulations, the agencies are proposing changes to its wording to incorporate the proposed definition of ''residential real estate transaction,'' to introduce the $400,000 threshold, and to make other technical and conforming changes. The agencies are also proposing to amend the definitional term ''complex 1-to-4 family residential property appraisal'' to ''complex appraisal for a residential real estate transaction'' to conform to the definition of residential real estate transaction. The amendments to these provisions would be conforming changes that would not alter any substantive requirements.

Evaluations for transactions exempted by the rural residential appraisal exemption. Congress recently amended Title XI to exclude loans made by a financial institution from the requirement to obtain a Title XI appraisal if certain conditions are met.[98] The property must be located in a rural area; the transaction value must be less than $400,000; the financial institution must retain the loan in portfolio, subject to exceptions; and not later than three days after the Closing Disclosure is given to the consumer, the financial institution or its agent must have contacted not fewer than three state certified or state licensed appraisers, as applicable, and documented that no such appraiser was available within five business days beyond customary and reasonable fee and timeliness standards for comparable appraisal assignments.[99]

The proposed rule would amend the agencies' appraisal regulations to reflect the rural residential appraisal exemption in the list of transactions that are exempt from the agencies' appraisal requirement. The amendment to this provision would be a technical change that would not alter any substantive requirement, because the statutory provision is self-effectuating. In addition, the proposed rule would require evaluations for transactions that are exempt from the agencies' appraisal requirement under the rural residential appraisal exemption. The agencies are proposing that financial institutions obtain evaluations for these transactions that will be retained in their portfolios, because evaluations protect the safety and soundness of financial institutions. Since the early 1990's, the agencies' appraisal regulations have required that regulated institutions obtain evaluations for certain other exempt residential real estate transactions (which in practice are generally retained in their portfolios). Requiring evaluations for transactions exempted by the rural residential appraisal exemption reflects the agencies' long-standing view that safety and soundness principles require institutions to obtain an understanding of the value of real estate collateral underlying most real estate-related transactions they originate. As discussed earlier, evaluations should contain sufficient information and analysis to support the financial institution's decision to engage in the transaction and are important to safety and soundness.

Question 12. What challenges, if any, are posed by using evaluations for transactions that are exempt from the agencies' appraisal requirement due to the rural residential appraisal exemption?

Appraisal review. Section 1473(e) of the Dodd-Frank Act amended Title XI to add that appraisals be subject to appropriate review for compliance with USPAP to the minimum standards that the agencies must require for appraisal for federally related transactions.[100] The proposed rule would make a conforming amendment to the minimum requirements in the agencies' appraisal regulations to add appraisal review. The agencies propose to mirror the statutory language for this standard. As outlined in the Guidelines, which provide guidance on the review process, the agencies have long recognized that appraisal review is consistent with safe and sound banking practices.[101]

Question 13. What, if any, concerns are posed by adding a requirement to review appraisals that is consistent with the statutory language for this standard to the minimum requirements for an appraisal?

III. Request for Comments

The agencies invite comment on all aspects of the proposed rulemaking.

IV. Regulatory Analysis

A. Proposed Waiver of Delayed Effective Date

The agencies propose to make all provisions of the rule, other than the evaluation requirement for transactions exempted by the rural residential appraisal exemption[102] and the appraisal review provision (as discussed below), effective the first day after publication of the final rule in the **Federal Register**. The agencies propose to waive the 30-day delayed effective date required under the Administrative Procedure Act (APA) for these provisions, pursuant to 5 U.S.C. 553(d)(1), which provides for waiver when a substantive rule grants or recognizes an exemption or relieves a restriction. The amendments proposed to increase the residential threshold would exempt additional transactions from the agencies' appraisal requirement, which would have the effect of relieving restrictions. Consequently, the agencies propose that all provisions of this rule, except the evaluation requirement for transactions exempted by the rural residential appraisal exemption and the appraisal review provision, meet the requirements for waiver set forth in the APA.

B. Regulatory Flexibility Act

OCC: The Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.,* generally requires that, in connection with a

[97] OCC: 12 CFR 34.43(d)(3); Board: 12 CFR 225.63(d)(3); FDIC: 12 CFR 323.3(d)(3).

[98] *See supra* note 1.

[99] 12 U.S.C. 3356. The mortgage originator must be subject to oversight by a Federal financial institutions regulatory agency. Further, the exemption does not apply to loans that are high-cost mortgages, as defined in section 103 of TILA, or if a Federal financial institutions regulatory agency requires an appraisal because it believes it is necessary to address safety and soundness concerns. *Id.*

[100] Dodd-Frank Act, section 1473, Public Law 111–203, 124 Stat. 1376.

[101] Guidelines, 75 FR at 77461.

[102] *See supra* note 1.

rulemaking, an agency prepare and make available for public comment a regulatory flexibility analysis that describes the impact of the rule on small entities. However, the regulatory flexibility analysis otherwise required under the RFA is not required if an agency certifies that the rule will not have a significant economic impact on a substantial number of small entities (defined in regulations promulgated by the Small Business Administration (SBA) to include commercial banks and savings institutions, and trust companies, with assets of $550 million or less and $38.5 million or less, respectively) and publishes its certification and a brief explanatory statement in the **Federal Register** together with the rule.

The OCC currently supervises 1,260 institutions (commercial banks, trust companies, federal savings associations, and branches or agencies of foreign banks) of which approximately 886 are small entities.[103] The OCC estimates that the proposed rule may impact approximately 797 of these small entities.

The proposal to increase the residential threshold may result in cost savings for impacted institutions. For transactions at or below the proposed threshold, regulated institutions would be given the option to obtain an evaluation of the property instead of an appraisal. While the cost of obtaining appraisals and evaluations can vary and may be passed on to borrowers, evaluations generally cost less to perform than appraisals, given that evaluations are not required to comply with USPAP. In addition to costing less than an appraisal, evaluations may require less time to review than appraisals because evaluations typically contain less detailed information than appraisals.

In addition to savings relating to the relative costs associated with appraisals and evaluations, the proposed rule may also reduce burden for institutions in areas with appraiser shortages. In the course of the agencies' most recent Economic Growth and Regulatory Paperwork Reduction Act review, commenters contended that it can be difficult to find state certified and licensed appraisers, particularly in rural areas, which results in delays in completing transactions and sometimes increased costs for appraisals.[104] For this reason, substituting evaluations for appraisals may reduce burden for institutions in areas with appraiser shortages.[105]

The proposal to require institutions to obtain an evaluation for transactions that qualify for the rural residential appraisal exemption could be viewed as a new mandate. However, because the proposed rule would increase the residential threshold to $400,000 for all residential transactions, institutions would not need to comply with the detailed requirements of the rural residential appraisal exemption in order for such transactions to be exempt from the agencies' appraisal requirement. Therefore, complying with the evaluation requirement for below-threshold transactions would be significantly less burdensome than complying with the requirements of the rural residential appraisal exemption.

Because the proposal does not contain any new recordkeeping, reporting, or significant compliance requirements, the OCC anticipates that costs associated with the proposal, if any, will be *de minimis.* Therefore, the OCC certifies that the proposal, if adopted, would not have a significant economic impact on a substantial number of small entities.

Board: The Regulatory Flexibility Act (RFA),[106] requires an agency either to provide an initial regulatory flexibility analysis with a proposed rule or certify that the proposed rule will not have a significant economic impact on a substantial number of small entities. The proposed threshold increase applies to certain IDIs and non-bank entities that make loans secured by residential real estate.[107] The SBA establishes size standards that define which entities are small businesses for purposes of the RFA.[108] The size standard to be considered a small business is: $550 million or less in assets for banks and other depository institutions; and $38.5 million or less in annual revenues for the majority of non-bank entities that are likely to be subject to the proposed regulation.[109] Based on the Board's analysis, and for the reasons stated below, the proposed rule may have a significant positive economic impact on a substantial number of small entities. Accordingly, the Board is publishing an initial regulatory flexibility analysis. The Board will consider whether to conduct a final regulatory flexibility analysis after consideration of comments received during the public comment period.

The Board requests public comment on all aspects of this analysis.

A. Reasons for the Proposed Rule

As discussed in sections I and II of the **SUPPLEMENTARY INFORMATION**, the agencies are proposing to increase the threshold from $250,000 to $400,000 at or below which a Title XI appraisal is not required for residential real estate transactions in order to reduce regulatory burden in a manner that is consistent with the safety and soundness of financial institutions. To ensure that the safety and soundness of regulated institutions is protected, the agencies are proposing to require evaluations for transactions that qualify for the residential appraisal threshold exemption and rural residential appraisal exemption. In order to fulfill the agencies' statutory responsibility under the Dodd-Frank Act, the agencies are proposing to add the requirement that appraisals be subject to appropriate review for compliance with USPAP.

B. Legal Basis

As discussed above, Title XI explicitly authorizes the agencies to establish a threshold level at or below which a Title XI appraisal is not required if the agencies determine in writing that the threshold does not represent a threat to the safety and soundness of financial institutions and receive concurrence from the BCFP that such threshold level provides reasonable protection for consumers who purchase 1-to-4 unit single-family residences.[110] For transactions exempted by the proposed residential appraisal threshold increase and the rural residential appraisal exemption, the agencies are proposing to require evaluations pursuant to their authority to prescribe standards for safe

[103] The OCC bases this estimate of the number of small entities on the SBA's size thresholds for commercial banks and savings institutions, and trust companies, which are $550 million and $38.5 million, respectively. Consistent with the General Principles of Affiliation, 13 CFR 121.103(a), the OCC includes the assets of affiliated financial institutions when determining whether to classify an OCC-supervised institution as a small entity. The OCC used December 31, 2017, to determine size because a "financial institution's assets are determined by averaging the assets reported in its four quarterly financial statements for the preceding year." *See* footnote 8 of the U.S. Small Business Administration's *Table of Size Standards.*

[104] *See* EGRPRA Report, *available at https://www.ffiec.gov/pdf/2017_FFIEC_EGRPRA_Joint-Report_to_Congress.pdf.*

[105] While the proposed threshold may decrease costs for institutions, the extent to which institutions will employ evaluations instead of appraisals is uncertain, given that institutions retain the option of using appraisals for below-threshold transactions.

[106] 5 U.S.C. 601 *et seq.*

[107] For its RFA analysis, the Board considered all Board-regulated creditors to which the proposed rule would apply.

[108] U.S. SBA, Table of Small Business Size Standards Matched to North American Industry Classification System Codes, *available at https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf.*

[109] Asset size and annual revenues are calculated according to SBA regulations. *See* 13 CFR 121 *et seq.*

[110] 12 U.S.C. 3341(b).

and sound banking practices, including for credit underwriting and real estate lending,[111] under the Federal Deposit Insurance Act. For transactions that remain subject to the agencies' appraisal requirement, the agencies are proposing to add the requirement that such appraisals be subject to appropriate review for USPAP, as required by Title XI.[112]

C. Projected Reporting, Recordkeeping and Other Compliance Requirements

The Board's proposed rule would apply to state chartered banks that are members of the Federal Reserve System (state member banks), as well as bank holding companies and nonbank subsidiaries of bank holding companies that engage in lending. There are approximately 607 state member banks and 77 nonbank lenders regulated by the Board that meet the SBA definition of small entities and would be subject to the proposed rule. Data currently available to the Board do not allow for a precise estimate of the number of small entities that would be affected by the proposed threshold increase and by the rural residential appraisal exemption, because the number of small entities that would engage in residential real estate transactions qualifying for these exemptions is unknown. The requirement that Title XI appraisals be subject to appropriate review would apply to all small entities regulated by the Board that engage in real estate lending; however, the Board does not believe this requirement would impose a significant additional burden on such institutions.

For the small entities that are affected by the threshold increase, the proposed rule would reduce reporting, recordkeeping, and other compliance requirements. For transactions at or below the proposed threshold, regulated institutions would be required to obtain an evaluation of the property instead of an appraisal. Unlike appraisals, evaluations may be performed by a lender's own employees and are not required to comply with USPAP. As previously discussed, the cost of obtaining appraisals and evaluations can vary and may be passed on to borrowers. Because of this variation in cost and practice, it is not possible to precisely determine the cost savings that regulated institutions will experience due to the decreased cost of obtaining an evaluation rather than an appraisal. However, based on information available to the Board, small entities and borrowers engaging in residential real estate transactions could experience significant cost reductions.

In addition to costing less to obtain than appraisals, evaluations also require less time to review than appraisals because they contain less detailed information. As previously discussed, the agencies estimate that, on average, the review process for an evaluation would take substantially less time than the review process for an appraisal. Thus, for affected transactions, the proposed rule could reduce the time required for employees to review transactions, potentially reducing delay and increasing cost savings of obtaining an evaluation instead of an appraisal.

The Board estimates that the number of residential real estate transactions exempted by the threshold would increase by approximately 29 percent under the proposed rule.[113] The Board expects this percentage to be higher for small entities, because a higher percentage of their loan portfolios are likely to be made up of small, below-threshold loans than those of larger entities. Thus, while the precise number of transactions that will be affected and the precise cost reduction per transaction cannot be determined, the proposed rule may have a significant positive economic impact on small entities that engage in residential real estate lending.

With respect to transactions that qualify for the rural residential appraisal exemption, the proposal to require that institutions obtain an evaluation could be viewed as an additional burden. However, because the agencies also proposed to increase the residential threshold to $400,000 for all residential transactions, regulated institutions, including small entities, would not need to comply with the detailed requirements of the rural exemption in order for such transactions to be exempt from the appraisal requirements. The Board believes that complying with the requirements of the threshold exemption would be significantly less burdensome than complying with the requirements of the rural residential threshold exemption, even if no evaluation was required for the latter.

Because the agencies' appraisal requirements already require that Title XI appraisals be performed in compliance with USPAP, the proposed requirement that such appraisals be subject to appropriate review for compliance with USPAP is not expected to impose a significant additional burden on regulated institutions, including small entities. Additionally, due to the proposed threshold increase, fewer transactions would be subject to the agencies' appraisal requirement and, thus, the review requirement.

Overall, the Board expects that the proposed rule may provide a significant burden reduction for small entities and borrowers that engage in real estate transactions.

D. Identification of Duplicative, Overlapping, or Conflicting Federal Regulations

The Board has not identified any federal statutes or regulations that would duplicate, overlap, or conflict with the proposed revisions.

E. Discussion of Significant Alternatives

The agencies considered additional burden-reducing measures, such as increasing the residential threshold to a higher dollar amount, but have not proposed such a measure at this time for the reasons previously discussed. For transactions exempted from the Title XI appraisal requirements, the proposed rule would require regulated institutions to obtain an evaluation. The agencies are proposing this provision to protect the safety and soundness of financial institutions and to protect consumers, which is a legal prerequisite to the establishment of any threshold. The Board is not aware of any other significant alternatives that would reduce burden on small entities without sacrificing the safety and soundness of financial institutions or consumer protections.

FDIC: The Regulatory Flexibility Act (RFA) generally requires that, in connection with a proposed rule, an agency prepare and make available for public comment an initial regulatory flexibility analysis describing the impact of the rulemaking on small entities.[114] A regulatory flexibility analysis is not required, however, if the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The Small Business Administration (SBA) has defined ''small entities'' to include banking organizations with total assets less than or equal to $550 million.[115] The FDIC supervises 3,643

[111] 12 U.S.C. 1831p–1; 12 U.S.C. 1844(b).

[112] 12 U.S.C. 3339(1).

[113] As shown in Table 2, approximately 750,000 transactions are exempted under the current $250,000 threshold, and an additional 214,000 transactions would be exempted under the proposed $400,000 threshold, representing an increase of approximately 29 percent over the number of transactions exempted by the current threshold.

[114] 5 U.S.C. 601 *et seq.*

[115] The SBA defines a small banking organization as having $550 million or less in assets, where ''a financial institution's assets are determined by averaging the assets reported on its four quarterly financial statements for the preceding year.'' 13 CFR 121.201 n.8 (2018). ''SBA counts the receipts,

depository institutions,[116] of which 2,840 are defined as small banking entities by the terms of the RFA.[117] In 2017, 1,216 small, FDIC-supervised institutions reported originating residential real estate loans. However, beginning in 2017, FDIC-supervised institutions ceased reporting residential loan origination data in compliance with HMDA if they originated less than 25 loans per year. Therefore, in order to more accurately assess the number of institutions that could be affected by the proposed rule we counted the number of existing institutions who reported any residential loan origination in 2015, 2016, or 2017. Thus, of the 2,840 small, FDIC-supervised entities, 1,524 (53.6 percent) are estimated to be affected by the proposed rule.[118]

The proposed rule is likely to reduce loan valuation-related costs for small, covered institutions. By increasing the residential real estate appraisal threshold, the proposed rule is expected to increase the number of residential real estate loans eligible for an evaluation, instead of an appraisal. The FDIC estimates that, on average, the review process for an appraisal would take approximately forty minutes, but only ten minutes, on average, for an evaluation. Therefore, the FDIC estimates that the proposed rule would reduce loan valuation-related costs for small, FDIC-supervised institutions by 30 minutes per transaction. According to the 2017 HMDA data, approximately eight percent of residential real estate loans originated by FDIC-insured institutions and affiliated institutions are subject to the Title XI appraisal requirements and have loan amounts between $250,000 and $400,000. Additionally, of the small, FDIC-supervised institutions that reported residential loan originations, the average number of originations per year was approximately 116. Using the average number of originations and the percent exempt from the rule, approximately an additional nine originations per year per small, FDIC-supervised institution may have an evaluation in lieu of an appraisal. Thus, by using evaluations instead of appraisals, a small, FDIC-supervised institution may reduce its total annual residential real estate transaction valuation-related labor hours by 4.5 hours. The FDIC estimates this will result in a potential cost savings for small, FDIC-supervised institutions of $321.75 per year, per institution.[119] The estimated reduction in costs would be smaller if lenders opt to not utilize an evaluation and require an appraisal on residential real estate transaction greater than $250,000 but not more than $400,000. The cost savings per institution represents less than 0.01 percent of non-interest expense per small, FDIC-supervised institution.[120] Thus, the FDIC believes the proposed rule will not have a significant economic impact on small, FDIC-supervised institutions.

The proposed rule is likely to reduce residential real estate transaction valuation-related costs for the parties involved. By increasing the residential real estate appraisal threshold, the proposed rule is expected to increase the number of residential real estate loans eligible for an evaluation, instead of an appraisal. As discussed previously, the United States Department of Veterans Affairs' appraisal fee schedule[121] for a single-family residence reflects that the cost of an appraisal generally ranges from $375 to $900, depending on the location of the property. While the FDIC does not have definitive information on the cost of evaluations, some of the comments from financial institutions and their trade associations to the CRE NPR indicated that evaluations cost substantially less than appraisals. For example, one commenter noted that third-party evaluations cost approximately 25 percent of the cost of an appraisal. Therefore, making more residential real estate transactions eligible for evaluations instead of appraisals is likely to reduce transaction valuation-related costs. However, the FDIC assumes that most, if not all, of these costs reductions are passed on to residential real estate buyers. Therefore, this effect of the proposed rule is likely to have little or no effect on small, FDIC-supervised entities.

The proposed rule is not likely to have any substantive effects on the safety and soundness of small, FDIC-supervised institutions. As discussed previously, historical loss information in the Call Reports reflect that the net charge-off rate for residential transactions did not increase after the increase in the appraisal threshold from $100,000 to $250,000 in June 1994, or during and after the recession in 2001 through year-end 2007. During this timeframe, the net charge-off rate ranged from 8 basis points to 30 basis points. However, the net charge-off rate for residential transactions increased significantly from 2008–2013, which was during and immediately after the recent recession, ranging from 63 basis points to 204 basis points. The increase in the net charge-off rate for loans secured by single 1-to-4 family residential real estate during the recent recession has been attributed to a number of factors, such as a weakening economy, declining home values, overstating the market value of homes in appraisal reports, increasing demand for residential mortgage backed securities, relaxing underwriting practices, and expanding the use of higher risk loan products. Therefore, data related to net charge-offs of loans secured by 1-to-4 family residential real estate at financial institutions suggests that an increase in the threshold would not pose a safety and soundness risk. The FDIC believes the proposed rule is unlikely to pose significant safety and soundness risks for small, FDIC-supervised entities.

The proposed rule is likely to pose relatively larger residential real estate valuation-related transaction cost reductions for rural buyers and small, FDIC-supervised institutions lending in rural areas, however these effects are difficult to accurately estimate. Home prices in rural areas are generally lower than those in suburban and urban areas. Therefore, residential real estate transactions in rural areas are likely to utilize evaluations more than appraisals, under the proposed rule. Additionally, there may be less delay in finding qualified personnel to perform an evaluation than to perform a Title XI appraisal, particularly in rural areas.

As described in the Guidelines, financial institutions should review the property valuation prior to entering into the transaction. As described previously, the FDIC estimates that financial institutions require less time to review evaluations than to review appraisals, because evaluations contain less detailed information. However, the

employees, or other measure of size of the concern whose size is at issue and all of its domestic and foreign affiliates. . . .'' 13 CFR 121.103(a)(6) (2018). Following these regulations, the FDIC uses a covered entity's affiliated and acquired assets, averaged over the preceding four quarters, to determine whether the covered entity is ''small'' for the purposes of RFA.

[116] FDIC-supervised institutions are set forth in 12 U.S.C. 1813(q)(2).

[117] Call Report, December 31, 2017.

[118] HMDA data, December 2015–2017.

[119] 4.5 hours * $71.50 per hour = $321.75. 4.5 hours * $71.50 per hour = $321.75. The FDIC estimates that the average hourly compensation for a loan officer is $71.50 an hour. The hourly compensation estimate is based on published compensation rates for Credit Counselors and Loan Officers ($44.70). The estimate includes the May 2017 75th percentile hourly wage rate reported by the Bureau of Labor Statistics, National Industry-Specific Occupational Employment and Wage Estimates for the Depository Credit Intermediation sector. The reported hourly wage rate is grossed up by 159.9 percent to account for non-monetary compensation as reported by the June 2018 Employer Costs for Employee Compensation Data. 4.5 hours * $71.50 per hour = $321.75. 4.5 hours * $71.50 per hour = $321.75.

[120] Call Report, December 31, 2017.

[121] *See https://www.benefits.va.gov/HOMELOANS/appraiser_fee_schedule.asp.*

relative distributional effects of the proposed rule for small, FDIC-supervised institutions engaging in residential real estate transactions in rural areas is difficult to accurately estimate because it depends on the current and future characteristics of rural residential real estate markets, future characteristics of residential collateral involved in transactions, the propensity of lenders to require an appraisal for transactions between $250,000 but not more than $400,000, among other things.

Finally, by potentially reducing valuation-related costs associated with residential real estate transactions for properties greater than $250,000 but not more than $400,000, the proposed rule could result in a marginal increase in lending activity of small, FDIC-supervised institutions for properties of this type. However, the FDIC assumes that this effect is likely to be negligible given that the potential cost savings of using an evaluation rather than an appraisal, represents between 0.05–0.15 percent of the median home price.[122]

For the reasons described above and under section 605(b) of the RFA, the FDIC certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities.

The FDIC invites comments on all aspects of the supporting information provided in this RFA section. In particular, would this rule have any significant effects on small entities that the FDIC has not identified?

C. Paperwork Reduction Act

In accordance with the requirements of the Paperwork Reduction Act of 1995 (PRA), [123] the agencies may not conduct or sponsor, and a respondent is not required to respond to, an information collection unless it displays a currently-valid Office of Management and Budget (OMB) control number. The agencies have reviewed this proposed rule and determined that it would not introduce any new or revise any collection of information pursuant to the PRA. Therefore, no submissions will be made to OMB for review.

D. Riegle Community Development and Regulatory Improvement Act of 1994

Pursuant to section 302(a) of the Riegle Community Development and Regulatory Improvement Act (RCDRIA),[124] in determining the effective date and administrative compliance requirements for new regulations that impose additional reporting, disclosure, or other requirements on IDIs, each Federal banking agency must consider, consistent with principles of safety and soundness and the public interest, any administrative burdens that such regulations would place on depository institutions, including small depository institutions, and customers of depository institutions, as well as the benefits of such regulations. In addition, section 302(b) of RCDRIA requires new regulations and amendments to regulations that impose additional reporting, disclosures, or other new requirements on IDIs generally to take effect on the first day of a calendar quarter that begins on or after the date on which the regulations are published in final form.[125]

The agencies recognize that the requirement to obtain an evaluation for transactions exempted by the rural residential appraisal exemption [126] could be considered a new requirement for IDIs, despite the longstanding requirements for IDIs to obtain evaluations for transactions exempt from agencies' appraisal requirement under a threshold exemption. The agencies also recognize that the requirement for an appraisal review could be considered a new requirement for IDIs. Accordingly, with respect to the requirement that financial institutions obtain evaluations for transactions exempted by the rural residential appraisal exemption and the requirement for appraisal review, the agencies are proposing an effective date of the first day of a calendar quarter which begins on or after the date on which the regulations are published in final form, consistent with RCDRIA.

Otherwise, the proposed rule would reduce burden and would not impose any reporting, disclosure, or other new requirements on IDIs. For transactions exempted from the agencies' appraisal requirement by the proposed rule (*i.e.,* residential real estate transactions between $250,000 and $400,000), lenders would be required to get an evaluation if they chose not to get an appraisal. However, the agencies do not view the option to obtain an evaluation instead of an appraisal as a new or additional requirement for purposes of RCDRIA. First, the process of obtaining an evaluation is not new since IDIs already obtain evaluations for transactions at or below the current $250,000-threshold. Second, for residential real estate transactions between $250,000 and $400,000, IDIs could continue to obtain appraisals instead of evaluations. Because the proposed rule would impose no new requirements on IDIs, the agencies are not required by RCDRIA to consider the administrative burdens and benefits of the rule or delay its effective date (other than the evaluation provision for transactions exempted by the rural residential appraisal exemption or and the appraisal review provision, as discussed above).

Because delaying the effective date of the proposed rule's threshold increase is not required and would serve no purpose, the agencies propose to make the threshold increase and all other provisions of the proposed rule, other than the evaluation requirement for transactions exempt under 103 and the appraisal review provision, effective on the first day after publication of the final rule in the **Federal Register**. Additionally, although not required by RCDRIA, the agencies did consider the administrative costs and benefits of the rule while developing the proposal. In designing the scope of the threshold increase, the agencies chose to align the definition of residential real estate transaction with industry practice, regulatory guidance, and the categories used in the Call Report in order to reduce the administrative burden of determining which transactions were exempted by the rule. The agencies also considered the cost savings that IDIs would experience by obtaining evaluations instead of appraisals and set the proposed threshold at a level designed to provide significant burden relief without sacrificing safety and soundness.

The agencies note that comment on these matters has been solicited in the **SUPPLEMENTARY INFORMATION**, and that the requirements of RCDRIA will be considered as part of the overall rulemaking process. In addition, the agencies invite any other comments that further will inform the agencies' consideration of RCDRIA.

E. Solicitation of Comments on Use of Plain Language

Section 722 of the Gramm-Leach-Bliley Act [127] requires the Federal banking agencies to use plain language in all proposed and final rules published after January 1, 2000. The agencies have sought to present the proposed rule in a simple and straightforward manner and invite

[122] $325/$597,147 = 0.0544 percent; $900/$597,147 = 0.1507 percent.

[123] 44 U.S.C. 3501–3521.

[124] 12 U.S.C. 4802(a).

[125] *Id.* at 4802(b).

[126] *See supra* note 1.

[127] Public Law 106–102, section 722, 113 Stat. 1338, 1471 (1999).

comment on the use of plain language. For example:

- Have the agencies organized the material to suit your needs? If not, how could they present the proposed rule more clearly?
- Are the requirements in the proposed rule clearly stated? If not, how could the proposed rules be more clearly stated?
- Do the regulations contain technical language or jargon that is not clear? If so, which language requires clarification?
- Would a different format (grouping and order of sections, use of headings, paragraphing) make the regulation easier to understand? If so, what changes would achieve that?
- Would more, but shorter, sections be better? If so, which sections should be changed?
- What other changes can the agencies incorporate to make the regulation easier to understand?

F. Unfunded Mandates Act

OCC Unfunded Mandates Reform Act of 1995 Determination

The OCC has analyzed the proposed rule under the factors in the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1532). Under this analysis, the OCC considered whether the proposed rule includes a Federal mandate that may result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year (adjusted annually for inflation). As discussed in the OCC's Regulatory Flexibility Act section, the costs associated with the proposed rule, if any, would be *de minimis.* Therefore, the OCC concludes that the proposed rule, if adopted as final, would not result in an expenditure of $100 million or more annually by state, local, and tribal governments, or by the private sector.

List of Subjects

12 CFR Part 34

Appraisal, Appraiser, Banks, Banking, Consumer protection, Credit, Mortgages, National banks, Reporting and recordkeeping requirements, Savings associations, Truth in lending.

12 CFR Part 225

Administrative practice and procedure, Banks, banking, Federal Reserve System, Capital planning, Holding companies, Reporting and recordkeeping requirements, Securities, Stress testing

12 CFR Part 323

Banks, banking, Mortgages, Reporting and recordkeeping requirements, Savings associations.

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

12 CFR Part 34

For the reasons set forth in the joint preamble, the OCC proposes to amend part 34 of chapter I of title 12 of the Code of Federal Regulations as follows:

PART 34—REAL ESTATE LENDING AND APPRAISALS

■ 1. The authority citation for part 34 continues to read as follows:

Authority: 12 U.S.C. 1, 25b, 29, 93a, 371, 1462a, 1463, 1464, 1465, 1701j–3, 1828(o), 3331 *et seq.,* 5101 *et seq.,* and 5412(b)(2)(B), and 15 U.S.C. 1639h.

■ 2. Section 34.42 is amended by:
■ a. Revising paragraph (f);
■ b. Redesignating paragraphs (k) through (n) as (l) through (o), respectively; and
■ c. Adding a new paragraph (k).

The revisions and addition read as set forth below.

§ 34.42 Definitions.

* * * * *

(f) Complex appraisal for a residential real estate transaction means one in which the property to be appraised, the form of ownership, or market conditions are atypical.

* * * * *

(k) Residential real estate transaction means a real estate-related financial transaction that is secured by a single 1-to-4 family residential property.

* * * * *

■ 3. Section 34.43 is amended by:
■ a. Revising paragraphs (a)(1), (b), and (d)(3);
■ b. Removing the word ''or'' at the end of paragraph (a)(12);
■ c. Removing the period at the end of paragraph (a)(13) and adding ''; or'' in its place; and
■ d. Adding paragraph (a)(14).

The addition and revisions read as set forth below.

§ 34.43 Appraisals required; transactions requiring a State certified or licensed appraiser.

(a) * * *

(1) The transaction is a residential real estate transaction that has a transaction value of $400,000 or less;

* * * * *

(14) The transaction is exempted from the appraisal requirement pursuant to the rural residential exemption under 12 U.S.C. 3356.

(b) *Evaluations required.* For a transaction that does not require the services of a State certified or licensed appraiser under paragraph (a)(1), (a)(5), (a)(7), (a)(13), or (a)(14) of this section, the institution shall obtain an appropriate evaluation of real property collateral that is consistent with safe and sound banking practices.

* * * * *

(d) * * *

(3) *Complex appraisals for residential real estate transactions of more than $400,000.* All complex appraisals for residential real estate transactions rendered in connection with federally related transactions shall require a State certified appraiser if the transaction value is more than $400,000. A regulated institution may presume that appraisals for residential real estate transactions are not complex, unless the institution has readily available information that a given appraisal will be complex. The regulated institution shall be responsible for making the final determination of whether the appraisal is complex. If during the course of the appraisal a licensed appraiser identifies factors that would result in the property, form of ownership, or market conditions being considered atypical, then either:

(i) The regulated institution may ask the licensed appraiser to complete the appraisal and have a certified appraiser approve and co-sign the appraisal; or

(ii) The institution may engage a certified appraiser to complete the appraisal.

* * * * *

■ 4. Section 34.44 is amended by:
■ a. Republishing the introductory text
■ b. Redesignating paragraphs (c), (d), and (e) as (d), (e), and (f), respectively; and
■ c. Adding a new paragraph (c).

The addition reads as set forth below.

§ 34.44 Minimum appraisal standards.

For federally related transactions, all appraisals shall, at a minimum:

* * *

(c) Be subject to appropriate review for compliance with the Uniform Standards of Professional Appraisal Practice;

* * * * *

Federal Reserve Board

For the reasons set forth in the joint preamble, the Board amends part 225 of chapter II of title 12 of the Code of Federal Regulations as follows:

PART 225—BANK HOLDING COMPANIES AND CHANGE IN BANK CONTROL (REGULATION Y)

■ 5. The authority citation for part 225 continues to read as follows:

Authority: 12 U.S.C. 1817(j)(13), 1818, 1828(o), 1831i, 1831p–1, 1843(c)(8), 1844(b), 1972(l), 3106, 3108, 3310, 3331 *et seq.,* 3906, 3907, and 3909; 15 U.S.C. 1681s, 1681w, 6801 and 6805.

■ 6. Section 225.62 is amended by:
■ a. Revising paragraph (f);
■ b. Redesignating paragraphs (k) through (n) as (l) through (o), respectively; and
■ c. Adding a new paragraph (k).

The revisions and addition read as set forth below.

§ 225.62 Definitions.

* * * * *

(f) Complex appraisal for a residential real estate transaction means one in which the property to be appraised, the form of ownership, or market conditions are atypical.

* * * * *

(k) Residential real estate transaction means a real estate-related financial transaction that is secured by a single 1-to-4 family residential property.

* * * * *

■ 7. Section 225.63 is amended by:
■ a. Revising paragraphs (a)(1), (b), and (d)(3);
■ b. Removing the word ''or'' at the end of paragraph (a)(13);
■ c. Removing the period at the end of paragraph (a)(14) and adding ''; or'' in its place; and
■ d. Adding paragraph (a)(15).

The addition and revisions read as set forth below.

§ 225.63 Appraisals required; transactions requiring a State certified or licensed appraiser.

(a) * * *

(1) The transaction is a residential real estate transaction that has a transaction value of $400,000 or less;

* * * * *

(15) The transaction is exempted from the appraisal requirement pursuant to the rural residential exemption under 12 U.S.C. 3356.

(b) *Evaluations required.* For a transaction that does not require the services of a State certified or licensed appraiser under paragraph (a)(1), (a)(5), (a)(7), (a)(14), or (a)(15) of this section, the institution shall obtain an appropriate evaluation of real property collateral that is consistent with safe and sound banking practices.

* * * * *

(d) * * *

(3) *Complex appraisals for residential real estate transactions of more than $400,000.* All complex appraisals for residential real estate transactions rendered in connection with federally related transactions shall require a State certified appraiser if the transaction value is more than $400,000. A regulated institution may presume that appraisals for residential real estate transactions are not complex, unless the institution has readily available information that a given appraisal will be complex. The regulated institution shall be responsible for making the final determination of whether the appraisal is complex. If during the course of the appraisal a licensed appraiser identifies factors that would result in the property, form of ownership, or market conditions being considered atypical, then either:

(i) The regulated institution may ask the licensed appraiser to complete the appraisal and have a certified appraiser approve and co-sign the appraisal; or

(ii) The institution may engage a certified appraiser to complete the appraisal.

* * * * *

■ 8. Section 225.64 is amended by:
■ a. Republishing the introductory text;
■ b. Redesignating paragraphs (c), (d), and (e) as (d), (e), and (f), respectively; and
■ c. Adding a paragraph (c).

The revisions and addition read as set forth below.

§ 225.64 Minimum appraisal standards.

For federally related transactions, all appraisals shall, at a minimum:

* * *

(c) Be subject to appropriate review for compliance with the Uniform Standards of Professional Appraisal Practice;

* * * * *

Federal Deposit Insurance Corporation

For the reasons set forth in the joint preamble, the FDIC amends part 323 of chapter III of title 12 of the Code of Federal Regulations as follows:

PART 323—APPRAISALS

■ 9. The authority citation for part 323 continues to read as follows:

Authority: 12 U.S.C. 1818, 1819(a) (''Seventh'' and ''Tenth''), 1831p–1 and 3331 *et seq.*

■ 10. Section 323.2 is amended by:
■ a. Revising paragraph (f);
■ b. Redesignating paragraphs (k) through (n) as (l) through (o), respectively; and
■ c. Adding a new paragraph (k).

The revisions and addition read as set forth below.

§ 323.2 Definitions.

* * * * *

(f) Complex appraisal for a residential real estate transaction means one in which the property to be appraised, the form of ownership, or market conditions are atypical.

* * * * *

(k) Residential real estate transaction means a real estate-related financial transaction that is secured by a single 1-to-4 family residential property.

* * * * *

■ 11. In Subpart A, section 323.3 is amended by:
■ a. Revising paragraphs (a)(1), (b), and (d)(3);
■ b. Removing the word ''or'' at the end of paragraph (a)(12);
■ c. Removing the period at the end of paragraph (a)(13) and adding ''; or'' in its place; and
■ d. Adding paragraph (a)(14).

The addition and revisions read as set forth below.

§ 323.3 Appraisals required; transactions requiring a State certified or licensed appraiser.

(a) * * *

(1) The transaction is a residential real estate transaction that has a transaction value of $400,000 or less;

* * * * *

(14) The transaction is exempted from the appraisal requirement pursuant to the rural residential exemption under 12 U.S.C. 3356.

(b) *Evaluations required.* For a transaction that does not require the services of a State certified or licensed appraiser under paragraph (a)(1), (a)(5), (a)(7), (a)(13), or (a)(14) of this section, the institution shall obtain an appropriate evaluation of real property collateral that is consistent with safe and sound banking practices.

* * * * *

(d) * * *

(3) *Complex appraisals for residential real estate transactions of more than $400,000.* All complex appraisals for residential real estate transactions rendered in connection with federally related transactions shall require a State certified appraiser if the transaction value is more than $400,000. A regulated institution may presume that appraisals for residential real estate transactions are not complex, unless the institution has readily available information that a given appraisal will be complex. The regulated institution shall be responsible for making the final determination of whether the appraisal is complex. If during the course of the appraisal a licensed appraiser identifies factors that would result in the property, form of ownership, or market conditions being considered atypical, then either:

(i) The regulated institution may ask the licensed appraiser to complete the appraisal and have a certified appraiser approve and co-sign the appraisal; or

(ii) The institution may engage a certified appraiser to complete the appraisal.

* * * * *

■ 12. Section 323.4 is amended by

■ a. Republishing the introductory text;

■ b. Redesignating paragraphs (c), (d), and (e) as (d), (e), and (f), respectively; and

■ c. Adding a paragraph (c).

The addition reads as set forth below.

§ 323.4 Minimum appraisal standards.

For federally related transactions, all appraisals shall, at a minimum:

* * *

(c) Be subject to appropriate review for compliance with the Uniform Standards of Professional Appraisal Practice;

* * * * *

Dated: November 15, 2018

Joseph M. Otting

Comptroller of the Currency

By order of the Board of Governors of the Federal Reserve System.

Margaret McCloskey Shanks,

Deputy Secretary of the Board.

Dated at Washington, DC, on November 20, 2018.

By order of the Board of Directors.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2018–26507 Filed 12–6–18; 8:45 am]

BILLING CODE 4810–33–6210–01;6714–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 860

[Docket No. FDA–2018–N–0236]

RIN 0910–AH53

Medical Device De Novo Classification Process

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) proposes to establish requirements for the medical device De Novo classification process under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The proposed requirements establish procedures and criteria related to requests for De Novo classification (''De Novo request''). These requirements are intended to ensure the most appropriate classification of devices consistent with the protection of the public health and the statutory scheme for device regulation, as well as to limit the unnecessary expenditure of FDA and industry resources that may occur if devices for which general controls or general and special controls provide a reasonable assurance of safety and effectiveness are subject to premarket approval. The proposed rule, if finalized, would implement the De Novo classification process under the FD&C Act, as enacted by the Food and Drug Administration Modernization Act of 1997 and modified by the Food and Drug Administration Safety and Innovation Act and the 21st Century Cures Act.

DATES: Submit either electronic or written comments on the proposed rule by March 7, 2019. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by January 7, 2019.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before March 7, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 7, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

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

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

Written/Paper Submissions

Submit written/paper submissions as follows:

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

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–N–0236 for Medical Device De Novo Classification Process. Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• *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.

Submit comments on information collection issues to the Office of Management and Budget (OMB) 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, ''Medical Device De Novo Classification Process.''

FOR FURTHER INFORMATION CONTACT: Sergio de del Castillo, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1538, Silver Spring, MD 20993, 301–796–6419.

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I. Executive Summary

A. Purpose of the Proposed Rule

This proposed rule implements the medical device De Novo classification process under the FD&C Act (section 513(f)(2) (21 U.S.C. 360c(f)(2)), which provides a pathway for certain new types of devices to obtain marketing authorization as class I or class II devices, rather than remaining automatically designated as a class III device which would require premarket approval under the postamendments device classification section of the FD&C Act (section 513(f)(1) (21 U.S.C. 360c(f)(1)).

The De Novo classification process is intended to provide an efficient pathway to ensure the most appropriate classification of a device consistent with the protection of the public health and the statutory scheme for device regulation.

When FDA classifies a device type as class I or II via the De Novo classification process, other manufacturers do not necessarily have to submit a De Novo request or premarket approval application (PMA) in order to legally market a device of the same type. Instead, manufacturers can use the less burdensome pathway of premarket notification (section 510(k) of the FD&C Act (21 U.S.C. 360(k)), when applicable, to legally market their device, because the device that was the subject of the original De Novo request can serve as a predicate device for a substantial equivalence determination.

B. Summary of the Major Provisions of the Proposed Rule

If this rule is finalized as proposed, it will establish procedures and criteria for the submission and withdrawal of a De Novo request. It would also establish procedures and criteria for FDA to accept, review, grant and/or decline a De Novo request. The proposed rule provides that:

- A person may submit a De Novo request after submitting a 510(k) and receiving a not substantially equivalent (NSE) determination.
- A person may also submit a De Novo request without first submitting a 510(k), if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence (SE).
- FDA will classify devices according to the classification criteria in the FD&C Act. FDA classifies devices into class I (general controls) if there is information showing that the general controls of the FD&C Act are sufficient to reasonably assure safety and effectiveness; into class II (special controls), if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance; and into class III (premarket approval), if there is insufficient information to support classifying a device into class I or class II and the device is a life-sustaining or life-supporting device or is for a use which is of substantial importance in preventing impairment of human health or presents a potential unreasonable risk of illness or injury.
- Devices will be classified by FDA by written order.
- A De Novo request includes administrative information, regulatory history, device description, classification summary information, benefits and risks of device use, and performance data to demonstrate reasonable assurance of safety and effectiveness.
- FDA may refuse to accept a De Novo request that is ineligible or is incomplete on its face.
- After a De Novo request is accepted, FDA will begin a substantive review of the De Novo request that may result in either FDA requesting additional information, issuing an order granting the request, or declining the De Novo request.
- FDA may decline a De Novo request if, among other things, the device is ineligible or insufficient information is provided to support De Novo classification.

The proposed rule also describes our practices for the conditions under which the confidentiality of a De Novo request is maintained.

C. Legal Authority

FDA is issuing this rule under the De Novo classification section of the FD&C Act, the device classification section of the FD&C Act, and the general rulemaking section of the FD&C Act. (See section 513(f)(2), section 513(a)(1), and section 701(a) of the FD&C Act (21 U.S.C. 371(a).)

D. Costs and Benefits

The proposed rule would clarify and make more efficient the De Novo classification process for certain medical devices to obtain marketing authorization as class I or class II devices, rather than remaining automatically designated as class III devices under the FD&C Act. A more transparent De Novo classification process would improve the efficiency of obtaining marketing authorization for certain novel medical devices. Over 10 years, the annualized cost estimates

range from $0.0 million to $0.08 million with a 7 percent discount rate, and range from $0.0 million to $0.03 million with a 3 percent discount rate.

II. Table of Abbreviations/Commonly Used Acronyms in This Document

TABLE 1—ABBREVIATIONS AND ACRONYMS

Abbreviation or acronym	What it means
510(k)	Premarket Notification.
CFR	Code of Federal Regulations.
EUA	Emergency Use Authorization.
FDA	Food and Drug Administration.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FR	**Federal Register**.
GLP	Good Laboratory Practice.
HDE	Humanitarian Device Exemption.
IDE	Investigational Device Exemption.
MDR	Medical Device Reporting.
NSE	Not Substantially Equivalent.
OMB	Office of Management and Budget.
PMA	Premarket Approval Application.
PRA	Paperwork Reduction Act of 1995.
Pub. L.	Public Law.
Ref.	Reference.
RFD	Requests for Designation under § 3.7.
SE	Substantially Equivalent.
U.S.C.	United States Code.

III. Background

The De Novo classification process provides a pathway to ensure the most appropriate classification of a device consistent with the protection of the public health and the statutory scheme for device regulation. This pathway is intended to limit unnecessary expenditure of FDA and industry resources that may occur if devices for which general controls or general and special controls provide a reasonable assurance of safety and effectiveness are subject to a PMA due to a lack of a predicate.

When FDA classifies a device type as class I or II via the De Novo classification pathway, other manufacturers do not have to submit a De Novo request or PMA in order to market the same device type, unless the device has a new intended use or technological characteristics that raise different questions of safety or effectiveness. Instead, manufacturers can use the less burdensome 510(k) pathway, when applicable, to market their device, because the device that was the subject of the original De Novo classification can serve as a predicate device.

On October 30, 2017, FDA issued a final guidance (Ref. 1) to provide recommendations on the process for the submission and review of a De Novo request. The guidance provides recommendations for interactions with FDA related to the De Novo classification process, including what information to submit when seeking a path to market via the De Novo classification process. Nevertheless, some De Novo requests lack crucial data or other information rendering the requests incomplete and requiring additional reviews.

To enhance regulatory clarity and predictability, FDA is also conducting this rulemaking. We believe it will, when finalized, provide a regulatory framework that sets clear standards, expectations and processes for De Novo classification. The statutory language on the content of De Novo requests is vague regarding what specific information is expected from the requester. With codified minimum content requirements, industry will be better able to anticipate what is necessary for successful De Novo classification, and FDA staff will have clear standards for the content and process for De Novo classification. This may also reduce the number of questions raised by FDA during the review of the De Novo request and may reduce the total review time needed to render a final decision. It is important to have enforceable content requirements for De Novo requests as well as additional clarity regarding FDA's review and ultimate decision on a De Novo request. A regulation will allow FDA to communicate minimum content requirements, which will thereby give FDA the ability to triage inadequate De Novo requests by refusing to accept such De Novo requests.

IV. Statutory Framework and Authority

The FD&C Act establishes a comprehensive system for the regulation of medical devices intended for human use. The FD&C Act establishes three categories (classes) of medical devices based on the extent of the regulatory controls necessary and sufficient to provide reasonable assurance of safety and effectiveness of the device. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

FDA refers to devices that were not in commercial distribution before May 28, 1976, the enactment date of the Medical Device Amendments of 1976, as ''postamendments'' devices. Postamendments devices are classified into class III ''automatically'' or ''statutorily.'' (Section 513(f)(1) of the FD&C Act.) These devices are automatically designated as class III devices and require premarket approval, unless: (1) FDA issues an order classifying the device into class I or II; (2) FDA reclassifies the device into class I or II; or (3) FDA issues an order finding the device to be SE to a predicate device that does not require premarket approval. Under this third option, FDA determines whether a postamendments device is SE to a previously cleared device (predicate device) by means of its 510(k) procedures (section 510(k) of the FD&C Act; 21 CFR part 807). Legally marketed devices that may serve as a predicate device include: A device that has been cleared through the 510(k) process, including a device that is not currently being marketed; a device that was legally marketed prior to May 28, 1976 (''preamendments device'') for which a PMA is not required; a device that has been reclassified from class III into class II or I; or a device that by

regulation is exempted from premarket notification (''510(k)-exempt device''). A device removed from the market at the initiative of the Commissioner of Foods and Drugs or that has been determined by judicial order to be misbranded or adulterated cannot serve as a predicate device (section 513(i)(2) of the FD&C Act and § 807.100(b)(3)).

In 1997, Congress enacted a new De Novo classification pathway. (Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115)). Congress included this new pathway to limit unnecessary expenditure of FDA and industry resources that may occur if devices for which general controls or general and special controls would provide a reasonable assurance of safety and effectiveness were, nevertheless, subject to premarket approval by operation of law because a predicate device could not be identified. In 2012, Congress streamlined the De Novo classification process by providing that FDA may classify certain medical devices under the De Novo classification process without first issuing a determination that such devices are NSE to legally marketed devices (Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144)). In 2016, the process was further modified so that a De Novo request need not be submitted within 30 days of receiving an NSE determination (Section 3101 of the 21st Century Cures Act (Pub. L. 114–255)).

A De Novo request may recommend to FDA whether the device should be class I or class II. The De Novo request should describe why general controls or general and special controls are adequate to provide reasonable assurance of safety and effectiveness of the device. For any class II recommendation, the De Novo request must also provide an initial draft of proposed special controls along with a description of how the special controls provide reasonable assurance of safety and effectiveness. In response to a De Novo request, FDA will classify the device by written order within 120 days. This classification is the initial classification of the device. After the issuance of an order classifying the device, FDA will publish a notice in the **Federal Register** announcing this classification.[1]

FDA may decline a De Novo request when the device does not meet the statutory criteria for classification into class I or II. For De Novo requests that are not preceded by a 510(k) and an NSE determination, FDA may also decline to undertake the De Novo request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device, or when FDA determines that the device submitted is not of low to moderate risk or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be established. A device that remains in class III shall be deemed adulterated and may not be distributed until approved in a PMA or exempted from such approval by an investigational device exemption (IDE).

In addition, the general administrative provisions of the FD&C Act provide authority to issue regulations for the efficient enforcement of the FD&C Act (section 701(a) of the FD&C Act).

V. Proposed Rule

FDA is proposing to amend its regulations to establish a new subpart to the medical device classification procedures regulations. The proposed rule, if finalized, would establish requirements for the medical device De Novo classification process.

A. Scope (Adding Proposed Subpart D to Part 860 and Modifying § 860.1)

FDA proposes to add a new subpart to the medical device classification procedures regulations, subpart D (21 CFR part 860, subpart D). The new proposed subpart will describe the form and manner for submission of a De Novo request. It would also describe FDA's process for a review of a De Novo request, and the form and manner in which FDA would grant or decline a De Novo request. Lastly, it would also describe the form and manner for withdrawal of a De Novo request.

The proposed rule would clarify and explain the regulatory framework and process for submitting a De Novo classification request. A De Novo request can be submitted after the submission of a premarket notification (510(k)) and a subsequent order declaring the device NSE to legally marketed devices. Under the proposed rule, a De Novo request may also be submitted without first submitting a 510(k) for that device, if the submitter determines that there is no legally marketed device upon which to base a determination of substantial equivalence.

In response to a De Novo request, FDA would classify the device by written order. This classification would be the initial classification of the device (section 513(f)(1) of the FD&C Act). FDA would publish a notice in the **Federal Register** announcing the new classification and codifying it in the CFR.

FDA proposes to amend its regulations to prescribe the content and format of a De Novo request. FDA also proposes to amend its regulations to include processes and criteria for FDA to accept, review, grant, and decline a De Novo request.

The proposed regulation would define the scope of the medical device classification procedures (§ 860.1 (21 CFR 860.1)). It includes the criteria and procedures used by classification panels and the FDA Commissioner in the classification and reclassification of devices (sections 513, 514(b), (21 U.S.C. 360d(b)), 515(b) (21 U.S.C. 360e(b)) and 520(*l*) (21 U.S.C. 360j(*l*)) of the FD&C Act). FDA proposes to update the scope to add ''advisory committees,'' to authorize such committees to provide panel recommendations as to the classification or reclassification of medical devices. (§ 860.1(b).)

B. Definitions (Proposed § 860.3)

FDA proposes to add five new definitions to the definitions section of the medical device classification procedures regulations (§ 860.3). FDA also proposes to amend the definitions section to remove the paragraph designations and to list the definitions alphabetically. This proposed amendment would make adding any new definitions to this part easier in the future. Except for removing the paragraph designations, and deleting the definition for ''the act'' because we are replacing ''the act'' with ''Federal Food, Drug, and Cosmetic Act'' throughout part 860, FDA is not proposing in this rulemaking to change any of the definitions currently listed in the definitions section.

FDA proposes to add the term, *classification regulation,* to the definitions section. FDA proposes to define classification regulation to mean a regulation that identifies the generic type of device and its class. The proposed definition explains that FDA's medical device classification regulations are in parts 862 through 892 of FDA's regulations (21 CFR parts 862–892).

[1] The FD&C Act provides that a class I device is generally exempt from 510(k) requirements (section 510(*l*) of the FD&C Act (21 U.S.C. 360(*l*))). FDA also may exempt a class II device from 510(k) requirements if FDA determines that 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device (section 510(m) of the FD&C Act (21 U.S.C. 360(m))). The process to exempt a class II device from 510(k) requirements is separate from FDA's consideration and granting of a De Novo request. For more information about procedures for class II device exemptions from premarket notification, see FDA's guidance ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff'' (Ref. 2).

FDA proposes to add the term, *De Novo request,* to the definitions section. FDA proposes to define De Novo request to mean the information that is submitted as part of a request to FDA to issue an order to classify a device under the De Novo classification section of the FD&C Act (section 513(f)(2) of the FD&C Act). The proposed definition explains that information submitted as part of a De Novo request includes information incorporated into that request by reference.

For convenience, we propose to add a definition of *FDA*. FDA proposes to define FDA as the Food and Drug Administration. This addition is intended to remove the need to further define this term in the proposed De Novo regulation, as well as in the other subparts of medical device classification procedures regulations (part 860).

FDA proposes to add a definition of *general controls*. This proposed definition harmonizes with the definition in the FD&C Act and the definition of Class I currently listed in the definitions section of the medical device classification procedures regulations (section 513(a)(1)(A) of the FD&C Act and § 860.3). While the meaning of *general controls* has been provided in guidance, adding the definition to this regulation will provide another opportunity to explain which controls are included as general controls.

FDA proposes to add a definition of *special controls*. This proposed definition harmonizes with the definition in section of the FD&C Act and the definition of Class II currently listed in the definitions section of the medical device classification procedures regulations, and is intended to clarify the regulatory significance of special controls as the controls necessary to provide reasonable assurance of safety and effectiveness for a type of device classified as class II (section 513(a)(1)(B) of the FD&C Act and § 860.3). Special controls may include such things as performance standards, performance testing (*e.g.,* biocompatibility testing, sterilization validation, clinical investigations), postmarket surveillance, patient registries, and development and dissemination of guidelines (including guidelines for the submission of clinical data in premarket notification submissions in accordance with premarket notification of the FD&C Act). While explanations of special controls have been provided in guidance, adding the definition to this regulation will provide another opportunity to clarify which controls are special controls.

C. Confidentiality of Information and Data Related to a De Novo Request (Proposed § 860.5)

The proposed additions to confidentiality of information and data section of the medical device classification procedures regulations address the public disclosure of data and information submitted as part of a De Novo request (§ 860.5). FDA is proposing that the public disclosure of data and information in a De Novo request be governed by the confidentiality sections of the regulations (§ 860.5 and part 20 (21 CFR part 20)).

The proposed De Novo request confidentiality section discusses which De Novo request information is covered (§ 860.5(g)(1)). FDA proposes that information covered includes all information submitted or incorporated by reference in the De Novo request, any De Novo supplement, or any other submission relevant to the administrative file (as defined in 21 CFR 10.3(a)).

The proposed De Novo request confidentiality section discusses when FDA may disclose the existence of a De Novo request (§ 860.5(g)(2)). FDA is proposing that the existence of a De Novo request may not be disclosed before it issues an order granting the De Novo request. FDA is further proposing that when a De Novo requester itself has disclosed the existence of the De Novo request publicly, then FDA may also publicly disclose the existence of a De Novo request before issuing an order granting the De Novo request.

The proposed De Novo request confidentiality section discusses when FDA may publicly disclose data or information contained in a De Novo request before FDA issues an order granting the De Novo request (§ 860.5(g)(3)). The data or information contained in the De Novo request will not be disclosed unless the De Novo requestor has publicly disclosed or acknowledged the information.

The proposed De Novo request confidentiality section proposes that FDA may immediately disclose any safety and effectiveness information and any other information not exempt from release under the trade secret and confidential commercial information section of the regulations after FDA issues the order granting the De Novo request (§ 860.5(g)(4) and § 20.61).

D. De Novo Classification—General (Proposed § 860.201)

The proposed section provides the purpose of the new subpart and the devices to which the subpart is applicable (§ 860.201). In this proposed rule, FDA would add a new subpart to the medical device classification procedures regulations (part 860, subpart D). The new proposed subpart contains the procedures and criteria for the De Novo classification process (section 513(f)(2) of the FD&C Act).

The proposed purpose section states that the purpose of the new subpart is to establish an efficient and thorough process to facilitate the classification into class I or II for devices for which there are no legally marketed devices on which to base a review of substantial equivalence and which meet the requirements for class I or class II as described in (§ 860.201(a), and section 513(a)(1) of the FD&C Act and § 860.3).

The proposed purpose section would identify the devices for which a De Novo request may be submitted (§ 860.201(b)). Under the proposed purpose section, a De Novo request may be submitted after receiving a NSE determination in response to a 510(k) (§ 860.201(b)(1)). We note that devices that have been found to be NSE for lack of a predicate, new intended use, or different technological characteristics that raise different questions of safety and effectiveness will generally be eligible for the De Novo classification process. We further note that a De Novo request for more than one device type would not be eligible for the De Novo classification process as part of the same request.

Under the proposed purpose section, a De Novo request may also be submitted if a person, without first submitting a 510(k) and receiving an NSE determination, determines that there is no legally marketed device upon which to base a SE determination (§ 860.201(b)(2)).

The De Novo classification process is a pathway to market for devices for which there are no legally marketed devices on which to base a review of SE and which meet the requirements for class I or class II (as described in section 513(a)(1) of the FD&C Act and 21 CFR 860.3). Under the De Novo classification section of the FD&C Act, if FDA identifies a legally marketed device that could provide a reasonable basis for review of SE, FDA may decline to undertake a De Novo request (section 513(f)(2)(A)(iv) of the FD&C Act). A device that could provide a reasonable basis for review of SE with another device is known as a predicate device. Thus, devices that have been found to be NSE solely due to inadequate performance data to demonstrate SE will generally be ineligible for the De Novo classification process because a predicate device that could provide a

reasonable basis for review of SE exists. (The substantial equivalence section of the FD&C Act provides the criteria for FDA to determine SE (section 513(i) of the FD&C Act).)

E. De Novo Request Format (Proposed § 860.223)

FDA proposes a submission process and format for a De Novo request in this section (§ 860.223). FDA proposes in the format section that De Novo requests for a device be submitted to the FDA Center that has the lead in regulating that device (§ 860.223(a)(1)). FDA proposes that De Novo requests related to devices regulated by the Center for Devices for Radiological Health (CDRH) be submitted to CDRH and that those De Novo requests related to devices regulated by the Center for Biologics Evaluation and Research (CBER) be submitted to CBER. FDA provides the appropriate CBER and CDRH addresses as part of the proposed rule.

FDA also proposes in the format section that the De Novo request be signed by the requester or its authorized representative (§ 860.223(a)(2)).

FDA is proposing further format requirements for the De Novo request (§§ 860.223(a)(3) and (4)). These proposed requirements are intended to assist in the efficiency of FDA's processing and review of the De Novo request. FDA is proposing in the format requirements that a cover page designate the De Novo request as a ''De Novo Request'' (§ 860.223(a)(3)). FDA is proposing that the entire content of the submission be in English or translated into English (§ 860.223(a)(4)). FDA proposes this requirement because FDA does not have the resources to assure the accurate and timely English translation of documents written in a non-English language to facilitate the document's use in FDA's review. Please note FDA's ''eCopy Program for Medical Device Submissions'' guidance (Ref. 3), is applicable to De Novo requests.

F. De Novo Request Content (Proposed § 860.234)

FDA proposes requirements for the content of a De Novo request (§ 860.234). This proposed section would establish the types of information that must be included in each De Novo request. To adequately support a request for De Novo classification, FDA proposes that the De Novo request include the following information, unless the De Novo requester provides a justification for each particular omission.

FDA proposes the De Novo request must include a table of contents that identifies the volume and page number for each item listed (§ 860.234(a)(1)). A table of contents assists FDA in locating information included in the De Novo request, including during the review of the De Novo request.

To assist FDA in contacting the De Novo requester during review of a De Novo request, FDA is proposing that the De Novo request include the appropriate contact information of the De Novo requester (§ 860.234(a)(2)). During its review of a De Novo request, FDA may need to contact the De Novo requester for various reasons, including to ask questions. Contact information would assist in quick and efficient contact of the appropriate person. FDA is proposing to require that the De Novo request include the name, address, phone, fax, and email address of the De Novo requester.

FDA is also proposing to require that a De Novo request include the establishment registration number of the owner or operator submitting the De Novo request, if applicable (§ 860.234(a)(2)). FDA would use this information should FDA determine an onsite inspection is necessary.

FDA is proposing that a De Novo request include a statement regarding the regulatory history of the device, including if there have been prior submissions to FDA on the device (§ 860.234(a)(3)). If there has been a prior submission, FDA proposes to require that a De Novo request identify on the prior submission, including any 510(k)s and related NSE decisions, IDEs, requests for designation (RFD) under § 3.7 (21 CFR 3.7), Pre-Submission, PMAs, Humanitarian Device Exemptions (HDEs), Emergency Use Authorizations (EUAs), section 513(g) requests for information, and previously withdrawn or declined De Novo requests (§ 860.234(a)(3)). The identification of the prior submission would also be required to identify any feedback or deficiencies communicated to the requester during the Agency's review of the prior submission and how the feedback or deficiencies are addressed in the De Novo request, where applicable. This proposed requirement is useful for FDA in communicating with a firm or when determining whether there is an existing active submission for the same device. This information may also assist FDA in determining if feedback provided during a related submission noted above, including any deficiencies communicated to the requester, was addressed in a previous De Novo request. FDA also uses this regulatory history information when determining whether a potential predicate device exists or whether a more appropriate pathway to marketing exists for the device.

FDA is proposing that the De Novo request include the name of the device (§ 860.234(a)(4)). The name of the device would include any generic, proprietary, and trade names. These names help FDA identify the device.

FDA is proposing that the De Novo request include the device's indications for use, including whether the device would be prescription or over the counter (§ 860.234(a)(5)). As part of the indications for use, the De Novo request must describe the disease or condition the device would diagnose, treat, prevent, cure or mitigate, or how the device would affect the structure or function of the body, including a description of the patient population for which the device is intended. The indications would include all the labeled patient uses of the device. FDA uses this information to assess whether all of the risks associated with the device are identified, whether the indications for use are consistent with the labeling, and to determine whether the device is of a type that has already been classified. For more information about indications for use, see FDA's guidance ''The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)], Guidance for Industry and CDRH Staff'' (Ref. 1).

FDA is proposing that the De Novo request include a device description (§ 860.234(a)(6)). Proposed § 860.234(a)(6)(i) requires the submission of a complete description of the device. This may include a narrative description of the device pictorial representations, device specifications, and engineering drawings, where applicable.

FDA is proposing that the device description include a description of each of the functional components or ingredients of the device, if the device consists of more than one physical component or ingredient (§ 860.234(a)(6)(ii)).

FDA is proposing that the device description include a description of the properties of the device relevant to diagnosing, treating, preventing, curing, or mitigating the disease or condition, and/or the effect of the device on the structure or function of the body (§ 860.234(a)(6)(iii)). This description is intended to assist in FDA's assessment of the benefits and risks of the device type.

FDA is proposing that the De Novo request include a complete description of the operational principles of the device (§ 860.234(a)(6)(iv)). This would include the mode of operation through

which a device achieves its intended use. This information would be used during FDA's review of the De Novo request to help determine whether the device is of a type that has been previously classified.

FDA is proposing that the device description include FDA assigned reference numbers (*e.g.,* 510(k) number, classification regulation number) for any legally marketed devices (including accessories) that are intended to be used with the device (§ 860.234(a)(6)(v)).

FDA proposes that the De Novo request include a description of known or reasonably known existing alternative practices or procedures for diagnosing, treating, preventing, curing, or mitigating the disease or condition for which the device is intended, or which similarly affect the structure or function of the body (§ 860.234(a)(6)(v)). This information is intended to capture available alternative biologic, device, or drug practices or procedures during FDA's assessment of the benefits and risks of the device and device type.

FDA proposes a classification summary requirement for a De Novo request for a device that has not previously been the subject of a premarket notification under section 510(k) of the FD&C Act (§ 860.234(a)(8)(i)). This information would be intended to assist FDA to establish that the De Novo classification process is appropriate for the device or if a legally marketed device of the same type exists. For such devices, FDA proposes that the De Novo request include a complete description of the searches used to establish that no legally marketed device of the same type exists (§ 860.234(a)(8)(i)(A)). Further, for such devices, FDA proposes that the De Novo request include a list of potentially similar devices to the subject device, including any classification regulations, PMAs, HDEs, 510(k)s, EUAs, or product codes applicable to the other devices, and a rationale explaining how the subject device is different from these devices (§ 860.234(a)(8)(i)(B) and (C)). FDA intends to use this information in assessing the appropriate classification of the device.

FDA proposes a classification summary requirement for a De Novo request for a device that has been the subject of a premarket notification under section 510(k) of the FD&C Act (§ 860.234(a)(8)(ii)). For such devices, FDA proposes that the submitter include the relevant 510(k) number(s) to assist FDA in locating the previously submitted information. Further, for such devices, FDA proposes that the submitter include a summary of the search performed to confirm that no legally marketed device of the same type exists since the date FDA issued the NSE determination letter. This requirement would assist FDA in establishing that no legally marketed device of the same type exists.

In accordance with the De Novo classification section in the FD&C Act, FDA proposes that the De Novo request must recommend class I or II classification (section 513(f)(2)(A)(v) of the FD&C Act and § 860.234(a)(9)). FDA proposes that this classification recommendation include a description of why the De Novo requester believes general controls or general and special controls are adequate to provide reasonable assurance of safety and effectiveness. If the submitter recommends that the device be classified as class II, FDA proposes that the recommendation must include a draft proposal for applicable special controls, and a description of how those special controls provide reasonable assurance of safety and effectiveness of the device (§ 860.234(a)(10)).

FDA proposes that the De Novo request include a summary of known or reasonably known probable risks to health associated with the use of the device and any proposed mitigations for each probable risk (§ 860.234(a)(11)). FDA would use this information to assess the different types of harmful events that may potentially result from use of the device and when determining if the harmful events can be mitigated sufficiently. A summary of probable risks to health should be based on the best available information at the time of submission of the De Novo request. A summary of any proposed mitigation should identify whether the mitigation is a general control or a special control and provide details about each control. A summary of any proposed mitigation that involves specific performance testing or labeling must include references to the applicable section or pages in the De Novo request that support the proposed testing or labeling.

FDA proposes that the De Novo request include reference to any published standard relevant to the safety or effectiveness of the device and that are known or should reasonably be known to the requester (§ 860.234(a)(12)). The proposed standards section would require that the De Novo request provide adequate information to demonstrate how the device meets, or justify any deviation from, performance standards (§ 860.234(a)(12)(i)). These published standards include both voluntary consensus standards recognized under the recognition of standards section of the FD&C Act and any voluntary consensus standard not yet recognized by FDA but cited in the De Novo request (section 514(c) of the FD&C Act (21 U.S.C. 360d(c)). This explanation would specify what applicable voluntary consensus standards or parts of standard(s) the device does not meet and explain any deviations.

FDA proposes that the De Novo request summarize each study used to support the De Novo request (§ 860.234(a)(13)). This proposed requirement is intended to ensure the quality and integrity of data obtained from these studies. This proposed requirement would apply to nonclinical laboratory studies and clinical investigations involving human subjects. For nonclinical laboratory studies and clinical investigations involving human subjects, the summary would be required to include a description of the following: The study objective, the experimental design, any data collection and analysis, and any positive, negative, or inconclusive study results. For nonclinical laboratory studies, FDA proposes to require a summary of each study (§ 860.234(a)(13)(i)). For a clinical investigation involving human subjects, FDA proposes to require that a discussion of subject selection and exclusion criteria, investigation population, investigation period, safety and effectiveness data, adverse reactions and complications, patient discontinuation, patient complaints, device failures (including unexpected software events if applicable) and replacements, results of statistical analyses of the clinical investigation, contraindications and precautions for use of the device, and other information from the clinical investigation as appropriate (any investigation conducted under an IDE must be identified as such) must be included (§ 860.234(a)(13)(ii)). FDA proposes these requirements to assure that a study's data and reported results are credible and accurate and to ensure consistency in FDA clinical data requirements. FDA would use the summary of investigations in assessing safety and effectiveness of the device.

FDA proposes that the De Novo request include a discussion of benefit and risk considerations (§ 860.234(a)(14)). The proposed benefit and risk consideration section would require a discussion demonstrating that the data and information in the De Novo request constitute valid scientific evidence (§ 860.234(a)(14)(i)). Valid scientific evidence is evidence from well-controlled investigations, partially controlled investigations, investigations and objective trials without matched

controls, well-documented case histories conducted by qualified experts, and reports of significant human experience with a marketed device, from which it can fairly and responsibly be concluded by qualified experts that there is reasonable assurance of the safety and effectiveness of a device under its conditions of use (§ 860.7(c)(2)). The proposed benefit and risk considerations section would expressly require that, pursuant to the determination of safety and effectiveness section of the regulations, a discussion be included demonstrating that, when subject to general controls or general and special controls, the probable benefit to health from use of the device outweighs any probable injury or illness from such use (*i.e.,* a discussion demonstrating the safety and effectiveness of the device) when the device is used according to its labeling (§ 860.234(a)(14)(ii) and § 860.7). Factors to consider in discussing benefits and risks are discussed in the guidance FDA issued on August 24, 2016, entitled, ''Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications, Guidance for Industry and CDRH Staff'' (Ref. 6).

FDA proposes that a De Novo request must include technical sections that contain data and information in sufficient detail to permit FDA to reach a decision on whether to grant or decline the De Novo request (in § 860.234(a)(15)). This proposed section would require the inclusion of a section containing the nonclinical laboratory studies of the device (§ 860.234(a)(15)(i)). A nonclinical laboratory study is an in vivo or in vitro experiment in which a test article is studied prospectively in a test system under laboratory conditions to determine its safety (21 CFR 58.3(d)). The nonclinical laboratory studies' section would include information on microbiology, toxicology, immunology, biocompatibility (see FDA's guidance ''Use of International Standard ISO–10993, ''Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process'' (Ref. 7)), stress, wear, shelf life, electrical safety, electromagnetic compatibility, and other laboratory or animal tests results,[2] as appropriate (§ 860.234(a)(15)(i)). The information for the proposed technical sections would be required to include a statement that each study was conducted in compliance with the Good Laboratory Practice (GLP) for nonclinical laboratory studies (§ 860.234(a)(15)(i) and part 58). If the study is not compliant with GLP, the proposed technical section would require that the De Novo requester provide a brief statement explaining the reason for noncompliance with GLP. (§ 860.234(a)(15)(i)). The brief statement would assist FDA in determining whether the non-compliance may relate to potential bias or credibility of the study.

FDA proposes that, for all devices incorporating software, the De Novo request include a section containing all relevant information regarding software information and testing, including, but not limited to, appropriate device hazard analysis, hardware, and system information (§ 860.234(a)(15)(ii)). FDA recommends consulting FDA's ''Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices'' (Ref. 8).

FDA proposes that a section be included in a De Novo request that contains the results of any clinical investigation of the device involving human subjects (§ 860.234(a)(15)(iii)). This information is intended to assist FDA in its assessment of the quality and integrity of data obtained from these investigations. The following elements would be included in this section of the request, pursuant to the proposed rule:

- Discussion of clinical protocols in sufficient detail for FDA to assess the strengths and limitations of the investigation, which generally include a discussion of the objectives, design, methodology, and organization of the clinical investigation.
- The number of investigators and the number of subjects per investigator.
- Discussion of any subject selection and exclusion criteria, and the investigation population, to assist FDA in assessing whether the selection of clinical investigation subjects reflects the intended target population for the device. Selection and exclusion criteria typically include standards that investigation participants must meet or characteristics they must have, such as age, gender, type and stage of a disease, previous treatment history, and other medical conditions that may impact selection or exclusion criteria. To the extent a device has disparate safety or effectiveness outcomes or benefits in different demographic groups, differences in the race, ethnicity, age, gender, and sex of a subject population can affect the applicability of the investigation to the intended population. For more information, see FDA guidance documents ''Collection of Race and Ethnicity Data in Clinical Trials'' (Ref. 4) and ''Evaluation and Reporting of Age-, Race-, and Ethnicity-Specific Data in Medical Device Clinical Studies (Ref. 5).
- An investigation period description to assist FDA in assessing whether the clinical investigation period is applicable to the target population. The investigation period also would assist FDA in evaluating whether the clinical investigation supports the effectiveness of the device as labeled.
- Any safety and effectiveness data to assist FDA in assessing whether the clinical investigation supports that a reasonable assurance of safety and effectiveness exists. FDA would assess reasonable assurance of safety and effectiveness by evaluating the valid scientific evidence submitted to support the De Novo request. FDA would review the data to assess whether the data supports the claims made in the indications for use and demonstrates that the probable benefits of the device outweigh the probable risks. For more information, see FDA's guidance ''Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications'' (Ref. 6).
- Discussion of data on any adverse reactions to the use of the device (*e.g.,* any unfavorable response that caused or has potential to cause an injury) or complications related to the use of the device. An adverse reaction may occur as part of the effect of the device or may occur unpredictably. Frequency data and severity data are particularly useful in safety and effectiveness determinations. FDA would review the rates of complications in clinical investigations in assessing the safety and effectiveness of the device. The applicability of the adverse event information depends on the existing safety information and whether the population or use presents a new or serious safety issue.
- Discussion of data on any subject discontinuation that occurred in an investigation including the reasons for the discontinuation and the extent of the discontinuation of the subject. FDA would need all discontinuation data in order to determine the safety and effectiveness of the device. Whether the subject decides to discontinue participation in the clinical investigation, or is discontinued by the investigator because the subject no longer qualifies under the protocol, the data collected up to withdrawal of the subject are required for clinical investigation data to be complete.

[2] FDA supports the principles of the ''3Rs,'' to reduce, refine, and replace animal use in testing. We encourage sponsors to consult with us if they wish to use a non-animal testing method they believe is suitable, adequate, validated, and feasible. We will consider if such an alternative method could be assessed for equivalency to an animal test method.

Without such a control, *i.e.,* if a subject or an investigator were able to decide whether to include a subject's data, depending on whether a subject discontinues participation in the trial, the potential for bias could impact the credibility of the data.

- Discussion of any identified trends after analyzing any subject complaints that occurred. In analyzing trends, factors such as location, user application, as well as repeat component or device events may apply. Trends in complaints may point to possible risks posed by the device. FDA would review such trend analyses in assessing the safety and effectiveness of the device.
- Discussion of any device failures and replacements. In analyzing failures, factors such as location, user application, and repeat component failures may apply. FDA would review such analyses in assessing the safety and effectiveness of the device.
- Discussion of any tabulations of data from all individual subject reporting forms and copies of such forms for each subject who died during a clinical investigation or who did not complete the investigation. Complete information for all subjects who died during the investigation would assist in assessing safety problems as well as to ensure that the investigation evaluation is as unbiased as possible.
- Statistical analysis of the results from each clinical investigation. The statistical analysis should specify and discuss all effects. FDA would review such analyses in assessing the safety and effectiveness of the device.
- Any contraindication, precaution, warning, or other limiting statement relevant to the use of the device (*e.g.,* a statement providing that the device is limited to prescription use only). This includes information regarding any special care to be exercised by a practitioner or patient for the safe and effective use of the device. This section should describe situations in which the device should not be used because the risk of use exceeds the benefit.
- Other appropriate information from the clinical investigation. For example, this section should identify any investigation conducted under an IDE.

For clinical investigations conducted in the United States, FDA proposes that the technical sections of the De Novo request would include a number of statements indicating compliance (or, if the investigation is noncompliant, a brief statement of the reason for the noncompliance) with the following FDA requirements with respect to each investigation conducted (§ 860.234(a)(15)(iii)(A)–(B)): (1) The institutional review board regulations (21 CFR part 56), or alternatively, a statement that the investigation was not subject to the regulations under § 56.104 or § 56.105; (2) the informed consent regulations (21 CFR part 50); and (3) the applicable IDE regulations concerning sponsors of clinical investigations and clinical investigators (21 CFR part 812). Proposed § 860.234(a)(15)(iii)(A)–(B) would also remind requesters that failure or inability to comply with the requirements does not justify failure to provide information on a relevant clinical investigation.

For clinical investigations conducted outside the United States that are intended to support a De Novo request, the requirements under 21 CFR 812.28 relating to Good Clinical Practice (GCP) would apply when they become effective on February 21, 2019 (83 FR 7366). Consistent with the new provisions for 510(k)s and PMAs that were promulgated as part of the GCP rulemaking (83 FR 7366, 7385 & 7387), FDA proposes to include a provision (§ 860.234(a)(15)(iii)(C)) stating that, for clinical investigations conducted outside the United States that are intended to support a De Novo request, the requirements under § 812.28 would apply. If any such investigation was not conducted in accordance with GCP, FDA proposes that the De Novo request would be required to include either a waiver request in accordance with § 812.28(c) or a brief statement of the reason for not conducting the investigation in accordance with GCP, as well as a description of steps taken to ensure that the data and results are credible and accurate and that the rights, safety, and well-being of subjects have been adequately protected. Proposed § 860.234(a)(15)(iii)(C) would also remind requesters that failure or inability to comply with the requirements does not justify failure to provide information on a relevant clinical investigation.

For clinical investigations conducted in the United States and outside the United States, FDA proposes to require the De Novo request include the following elements (§ 860.234(a)(15)(iii)(D)–(E)): (1) A statement that each investigation has been completed in accordance with the protocol or a summary of any deviations from the protocol; and (2) a financial certification or disclosure statement (21 CFR part 54). This information would assist FDA in its assessment of the quality and integrity of data obtained from these investigations, as well as to evaluate any uncertainty in the data as part of the benefit-risk assessment.

FDA further proposes that, if a De Novo request relies primarily on data from a single investigator at one investigation site, the De Novo request must include a justification showing why these data and other information are sufficient to demonstrate the safety and effectiveness of the device and to ensure that the results from a site are applicable to the intended population (§ 860.234(a)(15)(iii)(F)). This information would assist FDA in verifying that data from a single investigation site are representative of the safety and effectiveness of the device when used in the intended population.

FDA further proposes to require that a De Novo request include a discussion of the clinical significance of the results, pursuant to the determination of safety and effectiveness (§ 860.234(a)(15)(iii)(G) and § 860.7(e)).

FDA proposes to require that a De Novo request include a bibliography of all published reports not submitted under the technical sections in (§§ 860.234(a)(16)(i) and 860.234(a)(15)). These reports are in addition to, and not the same as, the data and information on any laboratory studies and any clinical investigations conducted by the requester. FDA proposes to require that the De Novo request include any other identification, discussion, and analysis of any other data, information, or report relevant to the safety and effectiveness of the device (§ 860.234(a)(16)(ii)). Under the proposed other information section, such information may be from foreign or domestic sources, and includes information obtained from investigations other than those in the De Novo request and from commercial marketing experience, if applicable (§ 860.234(a)(16)(ii)). FDA proposes that the De Novo request would be required to include copies of such reports or information, if requested by FDA (§ 860.234(a)(16)(iii)). Only those reports or information in the possession of the De Novo requester or reasonably obtainable by the De Novo requester would be required to be provided when requested.

FDA proposes that, if requested by FDA, the De Novo request would be required to include one or more samples of the device and its components, as requested (§ 860.234(a)(17)). If submitting samples of the device is impractical, the De Novo requester would be required to name the location where FDA may examine or test one or more of the devices.

FDA proposes to require that the De Novo request include any proposed labels, labeling, and advertisements for the device (§ 860.234(a)(18)). The

proposed labeling and advertisements would have to be sufficient to describe the device and its intended use, and provide adequate directions for its use. Photographs or engineering drawings would be required, where applicable.

FDA proposes that the De Novo request must include other information that is necessary for FDA to determine whether general controls or general and special controls provide a reasonable assurance of safety and effectiveness of the device (§ 860.234(a)(19)). Examples would include marketing experience outside the United States, medical device reporting (MDR) data (if the device is legally marketed in the United States for a different intended use, and such data may be relevant to an evaluation of safety of the device), and patient preference information (*e.g.,* testimonials from patients who were treated with or used the subject device). Patient preference information that may be used by FDA staff in decision making related to De Novo requests is discussed in the guidance FDA issued on August 24, 2016, entitled, ''Patient Preference Information—Voluntary Submission, Review in Premarket Approval Applications, Humanitarian Device Exemption Applications, and De Novo Requests, and Inclusion in Decision Summaries and Device Labeling, Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders'' (Ref. 9).

FDA proposes that pertinent information in FDA files specifically referred to by a De Novo requester may be included in a De Novo request by reference (§ 860.234(b)). This would include information that is specifically referred to and incorporated by reference from any of the De Novo requester's submissions or submissions of someone other than the De Novo requester. The De Novo requester would be required to include the written authorization to reference the information by the person who submitted that information.

FDA proposes to require that the De Novo request include a statement for any omission of any information required by the De Novo content regulation if the requester believes the information is not applicable to the device that is the subject of the De Novo request (in §§ 860.234(c) and 860.234(a)). The statement would have to be in a separate section of the De Novo request and listed in the table of contents. FDA would require the statement for any omission to specify the information omitted, and include a justification for the omission. FDA would notify the De Novo requester if the justification for the omission is not accepted.

FDA proposes to require the De Novo requester to update its pending De Novo request with new safety and effectiveness information learned about the device from ongoing or completed studies and investigations that may reasonably affect an evaluation of safety or effectiveness of the device as such information becomes available (§ 860.234(d)).

G. Accepting a De Novo Request (Proposed § 860.245)

The proposed section provides proposed criteria for FDA's acceptance of a De Novo request (§ 860.245). The purpose of the criteria for FDA's acceptance for review of the De Novo request would be to enable FDA to make a threshold determination whether the De Novo request contains the information necessary to permit a substantive review. FDA proposes that, after a De Novo request is received by FDA, FDA would notify the requester whether the submission has been accepted for review (§ 860.245(a)). FDA proposes that, if FDA does not find any reason to refuse to accept the De Novo request, or FDA fails to complete the acceptance review within 15 days, FDA would accept the De Novo request and notify the De Novo requester (§ 860.245(b)). For an accepted De Novo request, FDA proposes that the date of acceptance would be the date FDA received the De Novo request or the date FDA received additional information that results in acceptance of the De Novo request.

FDA proposes that, if a De Novo request contains one or more of the listed deficiencies, FDA would be able to refuse to accept the De Novo request (§ 860.245(c)). The deficiencies are as follows:

- The requester has a pending premarket submission, including a 510(k), HDE, EUA, PMA, or reclassification petition for the same device.
- The De Novo request does not contain either: (1) Each of the items required under the De Novo classification section of the FD&C Act or this part or (2) a justification for any omission of the items (section 513(f)(2) of the FD&C Act).
- The De Novo request is not in the required format set out in proposed § 860.223.
- The De Novo request is for more than one device type. A device type is a grouping of devices that do not differ significantly in purpose, design, materials, energy source, function, or any other feature related to safety and effectiveness, and for which similar regulatory controls are sufficient to provide reasonable assurance of safety and effectiveness.
- The requester has either not provided a complete response (*e.g.,* for each FDA additional information request, the requester has not provided a supplement or amendment to their De Novo request containing all information requested by FDA) to deficiencies identified by FDA in previous submissions for the same device, including those submissions described in the regulatory history, or the requester has failed to provide a rationale for not responding to those deficiencies as set out in proposed § 860.234(a)(3).

The proposed section on acceptance of a De Novo request provides that FDA would notify the De Novo requester of the reasons for refusal if FDA refuses to accept a De Novo request (§ 860.245(c)(2)). The notice would include the De Novo request reference number and will identify the deficiencies in the De Novo request. FDA proposes that, if FDA refuses to accept a De Novo request, the requester would be permitted to submit the additional information necessary to comply with the requirements of the De Novo classification section of the FD&C Act and applicable regulations, including the provisions of this part (§ 860.245(c)(3) and section 513(f)(2) of the FD&C Act). If FDA subsequently accepts the De Novo request, the acceptance date for the De Novo request would be the date FDA received the additional information.

H. Procedures for Review of a De Novo Request (Proposed § 860.256)

FDA proposes that FDA would substantively review and grant or decline a De Novo request within 120 days after the De Novo request is received or additional information is received that results in acceptance of the De Novo request (§ 860.256(a)). The 120 days would begin on the day FDA receives the most recent De Novo request or additional information that results in acceptance of the De Novo request (§ 860.245).

FDA proposes that a De Novo requester would be permitted to supplement or amend a pending De Novo request to revise existing information or provide additional information (§ 860.256(b)). Under the proposed rule, FDA may request this information, or a De Novo requester may submit this information on its own initiative. These responses to the FDA requests for additional information regarding a De Novo request under

review are referred to as amendments or supplements. If the requested information is not received within the timeframe specified in FDA's request for information, or the information is incomplete, the De Novo request would be placed on hold until the information is received. If additional information is submitted at the De Novo requester's own initiative, the reason for the additional information and the reference number for the original De Novo request should be included. Additional information may be used by FDA, or an advisory committee if appropriate, during review of the De Novo request.

FDA proposes that FDA would be able to inspect relevant facilities prior to granting or declining a De Novo request (§ 860.256(c)). Such an inspection is intended to assist FDA in determining whether a reasonable assurance of safety and effectiveness can be provided by general or general and special controls. FDA proposes to inspect to help determine that clinical or nonclinical data were collected in a manner that ensures the data accurately represents the risks and benefits of the device, and to help determine that that FDA's Quality System Regulation (QSR), in addition to other general and any special controls, are adequate to ensure that critical and/or novel manufacturing processes that may impact the safety and effectiveness of the device are controlled (21 CFR part 820). Inspection would allow FDA to verify the documentation and implementation of a facility's QSR.

I. Withdrawal of a De Novo Request (Proposed § 860.267)

The proposed section on withdrawal of a De Novo request specifies when FDA would notify a requester that FDA considers the De Novo request withdrawn (§ 860.267). Once a De Novo request has been withdrawn, the requester would be required to submit a new De Novo request to restart the De Novo review process.

The proposed section on withdrawal of a De Novo request provides when FDA would consider a De Novo request to have been withdrawn (§ 860.267(a)). Under the proposed section, if the De Novo requester fails to provide a complete response to a request for additional information within 180 days, FDA would consider the De Novo request withdrawn (§ 860.267(a)(1)). Under the proposed section, if the De Novo requester fails to provide a complete response to any deficiencies identified by FDA within 180 days of the date FDA notifies the requester of such deficiencies, FDA would also consider the De Novo request withdrawn (§ 860.267(a)(2)). In addition, under the proposed section, if the De Novo requester does not permit an authorized FDA employee an opportunity to inspect the facilities and to have access to copy and verify records pertinent to the De Novo request, FDA would consider the De Novo request withdrawn (section § 860.267(a)(3)). Finally, under the proposed section, if the De Novo requester submits a written notice to FDA that the De Novo request has been withdrawn, FDA would also consider the De Novo request withdrawn (§ 860.267(a)(4)).

Under the proposed section, if FDA considers a De Novo request withdrawn, FDA would notify the De Novo requester (§ 860.267(b)). The written notice would include the De Novo request reference number and the date FDA considered the De Novo request withdrawn.

J. Granting or Declining a De Novo Request (Proposed § 860.289)

FDA proposes the processes and criteria for granting and declining a De Novo request (§ 860.289). Pursuant to the De Novo classification section of the FD&C Act, a De Novo request will be granted by administrative order (section 513(f)(2)(B)(i) of the FD&C Act). The order will classify the device into class I or class II, and include any special controls, if applicable. Prior to the issuance of the administrative order, FDA will review the De Novo request under the criteria set forth in the classification section of the FD&C Act, determine the appropriate class of the device, and issue an order to the requester in the form of a letter that classifies the device (section 513(a)(1) of the FD&C Act). The proposed section on granting or declining a De Novo request provides that FDA would grant a De Novo request if none of the reasons listed in the section for denying a De Novo request applies (§§ 860.289(a)(1) and 860.289(b)). Under the proposed section, and as required by the De Novo classification section of the FD&C Act, FDA would subsequently publish a notice in the **Federal Register** announcing the classification order (§ 860.289(a)(2) and section 513(f)(2)(C) of the FD&C Act). This announcement would codify the classification of the device and establish the device type.

FDA proposes that it would decline a De Novo request by issuing a written order to the requester (§ 860.289(b)). If the De Novo request is declined, the device would remain in class III and may not be legally marketed unless and until it has been approved in a PMA, cleared in a 510(k), or a new De Novo request has been granted.

FDA proposes the following grounds for declining a De Novo request (§ 860.289(b)):

- The device does not meet the criteria under the classification section of the FD&C Act and the definitions section of the medical device classification procedures regulations for classification into class I or II (section 513(a)(1) of the FD&C Act and § 860.3).
- The De Novo request contains a false statement of material fact, or there is a material omission. FDA may rescind a De Novo request containing a false statement of material fact or a material omission.
- The proposed labeling for the device does not meet the requirements in the labeling part and the in vitro diagnostic products for human use part, as applicable (part 801 (21 CFR part 801) and part 809 (21 CFR part 809)).
- The product does not meet the definition of a device at section 201(h) in the FD&C Act (21 U.S.C. 321(h)) and is not a combination product as defined at § 3.2(e)) (21 CFR 3.2(e)). FDA generally intends to decline a De Novo request for a combination product that does not have a device primary mode of action (see § 3.2(m)). However, a De Novo request may be appropriate, for example, for the device constituent part of such a combination product if the constituent parts of the combination product are to be distributed separately (see § 3.2(e)(3)–(4)), and the other constituent part (drug or biological product) of the combination product is to be marketed under its own, separate application (*i.e.,* abbreviated new drug application, new drug application, or biologics license application). We welcome comment on this issue.
- The device is of a type which has already been approved in existing applications for PMAs submitted under the premarket approval of medical devices (21 CFR part 814).
- The device type has already been classified into class I, class II, or class III.
- An inspection of a relevant facility under the procedures for review of a De Novo request section results in a determination that general or general and special controls would not provide a reasonable assurance of safety and effectiveness (§ 860.256(c)).
- A nonclinical laboratory study that is described in the De Novo request, and that is essential to show the device there is a reasonable assurance of safety was not conducted in compliance with the GLP requirements and no reason for the noncompliance is provided or, if a reason for noncompliance with the GLP

requirements is provided, the practices used in the study do not support the validity of the study (part 58).

- A clinical investigation described in the De Novo request involving human subjects that is subject to the institutional review board regulations in part 56, the informed consent regulations in part 50, or GCP described in § 812.28(a), was not conducted in compliance with those regulations such that the rights or safety of human subjects were not adequately protected or the supporting data are otherwise unreliable.
- A clinical or nonclinical study necessary to demonstrate that general or general and special controls provide a reasonable assurance of safety and effectiveness has either not been completed according to the study protocol, or deficiencies about such a study identified in a request for additional information under the procedures for review of a De Novo request section have not been adequately addressed (§ 860.256(b)(1)).
- After the De Novo request has been accepted for review under the accepting a De Novo request section, the De Novo requester makes significant changes not solicited by FDA to either the device's indications for use or to the device's technological characteristics (§ 860.245(b)).

FDA proposes that FDA would issue an order declining a De Novo request that would inform the De Novo requester of the grounds for declining the request (§ 860.289(c)).

As noted in the list above, one of the grounds for declining a De Novo request is that the device is of a type which has already been approved in a PMA submitted under the premarket approval of medical devices (21 CFR part 814). With respect to such devices (section 513(f)(1) of the FD&C Act), the postamendments devices reclassification section of the FD&C Act (section 513(f)(3) of the FD&C Act), and not the De Novo classification section of the FD&C Act (section 513(f)(2) of the FD&C Act), is the appropriate pathway for reclassification of such devices. The classification section of the FD&C Act on classification and/or reclassification of postamendments devices (section 513(f)(2) and (3) of the FD&C Act), especially the unique provision (section 513(f)(3) of the FD&C Act) that supports reclassification of a group of devices, support the view that FD&C Act's provisions on reclassification of postamendments devices (section 513(f)(3) of the FD&C Act), rather than its De Novo classification section (section 513(f)(2) of the FD&C Act), is to be used for reclassification of device types already approved in a PMA.[2]

If a De Novo request is declined because a device was classified into class III under the classification section or the classification change section of the FD&C Act (section 513(d) or (e) of the FD&C Act), and there is evidence to support classification into class I or class II, a person, or FDA on its own initiative, may seek reclassification of the class III device under the classification change section of the FD&C Act (section 513(e) of the FD&C Act).

FDA proposes that FDA would determine the safety and effectiveness of the device using the criteria specified in the determination of safety and effectiveness section of the regulations (§§ 860.289(d) and 860.7). Under the proposed rule, FDA would be permitted to use information other than that submitted by the De Novo requester in making such determinations, *e.g.,* published literature.

VI. Proposed Effective Date

FDA proposes that this rule would go into effect 90 days after publication of a final rule.

VII. 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.'' We believe that 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 small entities affected by this rule would incur very small one-time costs to read and understand the rule, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes 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 $150 million, using the most current (2017) 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 clarify and create a more efficient De Novo classification process by specifying: (1) What medical devices are eligible for the De Novo classification process; (2) what information manufacturers must provide in De Novo requests; (3) how to organize these data. By clarifying and making more efficient these requirements, we expect the proposed rule, if finalized, would reduce the time and costs associated with reviewing De Novo requests, and generate net benefits in the form of cost savings. Moreover, the proposed rule, if finalized, would allow us to refuse to accept inappropriate and deficient De Novo requests, and require us to protect the confidentiality of certain data and information submitted with a request until we issue an order granting the request. Table 2 summarizes our estimate of the annualized costs and the annualized benefits of the proposed rule over 10 years.

[3] This interpretation is also consistent with FDA's historical use of the De Novo sections and the legislative history of the FD&C Act provisions on postabendments device relclassification.

TABLE 2—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				2016	7	10	
Monetized $millions/year				2016	3	10	
Annualized				2016	7	10	
Quantified				2016	3	10	
Qualitative							
Costs:							
Annualized	$0.04	$0.0	$0.08	2016	7	10	
Monetized $millions/year	$0.02	$0.0	$0.03	2016	3	10	
Annualized				2016	7	10	
Quantified				2016	3	10	
Qualitative							
Transfers:							
Federal				2016	7	10	
Annualized				2016	3	10	
Monetized $millions/year	From:			To:			
Other				2016	7	10	
Annualized				2016	3	10	
Monetized $millions/year	From:			To:			
Effects: State, Local or Tribal Government: None. Small Business: None. Wages: None. Growth: None.							

In line with Executive Order 13771, in Table 3 we estimate present and annualized values of the costs and cost-savings over an infinite time horizon.

TABLE 3—EXECUTIVE ORDER 13771 SUMMARY TABLE

[In $ million 2016 dollars over an infinite time horizon]

	Lower bound (7%)	Primary (7%)	Upper bound (7%)	Lower bound (3%)	Primary (3%)	Upper bound (3%)
Present Value of Costs	$0.0	$0.6	$1.1	$0.0	$0.6	$1.1
Present Value of Cost-Savings	0.0	0.0	0.0	0.0	0.0	0.0
Present Value of Net Costs [1]	0.0	0.6	1.1	0.0	0.6	1.1
Annualized Costs	0.0	0.0	0.0	0.0	0.0	0.0
Annualized Cost-Savings	0.0	0.0	0.0	0.0	0.0	0.0
Annualized Net Costs [1]	0.0	0.0	0.0	0.0	0.0	0.0

[1] We calculate net costs as costs minus cost savings.

We have developed a comprehensive Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full preliminary analysis of economic impacts is available in the docket for this proposed rule (Ref. 10) and at *https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

VIII. Analysis of Environmental Impact

We have determined that, under 21 CFR 25.34(b) and (f), this proposed action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. 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.

X. 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 burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Medical Device De Novo Classification Process (OMB Control Number 0910–0844)—Revision.

Description: This proposed rule implements the medical device De Novo classification process under section 513(f)(2) of the FD&C Act, which provides a pathway for certain new types of devices to obtain marketing authorization as class I or class II devices, rather than remaining automatically designated as a class III device which would require premarket approval under the postamendments device classification section of the FD&C Act (section 513(f)(1)).

On October 30, 2017, FDA issued a final guidance (De Novo Program guidance) (Ref. 1) to provide recommendations on the process for the submission and review of a De Novo request. The information collections associated with the guidance are approved under OMB control number 0910–0844. We provide below a revised burden estimate for the De Novo classification process as described in this proposed rule.

Proposed 860.201 explains the purpose of the proposed De Novo Classification regulations and provides the applicability of a De Novo request submission. Proposed 860.223 and 860.234 describe the format and content, respectively, of a De Novo request. Proposed 860.245 describes the conditions under which FDA may refuse to accept a De Novo request. Proposed 860.256(b) provides for supplemental, amendatory, or additional information for a pending De Novo request. Proposed 860.267(a)(4) provides that a requester may submit a written notice to FDA that the De Novo request has been withdrawn.

Description of Respondents: Respondents to the information collection are medical device manufacturers seeking to market medical device products that have been classified into class III under section 513(f)(2) of the FD&C Act.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

Activity; 21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Total operating and maintenance costs
De Novo request—proposed 860.201, 860.223, 860.234, 860.245, 860.256(b)	60	1	60	182	10,920	$7,278
Written notice of withdrawal—proposed 860.267(a)(4)	5	1	5	10	50	5
Total					10,970	7,283

Based on our recent experience with the De Novo Program, FDA estimates that the average burden per response for a De Novo request is 182 hours. This includes information collection associated with the proposed provisions described in 860.201, 860.223, 860.234, 860.245, and 860.256(b). Because the provisions under proposed 860.245 are not included in the information collection burden estimates associated with the De Novo Program guidance, we have included an additional 2 hours per response in the average burden per response for manufacturers to review their De Novo request for compliance with the acceptance criteria listed in proposed 860.245. Based on updated program data and trends, we expect to receive approximately 60 De Novo requests per year. This estimate is a 3,640-hour increase from the burden estimate approved for the De Novo Program guidance.

We estimate that the average burden per response for written notice of withdrawal of a De Novo request, as described in proposed 860.267(a)(4), is 10 minutes. The average burden per response is based on estimates by FDA administrative and technical staff who are familiar with the requirements for submission of a De Novo request (and related materials), have consulted and advised manufacturers on submissions, and have reviewed the documentation submitted. We expect that we will receive approximately five requests for withdrawal per year. There is no change to the currently approved burden estimate for this information collection.

The operating and maintenance cost for a De Novo submission includes the cost of printing, shipping, and the eCopy. We estimate the cost burden for a De Novo submission to be $121.30 ($90 printing + $30 shipping + $1.30 eCopy). The annual cost estimate for De Novo submissions is $7,278 (60 submissions × $121.30). We estimate the cost for a request for withdrawal to be $1 (rounded) ($0.09 printing 1 page + $0.03 shipping + $1.30 eCopy). The annual cost estimate for requests for withdrawal is $5.

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**.

This proposed rule also refers to previously approved collections of information. 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 the

guidance document entitled ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' have been approved under OMB control number 0910–0844; the collections of information in the guidance document entitled ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff'' have been approved under OMB control number 0910–0756; the collections of information in the guidance documents entitled ''Guidance for Industry and Food and Drug Administration Staff—User Fees for 513(g) Requests for Information'' and ''FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act—Guidance for Industry and Food and Drug Administration Staff'' have been approved under OMB control number 0910–0705; and the collections of information in the guidance document entitled ''Emergency Use Authorization of Medical Products and Related Authorities'' have been approved under OMB control number 0910–0595. The collections of information in Title 21 of the Code of Federal Regulations (CFR) are approved under the following OMB control numbers: Part 3 under 0910–0523; parts 50 and 56 under 0910–0755; part 54 under 0910–0396; part 58 under 0910–0119; parts 801 and 809 under 0910–0485; part 807, subpart E, under 0910–0120; part 812 under 0910–0078; part 814, subparts A through E under 0910–0231; part 814, subpart H under 0910–0332; part 820 under 0910–0073; part 860, subpart C under 0910–0138.

XI. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that the proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

XII. References

The following references are on display in the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.*

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. FDA's guidance ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' available at *https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm080197.pdf.*
2. FDA's guidance ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff''' available at *https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080199.pdf.*
3. FDA's guidance ''eCopy Program for Medical Device Submissions'' available at *https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm313794.pdf.*
4. FDA's guidance ''Collection of Race and Ethnicity Data in Clinical Trials,'' available at *https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm126396.pdf.*
5. FDA's guidance ''Evaluation and Reporting of Age-, Race-, and Ethnicity-Specific Data in Medical Device Clinical Studies,'' available at *https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM507278.pdf.*
6. FDA's guidance ''Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications, Guidance for Industry and CDRH Staff,'' available at (*https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm517504.pdf.*
7. FDA's guidance ''Use of International Standard ISO–10993, ''Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process,'') available at *https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm348890.pdf.*
8. FDA's guidance ''Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices,'' available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm.*
9. FDA's guidance ''Patient Preference Information—Voluntary Submission, Review in Premarket Approval Applications, Humanitarian Device Exemption Applications, and De Novo Requests, and Inclusion in Decision Summaries and Device Labeling, Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders'' available at *https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm446680.pdf.*
10. FDA's full preliminary analysis of economic impacts is available in the Docket No. FDA–2018–N–0236 for this proposed rule and at *https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

List of Subjects in 21 CFR Part 860

Administrative practice and procedure, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, we propose that 21 CFR part 860 be amended as follows:

PART 860—MEDICAL DEVICE CLASSIFICATION PROCEDURES

■ 1. The authority citation for part 860 is revised to read as follows:

Authority: 21 U.S.C. 321(h), 360c, 360d, 360e, 360i, 360j, 371, 374.

■ 2. Amend § 860.1 by revising paragraph (b) to read as follows:

§ 860.1 Scope.

* * * * *

(b) This part prescribes the criteria and procedures to be used by advisory committees, including classification panels, where applicable, in making their recommendations, and by the Commissioner in making the Commissioner's determinations regarding the class of regulatory control (class I, class II, or class III) appropriate for particular devices. Supplementing the general FDA procedures governing advisory committees (part 14 of this chapter), this part also provides procedures for manufacturers, importers, and other interested persons to participate in proceedings to classify and reclassify devices. This part also describes the kind of data required for determination of the safety and effectiveness of a device, and the circumstances under which information submitted to advisory committees, including classification panels, or to the Commissioner in connection with classification and reclassification proceedings will be available to the public.

■ 3. Revise § 860.3 to read as follows:

§ 860.3 Definitions.

For the purposes of this part:

Class means one of the three categories of regulatory control for medical devices, defined as follows:

Class I means the class of devices that are subject only to the general controls authorized by or under sections 501 (adulteration), 502 (misbranding), 510 (registration), 516 (banned devices), 518 (notification and other remedies), 519

(records and reports), and 520 (general provisions) of the Federal Food, Drug, and Cosmetic Act. A device is in class I if:

(1) General controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, or

(2) There is insufficient information from which to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish special controls to provide such assurance, but the device is not life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of human health, and which does not present a potential unreasonable risk of illness of injury.

Class II means the class of devices that is or eventually will be subject to special controls. A device is in class II if general controls alone are insufficient to provide reasonable assurance of its safety and effectiveness and there is sufficient information to establish special controls, including promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidance documents (including guidance on the submission of clinical data in premarket notification submissions in accordance with section 510(k) of the Federal Food, Drug, and Cosmetic Act), recommendations, and other appropriate actions, as the Commissioner deems necessary to provide such assurance. For a device that is purported or represented to be for use in supporting or sustaining human life, the Commissioner shall examine and identify the special controls, if any, which are necessary to provide adequate assurance of safety and effectiveness, and describe how such controls provide such assurance.

Class III means the class of devices for which premarket approval is or will be required in accordance with section 515 of the Federal Food, Drug, and Cosmetic Act. A device is in class III if insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of its safety and effectiveness, or that application of special controls described in the definition of ''*Class II*'' in this section in addition to general controls, would provide such assurance, and if, in addition, the device is life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of human health, or if the device presents a potential unreasonable risk of illness or injury.

Classification panel means one of the several advisory committees established by the Commissioner under section 513 of the Federal Food, Drug, and Cosmetic Act and part 14 of this chapter for the purpose of making recommendations to the Commissioner on the classification and reclassification of devices and for other purposes prescribed by the Federal Food, Drug, and Cosmetic Act or by the Commissioner.

Classification questionnaire means a specific series of questions prepared by the Commissioner for use as guidelines by classification panels preparing recommendations to the Commissioner regarding classification and by petitioners submitting petitions for reclassification. The questions relate to the safety and effectiveness characteristics of a device and the answers are designed to help the Commissioner determine the proper classification of the device.

Classification regulation means a section under parts 862 through 892 of this chapter that contains the identification (general description and intended use) and classification (class I, II or III) of a single device type or more than one related device type(s).

Commissioner means the Commissioner of Food and Drugs, Food and Drug Administration, United States Department of Health and Human Services, or the Commissioner's designee.

De Novo request means any submission under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act for a medical device, requesting classification into class I or class II, including all information submitted with or incorporated by reference therein.

FDA means the Food and Drug Administration.

General controls mean the controls authorized by or under sections 501 (adulteration), 502 (misbranding), 510 (registration, listing, and premarket notification), 516 (banned devices), 518 (notification and other remedies), 519 (records, reports and unique device identification) and 520 (general provisions) of the Federal Food, Drug, and Cosmetic Act.

Generic type of device means a grouping of devices that do not differ significantly in purpose, design, materials, energy source, function, or any other feature related to safety and effectiveness, and for which similar regulatory controls are sufficient to provide reasonable assurance of safety and effectiveness.

Implant means a device that is placed into a surgically or naturally formed cavity of the human body. A device is regarded as an implant for the purpose of this part only if it is intended to remain implanted continuously for a period of 30 days or more, unless the Commissioner determines otherwise in order to protect human health.

Life-supporting or life-sustaining device means a device that is essential to, or that yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of human life.

Petition means a submission seeking reclassification of a device in accordance with § 860.123.

Special controls mean the controls necessary to provide reasonable assurance of safety and effectiveness for a generic type of device that is class II. Special controls include performance standards, performance testing, postmarket surveillance, patient registries, development and dissemination of guidelines (including guidelines for the submission of clinical data in premarket notification submissions in accordance with section 510(k) of the Federal Food, Drug, and Cosmetic Act), recommendations, and other appropriate actions, as the Commissioner deems necessary to provide such assurance.

Supplemental data sheet means information compiled by a classification panel or submitted in a petition for reclassification, including:

(1) A summary of the reasons for the recommendation (or petition);

(2) A summary of the data upon which the recommendation (or petition) is based;

(3) An identification of the risks to health (if any) presented by the device;

(4) To the extent practicable in the case of a class II or class III device, a recommendation for the assignment of a priority for the application of the requirements of performance standards or premarket approval;

(5) In the case of a class I device, a recommendation whether the device should be exempted from any of the requirements of registration, recordkeeping and reporting, or good manufacturing practice requirements of the quality system regulation;

(6) In the case of an implant or a life-supporting or life-sustaining device for which classification in class III is not recommended, a statement of the reasons for not recommending that the device be classified in class III;

(7) Identification of any needed restrictions on the use of the device, *e.g.,* whether the device requires special labeling, should be banned, or should be used only upon authorization of a

practitioner licensed by law to administer or use such device; and

(8) Any known existing standards applicable to the device, device components, or device materials.

■ 4. Amend § 860.5 by adding paragraph (g) to read as follows:

§ 860.5 Confidentiality and use of data and information submitted in connection with classification and reclassification.

* * * * *

(g) Confidentiality of data and information in a De Novo file is as follows:

(1) A ''De Novo file'' includes all data and information from the requester submitted with or incorporated by reference in the De Novo request, any De Novo supplement, or any other related submission relevant to the administrative file, as defined in § 10.3(a) of this chapter. Any record in the De Novo file will be available for public disclosure in accordance with the provisions of this section and part 20 of this chapter.

(2) The existence of a De Novo request may not be disclosed by FDA before an order granting the De Novo request is issued unless it previously has been publicly disclosed or acknowledged by the De Novo requester.

(3) Before an order granting the De Novo request is issued, data or information contained in the De Novo request is not available for public disclosure, except to the extent the existence of the De Novo request is disclosable under paragraph (2) of this section and such data or information has been publicly disclosed or acknowledged by the De Novo requester.

(4) After FDA issues an order granting a De Novo request, the data and information in the De Novo request that are not exempt from release under § 20.61 of this chapter are immediately available for public disclosure.

■ 5. Add subpart D, consisting of §§ 860.201 through 860.289, to read as follows:

Subpart D—De Novo Classification

Sec.
860.201 Purpose and applicability.
860.223 De Novo request format.
860.234 De Novo request content.
860.245 Accepting a De Novo request.
860.256 Procedures for review of a De Novo request.
860.267 Withdrawal of a De Novo request.
860.289 Granting or declining a De Novo request.

Subpart D—De Novo Classification

§ 860.201 Purpose and applicability.

(a) The purpose of this part is to establish an efficient, transparent, and thorough process to facilitate De Novo classification into class I or class II for devices for which there is no legally marketed device on which to base a review of substantial equivalence and which meet the definition of class I or class II as described in section 513(a)(1) of the Federal Food, Drug, and Cosmetic Act and § 860.3.

(b) De Novo requests can be submitted for a single device type:

(1) After receiving a not substantially equivalent determination in response to a premarket notification [510(k)], or

(2) If a person determines there is no legally marketed device upon which to base a determination of substantial equivalence.

§ 860.223 De Novo request format.

(a) Each De Novo request or information related to a De Novo request pursuant to this part must be formatted in accordance with this section. Each De Novo request must:

(1)(i) For devices regulated by the Center for Devices and Radiological Health, be sent to the current mailing address displayed on the website *https://www.fda.gov/cdrhsubmissionaddress.*

(ii) For devices regulated by the Center for Biologics Evaluation and Research, be sent to the current mailing address displayed on the website *https://www.fda.gov/BiologicsBloodVaccines/default.htm.*

(2) Be signed by the requester or an authorized representative.

(3) Be designated ''De Novo Request'' in the cover letter.

(4) Have all content used to support the request written in, or translated into, English.

§ 860.234 De Novo request content.

(a) Unless the requester justifies an omission in accordance with paragraph (c) of this section, a De Novo request must include:

(1) *Table of contents.* A table of contents that specifies the volume and page number for each item.

(2) *Administrative information.* The name, address, phone, fax, and email address of the requester and U.S. representative, if applicable. The establishment registration number, if applicable, of the owner or operator submitting the De Novo request.

(3) *Regulatory history.* Identify any prior submissions to FDA for the device, including, but not limited to, any premarket notifications (510(k)s) submitted under part 807 of this chapter, applications for premarket approval (PMAs) submitted under part 814 of this chapter, applications for humanitarian use exemption (HDE) submitted under part 814 of this chapter, applications for investigational device exemption (IDEs) submitted under part 812 of this chapter, requests for designation (RFD) under § 3.7 of this chapter, applications for emergency use authorization (EUA) under section 564 of the Federal Food, Drug, and Cosmetic Act, pre-submissions, or previously submitted De Novo requests, or state that there have been no prior submissions.

(4) *Device name.* The generic name of the device as well as any proprietary name or trade name.

(5) *Indications for use.* A general description of the disease or condition the device is intended to diagnose, treat, prevent, cure or mitigate, or affect the structure or function of the body, including a description of the patient population for which the device is intended. The indications for use include all the labeled patient uses of the device, including if it is prescription or over-the-counter.

(6) *Device description.* A complete description of:

(i) The device, including, where applicable, pictorial representations, device specifications, and engineering drawings;

(ii) Each of the functional components or ingredients of the device, if the device consists of more than one physical component or ingredient;

(iii) The properties of the device relevant to the diagnosis, treatment, prevention, cure, or mitigation of a disease or condition and/or the effect of the device on the structure or function of the body;

(iv) The principles of operation of the device; and

(v) The relevant FDA assigned reference number(s) for any medical devices (such as accessories or components) that are intended to be used with the device and that are already legally marketed.

(7) *Alternative practices and procedures.* A description of known or reasonably known existing alternative practices or procedures used in diagnosing, treating, preventing, curing, or mitigating the disease or condition for which the device is intended or which similarly affect the structure or function of the body.

(8) *Classification summary.* (i) For devices not the subject of a previous submission under section 510(k) of the Federal Food, Drug, and Cosmetic Act, a complete description of:

(A) The searches used to establish that no legally marketed device of the same type exists.

(B) A list of classification regulations, PMAs, humanitarian use devices

(HUDs), HDEs, premarket notifications (510(k)s), EUAs, and/or product codes regarding devices that are potentially similar to the subject device.

(C) A rationale explaining how the device that is the subject of the De Novo request is different from the devices covered by the classification regulations, PMAs, HUDs, HDEs, 510(k)s, EUAs, and/or product codes identified in paragraph (a)(8)(i)(B) of this section.

(ii) For devices which were the subject of a previous submission under section 510(k) of the Federal Food, Drug, and Cosmetic Act that were determined not substantially equivalent (NSE), the relevant 510(k) number, along with a summary of the search performed to confirm the device has not been classified or reclassified since the date the NSE order was issued by FDA pursuant to § 807.100(a) of this chapter.

(9) *Classification recommendation.* The recommended class (I or II) must be identified and must be supported by a description of why general controls, or general and special controls, are adequate to provide reasonable assurance of safety and effectiveness.

(10) *Proposed special controls.* If the classification recommendation from paragraph (a)(9) of this section is class II, then the summary must include an initial draft proposal for applicable special controls and a description of how those special controls provide reasonable assurance of safety and effectiveness.

(11) *Summary of risks and mitigations.* A summary of known or reasonably known probable risks to health associated with use of the device and the proposed mitigations, including general controls and, if the classification recommendation from paragraph (a)(9) of this section is class II, special controls for each risk. For each mitigation measure that involves specific performance testing or labeling, the De Novo request must provide a reference to the associated section or pages for the supporting information in the De Novo request.

(12) *Standards.* Reference to any published voluntary consensus standards that are relevant to any aspect of the safety or effectiveness of the device and that are known or should reasonably be known to the requester. Such standards include voluntary consensus standards whether recognized or not yet recognized under section 514(c) of the Federal Food, Drug, and Cosmetic Act. Provide adequate information to demonstrate how the device meets, or justify any deviation from, the referenced standard.

(13) *Summary of studies.* An abstract of any information or report described in the De Novo request under paragraph (a)(16)(ii) of this section and a summary of the results of technical data submitted under paragraph (a)(15) of this section. Each such study summary must include a description of the objective of the study, a description of the experimental design of the study, a brief description of how the data were collected and analyzed, and a brief description of the results, whether positive, negative, or inconclusive. This section must also include the following:

(i) A summary of each nonclinical laboratory study submitted in the De Novo request;

(ii) A summary of each clinical investigation involving human subjects submitted in the De Novo request, including a discussion of investigation design, subject selection and exclusion criteria, investigation population, investigation period, safety and effectiveness data, adverse reactions and complications, subject discontinuation, subject complaints, device failures (including unexpected software events, if applicable) and replacements, results of statistical analyses of the clinical investigations, contraindications and precautions for use of the device, and other information from the clinical investigations as appropriate. Any investigation conducted under an investigational device exemption (IDE) under part 812 of this chapter must be identified as such.

(14) *Benefit and risk considerations.* A discussion demonstrating that:

(i) The data and information in the De Novo request constitute valid scientific evidence within the meaning of § 860.7(c) and

(ii) Pursuant to § 860.7, when subject to general controls, or general and special controls, the probable benefit to health from use of the device outweighs any probable injury or illness from such use.

(15) *Technical sections.* The following technical sections, which must contain data and information in sufficient detail to permit FDA to determine whether to grant or decline the De Novo request:

(i) A section containing the results of the nonclinical laboratory studies of the device, including microbiological, toxicological, immunological, biocompatibility, stress, wear, shelf life, electrical safety, electromagnetic compatibility, and other laboratory or animal tests, as appropriate. Information on nonclinical laboratory studies must include a statement that each such study was conducted in compliance with part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(ii) For all devices that incorporate software, a section containing all relevant software information and testing, including, but not limited to, appropriate device hazard analysis, hardware, and system information.

(iii) A section containing results of each clinical investigation of the device involving human subjects, including clinical protocols, number of investigators and subjects per investigator, investigation design, subject selection and exclusion criteria, investigation population, investigation period, safety and effectiveness data, adverse reactions and complications, subject discontinuation, subject complaints, device failures (including unexpected software events if applicable) and replacements, tabulations of data from all individual subject report forms and copies of such forms for each subject who died during a clinical investigation or who did not complete the investigation, results of statistical analyses of the results of the clinical investigations, contraindications, warnings, precautions, and other limiting statements relevant to the use of the device type, and any other appropriate information from the clinical investigations. Any investigation conducted under an IDE under part 812 of this chapter must be identified as such. Information on clinical investigations involving human subjects must include the following:

(A) For clinical investigations conducted in the United States, a statement with respect to each investigation that it either was conducted in compliance with the institutional review board regulations in part 56 of this chapter, or was not subject to the regulations under § 56.104 or § 56.105 of this chapter, and that it was conducted in compliance with the informed consent regulations in part 50 of this chapter; or if the investigation was not conducted in compliance with those regulations, a brief statement of the reason for the noncompliance. Failure or inability to comply with these requirements does not justify failure to provide information on a relevant clinical investigation.

(B) For clinical investigations conducted in the United States, a statement that each investigation was conducted in compliance with part 812 of this chapter concerning sponsors of clinical investigations and clinical investigators, or if the investigation was not conducted in compliance with those regulations, a brief statement of the reason for the noncompliance. Failure

or inability to comply with these requirements does not justify failure to provide information on a relevant clinical investigation.

(C) For clinical investigations conducted outside the United States that are intended to support the De Novo request, the requirements under § 812.28 of this chapter apply. If any such investigation was not conducted in accordance with good clinical practice (GCP) as described in § 812.28(a) of this chapter, include either a waiver request in accordance with § 812.28(c) of this chapter or a brief statement of the reason for not conducting the investigation in accordance with GCP and a description of steps taken to ensure that the data and results are credible and accurate and that the rights, safety, and well-being of subjects have been adequately protected. Failure or inability to comply with these requirements does not justify failure to provide information on a relevant clinical investigation.

(D) A statement that each investigation has been completed per the protocol or a summary of any protocol deviations.

(E) A financial certification or disclosure statement or both as required by part 54 of this chapter.

(F) For a De Novo request that relies primarily on data from a single investigator at one investigation site, a justification showing that these data and other information are sufficient to reasonably demonstrate the safety and effectiveness of the device when subject to general controls or general and special controls, and to ensure that the results from a site are applicable to the intended population.

(G) A discussion of how the investigation data represent clinically significant results, pursuant to § 860.7(e).

(16) *Other information.* (i) A bibliography of all published reports not submitted under paragraph (a)(15) of this section, whether adverse or supportive, known to or that should reasonably be known to the requester and that concern the safety or effectiveness of the device.

(ii) An identification, discussion, and analysis of any other data, information, or report relevant to an evaluation of the safety and effectiveness of the device known to or that should reasonably be known to the requester from any source, foreign or domestic, including information derived from investigations other than those in the request and from commercial marketing experience.

(iii) Copies of such published reports or unpublished information in the possession of or reasonably obtainable by the requester, if requested by FDA.

(17) *Samples.* If requested by FDA, one or more samples of the device and its components. If it is impractical to submit a requested sample of the device, the requester must name the location at which FDA may examine and test one or more of the devices.

(18) *Labeling and advertisements.* Labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use. Where applicable, photographs or engineering drawings must be supplied.

(19) *Other information.* Such other information as is necessary to determine whether general controls or general and special controls provide reasonable assurance of safety and effectiveness of the device.

(b) Pertinent information in FDA files specifically referred to by a requester may be incorporated into a De Novo request by reference. Information submitted to FDA by a person other than the requester will not be considered part of a De Novo request unless such reference is authorized in writing by the person who submitted the information.

(c) If the requester believes that certain information required under paragraph (a) of this section to be in a De Novo request is not applicable to the device that is the subject of the De Novo request, and omits any such information from the De Novo request, the requester must submit a statement that specifies the omitted information and justifies the omission. The statement must be submitted as a separate section in the De Novo request and listed in the table of contents. If the justification for the omission is not accepted by FDA, FDA will so notify the requester.

(d) The requester must update its pending De Novo request with new safety and effectiveness information learned about the device from ongoing or completed studies and investigations that may reasonably affect an evaluation of the safety or effectiveness of the device as such information becomes available.

§ 860.245 Accepting a De Novo request.

(a) The acceptance of a De Novo request means that FDA has made a threshold determination that the De Novo request contains the information necessary to permit a substantive review. Within 15 days after a De Novo request is received by FDA, FDA will notify the requester whether the De Novo request has been accepted.

(b) If FDA does not find that any of the reasons in paragraph (c)(1) of this section for refusing to accept the De Novo request apply or FDA fails to complete the acceptance review within 15 days, FDA will accept the De Novo request for review and will notify the requester. The notice will include the De Novo request reference number and the date FDA accepted the De Novo request. The date of acceptance is the date that an accepted De Novo request was received by FDA.

(c)(1) FDA may refuse to accept a De Novo request if any of the following applies:

(i) The requester has an open or pending premarket submission or reclassification petition for the device;

(ii) The De Novo request is incomplete because it does not on its face contain all the information required under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act or does not contain each of the items required under this part, or a justification for omission of any item;

(iii) The De Novo request is not formatted as required under § 860.223;

(iv) The De Novo request is for multiple devices and those devices are of more than one type; or

(v) The requester has not responded to, or has failed to provide a rationale for not responding to, deficiencies identified by FDA in previous submissions for the same device, including those submissions described in § 860.234(a)(3).

(2) If FDA refuses to accept a De Novo request, FDA will notify the requester of the reasons for the refusal. The notice will identify the deficiencies in the De Novo request that prevent accepting and will include the De Novo request reference number.

(3) If FDA refuses to accept a De Novo request, the requester may submit the additional information necessary to comply with the requirements of section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act and this part. The additional information must include the De Novo request reference number of the original submission. If the De Novo request is subsequently accepted, the date of acceptance is the date FDA receives the additional information.

§ 860.256 Procedures for review of a De Novo request.

(a) FDA will begin substantive review of a De Novo request after the De Novo request is accepted under § 860.245. Within 120 days after receipt of a De Novo request or receipt of additional information that results in the De Novo request being accepted under § 860.245, FDA will review the De Novo request and send the requester an order granting the De Novo request under § 860.289(a)

or an order declining the De Novo request under 860.289(b).

(b) A requester may supplement or amend a pending De Novo request to revise existing information or provide additional information.

(1) FDA may require additional information regarding the device that is necessary for FDA to complete the review of the De Novo request.

(2) Additional information submitted to FDA must include the reference number assigned to the original De Novo request and, if submitted on the requester's own initiative, the reason for submitting the additional information.

(c) Prior to granting or declining a De Novo request, FDA may inspect relevant facilities to help determine:

(1) That clinical or nonclinical data were collected in a manner that ensures that the data accurately represents the benefits and risks of the device; or

(2) That implementation of Quality System Regulation (part 820 of this chapter) requirements, in addition to other general controls and any specified special controls, provide adequate assurance that critical and/or novel manufacturing processes produce devices that meet specifications necessary to ensure reasonable assurance of safety and effectiveness.

§ 860.267 Withdrawal of a De Novo request.

(a) FDA will consider a De Novo request to have been withdrawn if:

(1) The requester fails to provide a complete response to a request for additional information pursuant to § 860.256(b)(1) within 180 days after the date FDA issues such request;

(2) The requester fails to provide a complete response to the deficiencies identified by FDA pursuant to § 860.245(c)(2) within 180 days of the date notification was issued by FDA;

(3) The requester does not permit an authorized FDA employee an opportunity to inspect the facilities, pursuant to § 860.256(c), at a reasonable time and in a reasonable manner, and to have access to copy and verify all records pertinent to the De Novo request; or

(4) The requester submits a written notice to FDA that the De Novo request has been withdrawn.

(b) If FDA considers a De Novo request to be withdrawn, the Agency will notify the requester. The notice will include the De Novo request reference number and the date FDA considered the De Novo request withdrawn.

§ 860.289 Granting or declining a De Novo request.

(a)(1) FDA will issue to the requester an order granting a De Novo request if none of the reasons in paragraph (b) of this section for declining the De Novo request applies.

(2) If FDA grants a De Novo request, FDA will subsequently publish in the **Federal Register** a notice of the classification order, including any special controls.

(b) FDA may issue written notice to the requester declining a De Novo request if the requester fails to follow the requirements of this part or if, upon the basis of the information submitted in the De Novo request or any other information before FDA, FDA determines:

(1) The device does not meet the criteria under section 513(a)(1) of the Federal Food, Drug, and Cosmetic Act and § 860.3 for classification into class I or II;

(2) The De Novo request contains a false statement of material fact or there is a material omission;

(3) The device's labeling does not comply with the requirements in parts 801 and 809 of this chapter, as applicable;

(4) The product described in the De Novo request does not meet the definition of a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act and is not a combination product as defined at § 3.2(e) of this chapter;

(5) The device is of a type which has already been approved in existing applications for premarket approval (PMAs) submitted under part 814 of this chapter;

(6) The device is of a type that has already been classified into class I, class II, or class III;

(7) An inspection of a relevant facility under § 860.256(c) results in a determination that general or general and special controls would not provide reasonable assurance of safety and effectiveness;

(8) A nonclinical laboratory study that is described in the De Novo request, and that is essential to show there is reasonable assurance of safety was not conducted in compliance with the good laboratory practice regulations in part 58 of this chapter and no reason for the noncompliance is provided or, if a reason is provided, the practices used in conducting the study do not support the validity of the study;

(9) A clinical investigation described in the De Novo request involving human subjects that is subject to the institutional review board regulations in part 56 of this chapter, informed consent regulations in part 50 of this chapter, or GCP described in 812.28(a) of this chapter, was not conducted in compliance with those regulations such that the rights or safety of human subjects were not adequately protected or the supporting data were determined to be otherwise unreliable;

(10) A clinical or nonclinical study necessary to demonstrate that general controls or general and special controls provide reasonable assurance of safety and effectiveness:

(i) Has not been completed per the study protocol, or

(ii) Deficiencies related to the investigation and identified in any request for additional information under § 860.256(b)(1) have not been adequately addressed; or

(11) After a De Novo request is accepted for review under § 860.245(b), the requester makes significant unsolicited changes to the device's:

(i) Indications for use; or

(ii) Technological characteristics.

(c) An order declining a De Novo request will inform the requester of the deficiencies in the De Novo request, including each applicable ground for declining the De Novo request.

(d) FDA will use the criteria specified in § 860.7 to determine the safety and effectiveness of a device in deciding whether to grant or decline a De Novo request. FDA may use information other than that submitted by the requester in making such determination.

■ 6. In part 860, remove all references to ''the act'' and add in their place ''the Federal Food, Drug, and Cosmetic Act''.

Dated: November 27, 2018.

Scott Gottlieb,

Commissioner of Food and Drugs.

[FR Doc. 2018–26378 Filed 12–4–18; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–HQ–SFUND–1987–0002; FRL–9987–15–Region 5]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List: Deletion of the Tomah Armory Landfill Superfund Site

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; notification of intent.

SUMMARY: The Environmental Protection Agency (EPA) Region 5 is issuing a Notice of Intent to Delete the Tomah Armory Landfill Superfund Site (Tomah Armory Site), located in Tomah, Wisconsin, from the National Priorities

List (NPL) and requests public comments on this proposed action. 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). EPA and the State of Wisconsin, through the Wisconsin Department of Natural Resources (WDNR), have determined that all appropriate response actions under CERCLA, other than operation and maintenance, monitoring and five-year reviews, have been completed. However, this deletion does not preclude future actions under Superfund.

DATES: Comments must be received by January 7, 2019.

ADDRESSES: Submit your comments, identified by Docket ID no. EPA–HQ–SFUND–1987–0002, by mail to Randolph Cano, NPL Deletion Coordinator, U.S. Environmental Protection Agency Region 5 (SR–6J), 77 West Jackson Boulevard, Chicago, IL 60604. Comments may also be submitted electronically or through hand delivery/courier by following the detailed instructions in the **ADDRESSES** section of the direct final rule located in the ''Rules and Regulations'' section of this **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Randolph Cano, NPL Deletion Coordinator, U.S. Environmental Protection Agency Region 5 (SR–6J), 77 West Jackson Boulevard, Chicago, IL 60604, (312) 886–6036, email: *cano.randolph@epa.gov.*

SUPPLEMENTARY INFORMATION: In the ''Rules and Regulations'' section of today's **Federal Register**, we are publishing a direct final Notice of Deletion of the Tomah Armory Superfund Site without prior Notice of Intent to Delete because EPA views this as a noncontroversial revision and anticipates no adverse comment. We have explained our reasons for this deletion in the preamble to the direct final Notice of Deletion, and those reasons are incorporated herein. If we receive no adverse comment(s) on this deletion action, we will not take further action on this Notice of Intent to Delete. If we receive adverse comment(s), we will withdraw the direct final Notice of Deletion, and it will not take effect. We will, as appropriate, address all public comments in a subsequent final Notice of Deletion based on this Notice of Intent to Delete. We will not institute a second comment period on this Notice of Intent to Delete. Any parties interested in commenting must do so at this time.

For additional information, see the direct final Notice of Deletion which is located in the ''Rules and Regulations'' section of this **Federal Register**.

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.

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.

Dated: October 30, 2018.

Cathy Stepp,

Regional Administrator, Region 5.

[FR Doc. 2018–26492 Filed 12–6–18; 8:45 am]

BILLING CODE 6560–50–P

Notices

Federal Register

Vol. 83, No. 235

Friday, December 7, 2018

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Performance Review Board Membership

AGENCY: Office of Human Resource Management, Departmental Administration, USDA.

ACTION: Notice of Performance Review Board appointments.

SUMMARY: This notice announces the members of the Senior Executive Service (SES) and Senior Level (SL) and Scientific or Professional (ST) Performance Review Board. Agriculture has two PRBs that are represented by each Mission Area. The PRB is comprised of a Chairperson and a mix of career and noncareer senior executives and senior professionals that meet annually to review and evaluate performance appraisal documents and provides a written recommendation to the Secretary for final approval of each executive's performance rating, performance-based pay adjustment, and performance award.

DATES: The board membership is applicable beginning on November 20, 2018.

FOR FURTHER INFORMATION CONTACT: Mary Pletcher Rice, Chief Human Capital Officer, Office of Human Resources Management, telephone: (202) 756–7149, or Natalie Duncan, Executive Director, Executive Resources Management Division, telephone: (202) 720–8629.

SUPPLEMENTARY INFORMATION: In accordance with 5 U.S.C. 4314(c)(4), the USDA PRB members are named below:

Adcock, Rebeckah; Bucknall, Janet; Christensen, Thomas; Dixon, Antoine; Fontinato, Jessica; Hafemeister, Jason; Hamer Jr., Hubert; Harwood, Joy; Hohenstein, William; Jacobs-Young, Chavonda; Jiron, Daniel; Kiecker, Paul; Kriviski, Diane; Leland, Arlean; Liu, Simon; Lyons, Margaret; Mattoo, Autar; McLean, Christopher; McMichael, Stanley; Morris, Erin; Ponti-Lazaruk, Jacqueline; Ricci, Carrie; Wear, David; Williams, Duane; Zakarka, Christine; and Zehren, Christopher J.

Mary Pletcher Rice,

Chief Human Capital Officer, Office of Human Resources Management.

[FR Doc. 2018–26255 Filed 12–6–18; 8:45 am]

BILLING CODE 3410–96–P

DEPARTMENT OF AGRICULTURE

Farm Service Agency

Information Collection Request; Agricultural Foreign Investment Disclosure Act Report

AGENCY: Farm Service Agency, USDA.

ACTION: Notice; request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Farm Service Agency (FSA) is requesting comments from all interested individuals and organizations on an extension of a currently approved information collection request associated with the Agricultural Foreign Investment Disclosure Act (AFIDA) of 1978.

DATES: We will consider comments that we receive by February 5, 2019.

ADDRESSES: We invite you to submit comments on the notice. In your comments, include date, volume, and page number of this issue of the **Federal Register**. You may submit comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail:* Philip Sronce, Branch Chief, Agricultural Foreign Investment Disclosure Act (AFIDA), Data Analysis Branch, Economic and Policy Analysis Division, USDA, FSA, STOP 0508, 1400 Independence Avenue SW, Washington, DC 20250–0531.

You may also send comments to the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503. Copies of the information collection may be requested by contacting Philip Sronce at the above addresses.

FOR FURTHER INFORMATION CONTACT: Philip Sronce, (202) 720–2711.

SUPPLEMENTARY INFORMATION:

Title: Agricultural Foreign Investment Disclosure Act Report.

OMB Control Number: 0560–0097.

Expiration Date of Approval: April 30, 2019.

Type of Request: Extension of a currently approved information collection.

Abstract: AFIDA requires foreign persons who hold, acquire, or dispose of any interest in U.S. agricultural land to report the transactions and holdings to FSA on an AFIDA report (FSA–153). The information collected is made available to States. Also, although not required by law, the information collected from the AFIDA reports is used to prepare an annual report to Congress and the President concerning the effect of foreign investment upon family farms and rural communities so that Congress may review the annual report and decide if further regulatory action is required. There is no change to the numbers in the collection.

For the following estimated total annual burden on respondents, the formula used to calculate the total burden hour is the estimated average time per responses hours multiplied by the estimated total annual responses.

Estimate of Respondent Burden: Public reporting burden for the information collection is estimated to average 0.476 hours per response.

Respondents: Individuals or households, businesses or other for profit farms.

Estimated Annual Number of Respondents: 5,525.

Estimated Number of Reponses per Respondent: 1.

Estimated Total Annual Responses: 5,525.

Estimated Average Time per Response: 0.476 hours.

Estimated Total Annual Burden on Respondents: 2,631.25 hours.

We are requesting comments on all aspects of this information collection to help us to:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the FSA, including whether the information will have practical utility;

(2) Evaluate the accuracy of the FSA's estimate of burden including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility and clarity of the information to be collected;

(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.

All comments received in response to this notice, including names and addresses when provided, will be a matter of public record. Comments will be summarized and included in the submission for Office of Management and Budget approval.

Steve Peterson,

Acting Administrator, Farm Service Agency.

[FR Doc. 2018–26504 Filed 12–6–18; 8:45 am]

BILLING CODE 3410–05–P

DEPARTMENT OF AGRICULTURE

Farm Service Agency

Information Collection Request; Request for Special Priorities Assistance

AGENCY: Farm Service Agency, USDA.

ACTION: Notice; request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Farm Service Agency (FSA) is requesting comments from all interested individuals and organizations on an extension of a currently approved information collection request associated with the Request for Special Priorities Assistance. The information collection established by the Agriculture Priorities and Allocations System (APAS) regulation is necessary for the program applicant (person) to request prioritizing of a contract above all other contracts. The purpose of the priority rating is to obtain item(s) in support of national defense programs that they are not able to obtain in time through normal market channels.

DATES: We will consider comments that we receive by February 5, 2019.

ADDRESSES: We invite you to submit comments on the notice. In your comments, include date, volume, and page number of this issue of the **Federal Register**. You may submit comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail:* David Weschsler, USDA/FPAC/HS, 1400 Independence Ave. SW, Room 0092–S, Mail Stop 0560, Washington, DC 20250–0567.

You may also send comments to the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503. Copies of the information collection may be requested by contacting Lesa A. Johnson at the above addresses.

FOR FURTHER INFORMATION CONTACT: David Wechsler, (202) 720–2929.

SUPPLEMENTARY INFORMATION:

Title: Request for Special Priorities Assistance for APAS.

OMB Control Number: 0560–0280.

Expiration Date of Approval: March 31, 2019.

Type of Request: Extension of a currently approved information collection.

Abstract: APAS would efficiently place priority ratings on contracts or orders of agriculture commodities up through the wholesale levels, agriculture production equipment, allocate resources, and handle food claims within its authority as specified in the Defense Production Act (DPA) of 1950, as amended, when necessary to promote national defense. It was determined that food is a scarce and critical commodity essential to the national defense (including civil emergency preparedness and response). Unless its production, processing, storage, and wholesale distribution are regulated during times of emergencies, the national defense requirement for food and food production may not be met without creating hardship in the civilian marketplace. Applicants (Government agencies or private individuals with a role in emergency preparedness, response, and recovery functions) will request authorization from USDA to place a rating on a contract for items to support national defense activities. Priority rating request procedures and forms can be found on USDA's website. Applicants must supply, at time of request, their name, location, contact information, items for which the applicant is requesting assistance on, quantity, and delivery date. Applicants can submit the request by mail or fax. There are no changes to the burden hours since the last OMB approval.

For the following estimated total annual burden on respondents, the formula used to calculate the total burden hour is the estimated average time per responses hours multiplied by the estimated total annual responses.

Estimate of Respondent Burden: Public reporting burden for the information collection is estimated to average 30 minutes (0.50) per response.

Respondents: Individuals, businesses, and agencies with responsibilities for emergency preparedness and response.

Estimated Annual Number of Respondents: 100.

Estimated Number of Reponses per Respondent: 0.95.

Estimated Total Annual Responses: 95.

Estimated Average Time per Response: 0.5 hours.

Estimated Total Annual Burden on Respondents: 50 hours.

We are requesting comments on all aspects of this information collection to help us to:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the FSA, including whether the information will have practical utility;

(2) Evaluate the accuracy of the FSA's estimate of burden including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility and clarity of the information to be collected;

(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.

All comments received in response to this notice, including names and addresses when provided, will be a matter of public record. Comments will be summarized and included in the submission for Office of Management and Budget approval.

Steven Peterson,

Acting Administrator, Farm Service Agency.

[FR Doc. 2018–26505 Filed 12–6–18; 8:45 am]

BILLING CODE 3410–05–P

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

Cardinal-Hickory Creek 345-kV Transmission Line Project

AGENCY: Rural Utilities Service, USDA.

ACTION: Notice of availability of a draft environmental impact statement; notice of public meetings; and section 106 notification to the public.

SUMMARY: Notice is hereby given that the Rural Utilities Service (RUS) has prepared a Draft Environmental Impact Statement (EIS) to meet its responsibilities under the National Environmental Policy Act (NEPA) and environmental policies and procedures related to providing financial assistance

to Dairyland Power Cooperative (DPC). Further, in accordance with section 106 of the National Historic Preservation Act (NHPA) and pursuant to the regulations participation in the section 106 process and coordination with the National Environmental Policy Act, RUS is using its procedures for public involvement under NEPA to meet its responsibilities to solicit and consider the views of the public during the section 106 review for the proposed project. RUS would be providing financial assistance to DPC for its share in the construction of a proposed 345-kilovolt (kV) transmission line and associated infrastructure connecting the Hickory Creek Substation in Dubuque County, Iowa, with the Cardinal Substation in the Town of Middleton, Wisconsin (near Madison, Wisconsin). The Project also includes a new intermediate 345/138-kV substation near the Village of Montfort in either Grant County or Iowa County, Wisconsin. The total length of the 345-kV transmission lines associated with the proposed project will be approximately 125 miles. DPC and the other project participants have identified proposed and alternate segments and locations for transmission lines and associated facilities and for the intermediate substation. Dairyland Power Cooperative is requesting RUS to provide financing for its portion of the proposed project. DPC is participating in the proposed project with two other utilities, American Transmission Company LLC, and ITC Midwest LLC (Utilities).

The purpose of the proposed project is to: Address reliability issues on the regional bulk transmission system, alleviate congestion that occurs in certain parts of the transmission system and remove constraints that limit the delivery of power, expand the access of the transmission system to additional resources, increase the transfer capability of the electrical system between Iowa and Wisconsin, reduce the losses in transferring power and increase the efficiency of the transmission system, and respond to public policy objectives aimed at enhancing the nation's transmission system and to support the changing generation mix. A more detailed explanation of the purpose and need for the project can be found in the Draft EIS.

DATES: Written comments on this Draft EIS will be accepted for 60 calendar days following the publication of the U.S. Environmental Protection Agency's notice of receipt of the Draft EIS in the **Federal Register**. RUS will conduct six formal public meetings in the project area. A court reporter will be available to record agency and public comments.

Date	Location	Time	Venue
January 22, 2019	Peosta, IA	1:00–3:00 p.m	Peosta Community Center, 7896 Burds Road, Peosta, IA 52068.
January 22, 2019	Guttenberg, IA	6:00–8:00 p.m	Guttenberg Municipal Bldg., 502 First St., Guttenberg, IA 52052.
January 23, 2019	Cassville, WI	5:00–7:00 p.m	Cassville Middle School Cafeteria, 715 E Amelia St., Cassville, WI 53806.
January 24, 2019	Dodgeville, WI	5:00–7:00 p.m	Dodgeville Bowl Banquet Hall, 318 King St., Dodgerville, WI 53533.
January 28, 2019	Barneveld, WI	5:00–8:00 p.m	Deer Valley Lodge, 401 West Industrial Drive, Barneveld, WI 53507.
January 29, 2019	Middleton, WI	5:00–8:00 p.m	Madison Marriott West, 1313 John Q. Hammonds Drive, Middleton, WI 53562.

ADDRESSES: A copy of the Draft EIS may be viewed online at the following website: *https://www.rd.usda.gov/publications/environmental-studies/impact-statements/cardinal-%E2%80%93-hickory-creek-transmission-line* and Dairyland Power Cooperative, 3521 East Avenue South, La Crosse, WI 54602 and at 13 local libraries in the project area and the USFWS McGregor District Office in Prairie du Chien, WI.

FOR FURTHER INFORMATION CONTACT: To obtain copies of the Draft EIS, to request further participation or request consulting party status under section 106 of the NHPA or for further information, contact: Lauren Cusick or Dennis Rankin, Environmental Protection Specialist, USDA, Rural Utilities Service, 1400 Independence Avenue SW, Room 2244, Stop 1571, Washington, DC 20250–1571, by phone at (202) 720–1414 or email *Lauren.Cusick@usda.gov* or *Dennis.Rankin@usda.gov.*

SUPPLEMENTARY INFORMATION: RUS is the lead agency for the federal environmental review with cooperating and participating agencies as outlined in the Draft EIS. The first Notice of Intent (NOI) to Prepare an EIS and Hold Public Scoping Meeting was published in the **Federal Register** at 81 FR 71697, on October 18, 2016 to initiate a 30-day public scoping period. Four public scoping meetings for the EIS were held in the project area in October and November 2016, and the public comment was extended to 81 days and comments were accepted from October 18, 2016 through January 6, 2017. On November 22, 2016 RUS published a second NOI announcing a second round of public scoping meetings in December 2017. RUS issued a Scoping Report in May 2018.

The Draft EIS addresses the construction and operation of the proposed project, which, in addition to the 345-kV transmission line and associated infrastructure, includes the following facilities:

a. At the existing Cardinal Substation in Dane County, Wisconsin: A new 345-kV terminal within the substation;

b. At the new proposed Hill Valley Substation near the Village of Montfort, Wisconsin: A 10-acre facility with four 345-kV circuit breakers, one 345-kV shunt reactor, one 345-kV/138-kV autotransformer, and three 138-kV circuit breakers;

c. At the existing Eden Substation near the village of Montfort, Wisconsin: Transmission line protective relaying upgrades, ground grid improvements, and replacement of equipment within the Eden Substation;

d. Between the existing Eden Substation and the proposed Hill Valley Substation near the Village of Montfort, Wisconsin: A rebuild of the approximately 1-mile Hill Valley to Eden 138-kV transmission line;

e. At the existing Wyoming Valley Substation near Wyoming, Wisconsin: Ground grid improvements;

f. Between the existing Cardinal Substation and the proposed Hill Valley Substation: A new 50- to 53-mile (depending on the final route) 345-kV transmission line;

g. Between the proposed Hill Valley Substation and existing Hickory Creek

Substation: A new 50- to 70-mile (depending on the final route) 345-kV transmission line;

h. At the Mississippi River in Cassville, Wisconsin: A rebuild and possible relocation of the existing Mississippi River transmission line crossing to accommodate the new 345-kV transmission line and Dairyland's 161-kV transmission line, and which would be capable of operating at 345-kV/345-kV but will initially be operated at 345-kV/161-kV;

1. depending on the final route and the Mississippi River crossing locations:

i. A new 161-kV terminal and transmission line protective relaying upgrades within the existing Nelson Dewey Substation in Cassville, Wisconsin;

ii. a replaced or reinforced structure within the Stoneman Substation in Cassville, Wisconsin;

iii. multiple, partial, or complete rebuilds of existing 69-kV and 138-kV transmission lines in Wisconsin that would be collocated with the new 345-kV line;

i. At the existing Turkey River Substation in Dubuque County, Iowa: Two 161-/69-kV transformers, four 161-kV circuit breakers, and five 69-kV circuit breakers; and

j. At the existing Hickory Creek Substation in Dubuque County, Iowa: A new 345-kV terminal within the existing Hickory Creek Substation.

Among the alternatives addressed in the Draft EIS is the No Action alternative, under which the proposed project would not be undertaken. Additional alternatives addressed in the Draft EIS include six action alternatives connecting the Cardinal Station in Wisconsin with the Hickory Creek Station in Iowa. RUS has carefully studied public health and safety, environmental impacts, and engineering aspects of the proposed project.

RUS used input provided by government agencies, private organizations, and the public in the preparation of the Draft EIS. RUS will prepare a Final EIS that considers all comments received on the Draft EIS. Following the 30 calendar day comment period for the Final EIS, RUS will prepare a Record of Decision (ROD). Notices announcing the availability of the Final EIS and the ROD will be published in the **Federal Register** and in local newspapers.

In accordance with section 106 of the National Historic Preservation Act and its implementing regulation, ''Protection of Historic Properties'' (36 CFR part 800) and as part of its broad environmental review process, RUS must take into account the effect of the proposed project on historic properties. Pursuant to 36 CFR 800.2(d)(3), RUS is using its procedures for public involvement under NEPA to meet its responsibilities to solicit and consider the views of the public during section 106 review. Any party wishing to participate more directly with RUS as a ''consulting party'' in section 106 review may submit a written request to the RUS contact provided in this notice.

The proposed project involves unavoidable impacts to wetlands and floodplains; this Notice of Availability also serves as a statement of no practicable alternatives to impacts on wetlands and floodplains, in accordance with Executive Orders 11990 and 11988, respectively.

Any final action by RUS related to the proposed project will be subject to, and contingent upon, compliance with all relevant Federal, State and local environmental laws and regulations, and completion of the environmental review requirements as prescribed in the RUS Environmental Policies and Procedures (7 CFR part 1970).

Dated: November 8, 2018.

Christopher A. McLean,

Assistant Administrator, Electric Programs, Rural Utilities Service.

[FR Doc. 2018–26558 Filed 12–6–18; 8:45 am]

BILLING CODE 3410–15–P

DEPARTMENT OF COMMERCE

Census Bureau

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

Agency: U.S. Census Bureau.

Title: Annual Survey of Manufactures.

OMB Control Number: 0607–0449.

Form Number(s): MA–10000.

Type of Request: Reinstatement, with change of an expired collection.

Number of Respondents: 55,000.

Average Hours per Response: 3.5 hours.

Burden Hours: 192,500.

Needs and Uses: The Census Bureau is requesting a reinstatement with changes of the expired collection for the Annual Survey of Manufactures (ASM). The Census Bureau has conducted the ASM since 1949 to provide key measures of manufacturing activity during intercensal periods. In census years ending in ''2'' and ''7,'' we mail and collect the ASM as part of the Economic Census covering the Manufacturing Sector.

The Census Bureau allowed the previous clearance to lapse since ASM inquiries for survey year 2017 (collected in 2018) are cleared as part of the 2017 Economic Census (0607–0998). The Census Bureau is requesting reinstatement to continue annual collection of the ASM for survey years 2018, 2019, and 2020.

The ASM collects data on employment, payroll, hours, wages of production workers, value added by manufacture, cost of materials, value of shipments by North American Product Classification System (NAPCS) product code, inventories, cost of employer's fringe benefits, operating expenses, and expenditures for new and used plant and equipment. The Census Bureau tabulates and publishes data for most of these items by two-digit through six-digit North American Industry Classification System (NAICS) levels. The Census Bureau also publishes ASM data by state at the two-through four-digit NAICS levels.

Federal agencies use ASM data as benchmarks for their statistical programs, including the Federal Reserve Board's Index of Industrial Production and the Bureau of Economic Analysis' (BEA) National Income and Product Accounts. The Department of Energy relies on ASM estimates on the use of energy during production in the manufacturing sector. These data also are used as benchmark data for the Manufacturing Energy Consumption Survey, which is conducted for the Department of Energy by the Census Bureau. Within the Census Bureau, the ASM data are used to benchmark and reconcile monthly and quarterly estimates of manufacturing production and inventories.

The survey also provides valuable information to private companies, research organizations, and trade associations. Industry makes extensive use of the annual figures on NAPCS product shipments for market analysis, product planning, and investment planning. State development and planning agencies rely on ASM data for policymaking, planning, and administration.

The Census Bureau plans to make the following changes to the ASM data collection:

a. Elimination of the MA–10000(S)

The MA–10000(S) questionnaire will be eliminated. Historically, all locations of multiple-establishment firms and large single-establishment firms in the sample were asked to report on the MA–10000(L) questionnaire. The remaining

single-establishment firms in the sample were asked to report on the MA–10000(S). In 2014, approximately 3,000 out of 51,000 sampled establishments received the MA–10000(S). This change will impact less than 6% of respondents. The MA–10000(S) was an abbreviated version of the MA–10000(L), and collected significantly less detailed data. Data not collected on the MA–10000(S) were imputed. Imputation rates and estimates will improve by eliminating the MA–10000(S). The MA–10000(L) will be renamed MA–10000 and all ASM establishments will be required to complete the MA–10000.

The 2018 ASM will include two paths. The multiple-establishment firms will receive a questionnaire path that includes spreadsheet functionality. Firms will be able to enter data for their locations in a form view or select the spreadsheet option. Respondents have the ability to download, export, and import their spreadsheets. Respondents will have the option to ''add locations'' if there are establishments not listed for their firm. The path for single-establishment firms does not include spreadsheet functionality, or the ability to ''add locations''. The multiple-establishment path includes instructions and a question related to interplant transfers; single-establishment firms do not have interplant transfers.

b. Elimination of Item 5B, Exports and Item 11, Inventories Outside the U.S.

Item 5B, Exports and Item 11, Inventories Outside the U.S. are no longer needed by either the International Trade Administration (ITA) or the Bureau of Economic Analysis. The elimination of these items was not documented in the ASM pre-submission notice dated July 13, 2018, because the decision was made after the notice was published in the **Federal Register**. Eliminating collection of these items has no impact on data users since these data items were not published as part of the ASM. Historically, exports data was used to publish the Exports from Manufacturing report, funded by ITA. This report was published by the U.S. Census Bureau and sponsored by ITA. *https://www.census.gov/manufacturing/exports/*. The Exports from Manufacturing report was discontinued by ITA in 2012, due to lack of funding.

c. Addition of Item 17, Principal Business Activity

Item 17, Principal Business Activity on the MA–10000 will ask the respondent to identify their principal kind of business or activity. The question will pre-list suggested six-digit NAICS codes and descriptions for each establishment. The respondent will have the option to select the pre-listed NAICS that describes their principal business activity or to ''write-in'' their principal business activity if the pre-listed NAICS does not apply. Adding this question will help the Census Bureau identify out-of-scope establishments that do not conduct manufacturing activities and establishments which are classified in an incorrect manufacturing industry.

d. Change in Item 22, Product Classification

Previously, Item 22, Details of Sales Shipments Receipts or Revenue was collected on a NAICS basis. Beginning with the 2018 ASM, the collection of Item 22 will be based on the North American Product Classification System (NAPCS). NAPCS is a comprehensive demand-based hierarchical classification system for products that is not industry-of-origin based, but can be linked to the NAICS industry structure, and is consistent across the three North American countries. The primary objective of this product classification change is to identify, define, and classify the outputs produced and transacted (sold, transferred, or placed in inventory) by the reporting units within each industry regardless of their designation (intermediate or final). *https://www.census.gov/eos/www/napcs/*.

e. Elimination of Item 22, Miscellaneous Receipts

Due to the implementation of NAPCS, it is unnecessary to collect Miscellaneous Receipts. In previous ASM survey years, products were collected using only manufacturing sector NAICS codes. Non-manufacturing sector products, produced by manufacturing establishments were classified as Miscellaneous Receipts, which included contract work, resales, and other. NAPCS is an economy-wide solution, which allows ASM respondents to classify out of sector products in valid NAPCS codes.

f. Addition of Item 28, Special Inquiry on Robotic Use

Add a new Special Inquiry, Item 28 on basic robotic use in manufacturing to gauge the prevalence of robotics use in the manufacturing sector across different geographies and by firm size. Questions will be added to collect the number of industrial robots in operation, the number of industrial robots purchased, and the value of capital expenditures for robotic equipment.

g. Item 29, Burden Estimate

Firms will be asked to provide an estimate of how long it took to complete the MA–10000 questionnaire. Responses to this question will be used to re-evaluate the burden hours we impose on respondents, given the various question additions, changes and deletions we are making. The Census Bureau will submit a nonsubstantive change request to revise the burden of this collection if analysis indicates a change. Efforts to analyze paradata to assess burden are currently being evaluated. ASM instrument paradata shows time logged-in and patterns of movement through the instrument, but not time spent reviewing instructions and gathering the necessary data. Nor does it provide an indication of idle time while the respondent is logged in. Paradata can help the Census Bureau calculate the time spent in the instrument but may not be a true reflection of respondent burden.

Affected Public: Businesses or other for-profit.

Frequency: Annually.

Respondent's Obligation: Mandatory.

Legal Authority: Title 13 U.S.C., Sections 131 and 182.

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202)395–5806.

Sheleen Dumas,

Departmental Lead PRA Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2018–26537 Filed 12–6–18; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Census Bureau

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

Agency: U.S. Census Bureau.

Title: Automated Export System.

OMB Control Number: 0607–0152.

Form Number(s): Automated Commercial Environment (ACE) AESDirect Record Formats and related documents, including the AES Letter of Intent, ACE Exporter Account Application and Quick Reference Guide, AES Certification Statements, and the ACE AESDirect User Guide.

Type of Request: Revision of a currently approved collection.

Number of Respondents: 287,314 filers who submit 17,315,950 shipments annually through the AES.

Average Hours per Response: 3 minutes per AES transaction.

Burden Hours: 865,798.

Needs and Uses: The Census Bureau requires mandatory filing of all export information via the AES. This requirement is mandated through Public Law 107–228 of the Foreign Trade Relations Act of 2003. This law authorizes the Secretary of Commerce with the concurrences of the Secretary of State and the Secretary of Homeland Security to require all persons who file export information according to Title 13, United States Code (U.S.C.), Chapter 9, to file such information through the AES.

The AES is the primary instrument used for collecting export trade data, which are used by the Census Bureau for statistical purposes. The AES record provides the means for collecting data on U.S. exports. Title 13, U.S.C., Chapter 9, Sections 301–307, mandates the collection of these data. The regulatory provisions for the collection of these data are contained in the Foreign Trade Regulations (FTR), Title 15, Code of Federal Regulations (CFR), Part 30. The official export statistics collected from these tools provide the basic component for the compilation of the U.S. position on merchandise trade. These data are an essential component of the monthly totals provided in the U.S. International Trade in Goods and Services Press Release, a principal economic indicator and a primary component of the Gross Domestic Product. Traditionally, other federal agencies use the Electronic Export Information (EEI) for export control purposes to detect and prevent the export of certain items by unauthorized parties or to unauthorized destinations or end users. This information is noted in the ACE AESDirect User Guide.

Since 2016, the Census Bureau and the U.S. Customs and Border Protection (CBP) have implemented the following enhancements to the AES, in accordance with revisions to the FTR: (1) Added the Original Internal Transaction Number (ITN) to the AES. The Original ITN field is an optional data element and is utilized if the filer creates an additional AES record for a shipment that was previously filed; (2) added the Ultimate Consignee Type data field, which requires the filer to identify the ultimate consignee as a Direct Consumer, Government Entity, Reseller, or Other.

In addition, the Census Bureau and CBP implemented the following changes to the AES: (1) Added Bureau of Industry and Security (BIS) Export Control Classification Numbers (ECCNs) and increased edits and validations between License Codes and ECCNs, including the addition of the 600 series ECCNs; (2) renamed the country Swaziland to Eswatini in the AES; and (3) removed the BIS license codes C32, C49, C55, and C56.

The Census Bureau also revised the FTR to clarify the split shipment requirements (82 FR 18383) and the collection of the Kimberley Process Certificates (83 FR 17749). Additionally, the Census Bureau revised language in the FTR to reflect the implementation of the International Trade Data System, in accordance with the Executive Order 13659, Streamlining the Export/Import Process for America's Businesses.

These revisions made should not affect the average three-minute response time for the completion of the AES record: The Original ITN is an optional data element and filers will only report it when they choose to provide CBP with additional information about the export shipment; The Ultimate Consignee Type was added for the BIS for export enforcement purposes and is information that filers should know based on BIS's ''Know Your Customer'' guidance; The revision to the ECCNs and License Codes modified selections for fields that already exist.

Currently, the Census Bureau is drafting a Notice of Proposed Rulemaking (NPRM) to clarify the responsibilities of parties participating in routed and standard export transactions. The Census Bureau published an Advance Notice of Proposed Rulemaking (ANPRM) on October 6, 2017 (82 FR 46739) soliciting comments on the clarity, usability, and any other matters of interest to the trade community and the public related to the regulatory requirements for routed transactions. The Census Bureau considered all comments received in response to the ANPRM in drafting the NPRM. The NPRM potentially would propose revisions and add several key terms used in the regulatory provision of these transactions, including authorized agent, forwarding agent, standard export transaction and written release. While revisions to the FTR are necessary to improve clarity to the filing requirements for the routed export transaction, it is critical for the Census Bureau to ensure that any revisions made to the FTR will allow for the continued collection and compilation of accurate trade statistics. Additionally, it is important that the responsibilities of the U.S. Principal Party in Interest (USPPI) and the U.S. authorized agent are clearly defined to ensure that the Electronic Export Information is filed by the appropriate party to prevent receiving duplicate filings or in some cases, no filings. The changes proposed in the NPRM will not have an impact on the reporting burden of the export trade community.

The information collected via the AES conveys what is being exported (description and commodity classification number), how much is exported (quantity, shipping weight, and value), how it is exported (mode of transport, exporting carrier, and whether containerized), from where (state of origin and port of export), to where (port of unloading and country of ultimate destination), and when a commodity is exported (date of exportation). The identification of the USPPI shows who is exporting goods. The USPPI and/or the forwarding or other agent information provides a contact for verification of the information.

The U.S. Federal Government uses every data element on the AES record. The Census Bureau published the Final Rule ''Foreign Trade Regulations (FTR): Clarification on Filing Requirements'' on April 19, 2017 (82 FR 18383) to update the language in the Foreign Trade Regulations to reflect the implementation of the International Trade Data System (ITDS). The ITDS was established to eliminate the redundant information collection requirements, efficiently regulate the flow of commerce, and effectively enforce laws and regulations relating to international trade. ITDS establishes a single portal system for the collection and distribution of standard electronic import and export data required by all participating federal agencies. In addition, this Rule allows federal agencies with appropriate authority to access export data in the AES and ensure consistency with the Executive Order 13659, Streamlining the Export/Import Process for America's Businesses, issued on February 19, 2014.

The data collected from the AES serves as the official record of export transactions. The mandatory use of the AES enables the Federal Government to produce more accurate export statistics. The Census Bureau delegated the

authority to enforce the FTR to the BIS's Office of Export Enforcement and the Department of Homeland Security's CBP and Immigrations and Customs Enforcement. The mandatory use of the AES also facilitates the enforcement of the Export Administration Regulations for the detection and prevention of exports of high technology commodities to unauthorized destinations by the BIS and the CBP; the International Traffic in Arms Regulations by the U.S. Department of State for the exports of munitions; and the validation of the Kimberly Process Certificate for the exports of rough diamonds.

Other Federal agencies use these data to develop the components of the merchandise trade figures used to calculate the balance of payments and Gross Domestic Product accounts; to enforce U.S. export laws and regulations; to plan and examine export promotion programs and agricultural development and assistance programs; and to prepare for and assist in trade negotiations under the General Agreement on Tariffs and Trade. Collection of these data also eliminates the need for conducting additional surveys for the collection of information, as the AES shows the relationship of the parties to the export transaction (as required by the Bureau of Economic Analysis). These AES data are also used by the Bureau of Labor Statistics as a source for developing the export price index and by the U.S. Department of Transportation for administering the negotiation of reciprocal arrangements for transportation facilities between the United States and other countries.

Export statistics collected from the AES aid state governments, private sector companies, financial institutions, and transportation entities in conducting market analysis and market penetration studies for the development of new markets and market-share strategies. A collaborative effort among the Census Bureau, the National Governors' Association and other data users resulted in the development of export statistics using the state of origin reported on the AES. This information enables state governments to focus activities and resources on fostering the exports of goods that originate in their states. Port authorities, steamship lines, airlines, aircraft manufacturers, and air transport associations use these data for measuring the volume and effect of air or vessel shipments and the need for additional or new types of facilities.

Affected Public: Individuals, Businesses.

Frequency: On occasion.

Respondent's Obligation: Mandatory.

Legal Authority: Title 13 United States Code, Chapter 9, Section 301.

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–5806.

Sheleen Dumas,

Departmental Lead PRA Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2018–26538 Filed 12–6–18; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–49–2018]

Foreign-Trade Zone (FTZ) 18—San Jose, California, Authorization of Production Activity, Tesla, Inc. (Electric Passenger Vehicles and Components), Fremont and Palo Alto, California

On August 1, 2018, Tesla, Inc. submitted a notification of proposed production activity to the FTZ Board for its facilities within FTZ 18—Subzone 18G, in Fremont and Palo Alto, California.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (83 FR 40226, August 14, 2018). On November 29, 2018, the applicant was notified of the FTZ Board's decision that no further review of the activity is warranted at this time. The production activity described in the notification was authorized, subject to the FTZ Act and the FTZ Board's regulations, including Section 400.14.

Dated: November 29, 2018.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2018–26547 Filed 12–6–18; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–76–2018]

Foreign-Trade Zone (FTZ) 70—Detroit, Michigan, Notification of Proposed Production Activity, Fluid Equipment Development Company, LLC (Energy Recovery Turbines and Centrifugal Pumps), Monroe, Michigan

The Greater Detroit Foreign-Trade Zone, Inc., grantee of FTZ 70, submitted a notification of proposed production activity to the FTZ Board on behalf of Fluid Equipment Development Company, LLC (FEDCO), located in Monroe, Michigan. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on November 28, 2018.

The FEDCO facility is located within Site 77 of FTZ 70. The facility is used for the production of energy recovery turbines and centrifugal pumps used in water desalination. 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 FEDCO 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, FEDCO would be able to choose the duty rates during customs entry procedures that apply to: Energy recovery turbines; single-stage pumps under 2-inch discharge; single-stage pumps over 2-inch discharge; single-stage pumps over 3-inch discharge; multi-stage centrifugal pumps; and, pump spare parts (duty-free). FEDCO 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: Steel cast flanges; steel cast rings; steel cast cavity covers; steel cast bearing holders; steel cast pump inlets; steel cast housings; steel cast seal carriers; and, steel cast impellers (duty rate 2.9%). The request indicates that the materials/components are subject to special duties under Section 301 of the Trade Act of 1974 (Section 301), depending on the country of origin. The applicable 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 at the address below. The closing period for their receipt is January 16, 2019.

A copy of the notification will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230–0002, and 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: November 29, 2018.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2018–26549 Filed 12–6–18; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S–165–2018]

Approval of Subzone Status, Mayfield Consumer Products, Mayfield and Hickory, Kentucky

On October 11, 2018, the Executive Secretary of the Foreign-Trade Zones (FTZ) Board docketed an application submitted by the Paducah McCracken County Riverport Authority, grantee of FTZ 294, requesting subzone status subject to the existing activation limit of FTZ 294, on behalf of Mayfield Consumer Products, in Mayfield and Hickory, Kentucky.

The application was processed in accordance with the FTZ Act and Regulations, including notice in the **Federal Register** inviting public comment (83 FR 52382–52383, October 17, 2018). The FTZ staff examiner reviewed the application and determined that it meets the criteria for approval. Pursuant to the authority delegated to the FTZ Board Executive Secretary (15 CFR Sec. 400.36(f)), the application to establish Subzone 294A was approved on November 30, 2018, subject to the FTZ Act and the Board's regulations, including Section 400.13, and further subject to FTZ 294's 2,000-acre activation limit.

Dated: November 30, 2018.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2018–26548 Filed 12–6–18; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S–160–2018]

Approval of Subzone Status, Winpak Heat Seal Corporation, Pekin, Illinois

On October 9, 2018, the Executive Secretary of the Foreign-Trade Zones (FTZ) Board docketed an application submitted by the EDC, Inc., The Economic Development Council for the Peoria Area, grantee of FTZ 114, requesting subzone status subject to the existing activation limit of FTZ 114, on behalf of Winpak Heat Seal Corporation, in Pekin, Illinois.

The application was processed in accordance with the FTZ Act and Regulations, including notice in the **Federal Register** inviting public comment (83 FR 51926, October 15, 2018). The FTZ staff examiner reviewed the application and determined that it meets the criteria for approval. Pursuant to the authority delegated to the FTZ Board Executive Secretary (15 CFR Sec. 400.36(f)), the application to establish Subzone 114G was approved on November 30, 2018, subject to the FTZ Act and the Board's regulations, including Section 400.13, and further subject to FTZ 114's 990-acre activation limit.

Dated: November 30, 2018.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2018–26550 Filed 12–6–18; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–489–501]

Welded Carbon Steel Standard Pipe and Tube Products From Turkey: Final Results of Antidumping Duty Administrative Review; 2016–2017

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that welded carbon steel standard pipe and tube products (pipe and tube) from Turkey were sold at less than normal value during the period of review (POR), May 1, 2016, through April 30, 2017.

DATES: Applicable December 7, 2018.

FOR FURTHER INFORMATION CONTACT: Fred Baker, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2924.

SUPPLEMENTARY INFORMATION:

Background

On June 11, 2018, Commerce published the preliminary results of the administrative review of the antidumping duty order on pipe and tube from Turkey.[1] The review covers the following producers/exporters of the subject merchandise: Borusan Istikbal Ticaret T.A.S. (Borusan Istikbal) and Borusan Mannesmann Boru Sanayi ve Ticaret A.S. (Borusan Mannesmann) (collectively, Borusan); [2] Toscelik Profil ve Sac Endustrisi A.S., Tosyali Dis Ticaret A.S., and Toscelik Metal Ticaret A.S. (Toscelik Metal) (collectively, Toscelik); [3] Borusan Birlesik Boru Fabrikalari San ve Tic (Borusan Birlesik); Borusan Gemlik Boru Tesisleri A.S. (Borusan Gemlik); Borusan Ihracat Ithalat ve Dagitim A.S. (Borusan Ihracat); Borusan Ithicat ve Dagitim A.S. (Borusan Ithicat); Tubeco Pipe and Steel Corporation (Tubeco); Erbosan Erciyas Boru Sanayi ve Ticaret A.S. (Erbosan); and Yücel Boru ve Profil Endustrisi A.S. (Yücel Boru), Yücel boru Ihracat Ithalat ve Pazarlama A.S. (Yücel boru), and Cayirova Boru Sanayi ve Ticaret A.S. (Cayirova) (collectively, ''Yücel Group'').

On June 21, 2018, we placed on the record certain entry documents obtained from U.S. Customs and Border

[1] *See Welded Carbon Steel Standard Pipe and Tube Products from Turkey: Preliminary Results of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2016–2017,* 83 FR 26951 (June 11, 2018) (*Preliminary Results*) and accompanying Preliminary Decision Memorandum.

[2] As explained in the *Preliminary Results,* Commerce treated Borusan Mannesmann Boru Sanayi ve Ticaret A.S. and Borusan Istikbal Ticaret T.A.S. as a single entity in this administrative review. *See* Preliminary Decision Memorandum at 1, n.1.

[3] In prior segments of this proceeding, we treated Toscelik Profil ve Sac Endustrisi A.S., Tosyali Dis Ticaret A.S., and Toscelik Metal as a single entity. *See, e.g., Welded Carbon Steel Standard Pipe and Tube Products from Turkey: Final Results of Antidumping Duty Administrative Review; 2012–2013,* 79 FR 71087, 71088 n.8 (December 1, 2014). However, in a prior review, we found that Toscelik Metal has ceased to exist. *Id.* There is no record evidence that warrants altering this treatment. Therefore, for these final results, we are treating Toscelik and Tosyali as a single entity, and continue to find that Toscelik Metal no longer exists.

Protection (CBP)[4] and invited interested parties to comment on them. We received comments from the Yücel Group.[5] On June 26, 2018, we issued a supplemental questionnaire to Borusan, to which it responded on July 27, 2018.[6] We also invited parties to comment on the *Preliminary Results.* On August 22, 2018, we received case briefs from petitioner Wheatland Tube Company (Wheatland Tube), Borusan, and Toscelik.[7] On August 29, 2018, we received a rebuttal brief from the Yücel Group.[8]

Based on our analysis of the comments received, we have made certain changes in the margin calculations. The final weighted-average dumping margins for the reviewed firms are listed below in the section entitled, ''Final Results of the Review.'' Further, we continue to find that Erbosan, Borusan Birlesik, Borusan Gemlik, Borusan Ihracat, Borusan Ithicat, and Tubeco had no reviewable shipments of subject merchandise during the POR.

Scope of the Order

The merchandise subject to the order is welded pipe and tube. The welded pipe and tube subject to the order is currently classifiable under subheading 7306.30.1000, 7306.30.5025, 7306.30.5032, 7306.30.5040, 7306.30.5055, 7306.30.5085, and 7306.30.5090 of the Harmonized Tariff Schedule of the United States (HTSUS). The HTSUS subheadings are provided for convenience and customs purposes only. The written description is dispositive.[9]

Final Determination of No Shipments

In the *Preliminary Results,* we preliminarily determined that Cayirova, Yücel Boru, Yücel boru, Erbosan, Borusan Birlesik, Borusan Gemlik, Borusan Ihracat, Borusan Ithicat, and Tubeco had no shipments during the POR.[10] As we received no comments from interested parties and because the record contains no evidence to the contrary, we continue to find that these companies made no shipments during the POR. Accordingly, consistent with Commerce's practice, we intend to instruct CBP to liquidate any existing entries of merchandise produced by Erbosan, Borusan Birlesik, Borusan Gemlik, Borusan Ihracat, Borusan Ithicat, and Tubeco, but exported by other parties without their own rate, at the all-others rate.[11] Further, while Borusan Istikbal submitted a no-shipment certification, we continue to treat it as a single entity with Borusan Mannesmann. As such, we continue to find that the Borusan entity had shipments during this POR and are not making a final determination of no shipments with respect to Borusan Istikbal.[12]

As noted above, we also made a preliminary determination of no shipments with respect to the constituent members of the Yücel Group (*i.e.,* Cayirova, Yücel Boru and Yücel boru). However, since publication of the *Preliminary Results,* record evidence now indicates that the Yücel Group had shipments that were declared and entered as subject merchandise during the POR. Therefore, we are not making a final determination of no shipments with respect to the Yücel Group.

Analysis of the Comments Received

All issues raised in the case and rebuttal briefs submitted in this review are addressed in the Issues and Decision Memorandum, which is hereby adopted with this notice. A list of the issues raised is attached as an appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically *via* Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov* and it is available to all parties in the Central Records Unit, Room B8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/index.html.* The signed Issues and Decision Memorandum and the electronic versions of the Issues and Decision Memorandum are identical in content.

Changes Since the Preliminary Results

Based on our analysis of the comments received, we made certain changes to the *Preliminary Results.* For a full discussion of these changes, *see* Issues and Decision Memorandum.

Final Rates for Non-Examined Companies

The statute and Commerce's regulations do not address the establishment of a rate to be applied to companies not selected for examination when Commerce limits its examination in an administrative review pursuant to section 777A(c)(2) of the Act. Generally, Commerce looks to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in a market-economy investigation, for guidance when calculating the rate for companies which were not selected for individual review in an administrative review. Under section 735(c)(5)(A) of the Act, the all-others rate is normally ''an amount equal to the weighted average of the estimated weighted average dumping margins established for exporters and producers individually investigated, excluding any zero or *de minimis* margins, and any margins determined entirely {on the basis of facts available}.''

In this review, we have a calculated a weighted-average dumping margin for Borusan that is not zero, *de minimis,* or determined entirely on the basis of facts available. Accordingly, Commerce assigns to the companies not individually examined the 2.55 percent weighted-average dumping margin calculated for Borusan.

Final Results of the Review

As a result of this review, we determine that the following weighted-average dumping margins exist for the period May 1, 2016 through April 30, 2017:

[4] *See* Memorandum, ''Customs Entry Documents,'' dated June 21, 2018.

[5] *See* Yücel Group's Letter, ''Circular Welded Carbon Steel Pipe and Tube from Turkey; Yücel comments on entry documents,'' dated June 29, 2018.

[6] *See* Commerce Letter re: ''Administrative Review of the Antidumping Duty Order on Welded Carbon Steel Standard Pipe and Tube Products from Turkey: Supplemental Questionnaire,'' dated June 26, 2018; Borusan's July 27, 2018 Supplemental Questionnaire Response (Borusan July 27, 2018 SQR).

[7] *See* Petitioner's Case Brief, ''Welded Carbon Steel Pipe from Turkey: Case Brief,'' dated August 23, 2018 (Petitioner's Case Brief); Borusan's Case Brief, ''Circular Welded Carbon Steel Pipes and Tubes from Turkey, Case No. A–489–501: Case Brief,'' August 22, 2018 (Borusan Case Brief); Toscelik's Case Brief, ''Circular Welded Carbon Steel Standard Pipe and Tube from Turkey; Toscelik case brief,'' dated August 22, 2018 (Toscelik Case Brief).

[8] *See* Yücel Group's Rebuttal Brief, ''Circular Welded Carbon Steel Pipe and Tube from Turkey; Yücel rebuttal brief,'' dated August 29, 2018 (Yücel Group's Rebuttal Brief).

[9] A full written description of the scope of the order is contained in the memorandum to Gary Taverman, ''Issues and Decision Memorandum for the Final Results of the Antidumping Duty Administrative Review: Welded Carbon Steel Standard Pipe and Tube Products from Turkey; 2016–2017,'' (IDM), dated concurrently with this notice and incorporated herein by reference.

[10] *See Preliminary Results,* 83 FR at 26952, and accompanying Preliminary Decision Memorandum, at 4–5.

[11] *See, e.g., Magnesium Metal from the Russian Federation: Preliminary Results of Antidumping Duty Administrative Review,* 75 FR 26922, 26923 (May 13, 2010), unchanged in *Magnesium Metal from the Russian Federation: Final Results of Antidumping Duty Administrative Review,* 75 FR 56989 (September 17, 2010).

[12] *See* Preliminary Decision Memorandum at 5.

Producer or exporter	Weighted-average dumping margin (percent)
Borusan Mannesmann Boru Sanayi ve Ticaret A.S./Borusan Istikbal Ticaret T.A.S	2.55
Toscelik Profil ve Sac Endustrisi A.S./Tosyali Dis Ticaret A.S./Toscelik Metal Ticaret A.S	0.00
Cayirova Boru Sanayi ve Ticaret A.S	2.55
Yücel Boru ve Profil Endustrisi A.S	2.55
Yücel boru Ihracat Ithalat ve Pazarlama A.S	2.55

Disclosure

We intend to disclose the calculations performed for these final results of review within five days of the date of publication of this notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Duty Assessment

Commerce shall determine, and CBP shall assess, antidumping duties on all appropriate entries covered by this review pursuant to section 751(a)(2)(C) of the Act and 19 CFR 351.212(b)(1).

For Borusan, because its weighted-average dumping margin is not zero or *de minimis* (*i.e.,* less than 0.5 percent), Commerce has calculated importer-specific antidumping duty assessment rates. We calculated importer-specific *ad valorem* antidumping duty assessment rates by aggregating the total amount of dumping calculated for the examined sales of each importer and dividing each of these amounts by the total entered value associated with those sales. We will instruct CBP to assess antidumping duties on all appropriate entries covered by this review where an importer-specific assessment rate is not zero or *de minimis.* Pursuant to 19 CFR 351.106(c)(2), we will instruct CBP to liquidate without regard to antidumping duties any entries for which the importer-specific assessment rate is zero or *de minimis.*

For Toscelik, we will instruct CBP to liquidate its entries during the POR imported by the importers identified in its questionnaire responses without regard to antidumping duties because its weighted-average dumping margin in these final results is zero.[13]

For companies that were not selected for individual examination, we will instruct CBP to liquidate unreviewed entries based on the methodology described in the ''Final Rates for Non-Examined Companies'' section, above.

Consistent with Commerce's assessment practice, for entries of subject merchandise during the POR produced by any company upon which we initiated an administrative review, for which they did not know that the merchandise was destined for the United States, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.[14]

We intend to issue instructions to CBP 15 days after publication of the final results of this review.

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rates will be equal to the weighted-average dumping margins established in the final results of this review; (2) for previously reviewed or investigated companies not participating in this review, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment of this proceeding in which the company was reviewed; (3) if the exporter is not a firm covered in this review, a previous review, or the original less-than-fair-value (LTFV) investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recently completed segment of this proceeding for the manufacturer of subject merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 14.74 percent, the all-others rate established in the LTFV investigation.[15] These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.[16]

Administrative Protective Orders

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

We are issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.213(h) and 351.221(b)(5) of Commerce's regulations.

Dated: November 30, 2018.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

1. Summary
2. Background
3. Scope of the Order
4. Discussion of the Issues
   - Comment 1: Yucel Group's No-Shipments Claim
   - Comment 2: Calculation of Toscelik's Total Cost of Manufacture
   - Comment 3: Calculation of Toscelik's Average Cost of Production
   - Comment 4: Calculation of Borusan's Gross Unit Price
5. Recommendation

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[13] *See Antidumping Proceeding: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Duty Proceedings; Final Modification,* 77 FR 8103 (February 14, 2012).

[14] For a full discussion of this practice, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[15] *See Antidumping Duty Order; Welded Carbon Steel Standard Pipe and Tube Products from Turkey,* 51 FR 17784 (May 15, 1986).

[16] *See* 19 CFR 351.402(f)(3).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–520–803]

Polyethylene Terephthalate Film, Sheet, and Strip From the United Arab Emirates: Preliminary Results of Antidumping Duty Administrative Review; 2016–2017

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily finds that JBF RAK LLC, the sole producer/exporter

subject to this administrative review, has made sales of subject merchandise at less than normal value. Interested parties are invited to comment on these preliminary results.

DATES: Applicable December 7, 2018.

FOR FURTHER INFORMATION CONTACT: Andrew Huston, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4261.

SUPPLEMENTARY INFORMATION:

Background

Commerce is conducting an administrative review of the antidumping duty order on polyethylene terephthalate film, sheet, and strip (PET Film) from the United Arab Emirates (UAE). The notice of initiation of this administrative review was published on January 11, 2018.[1] This review only covers JBF RAK LLC, a producer and exporter of the subject merchandise. The period of review is November 1, 2016, through October 31, 2017.

Scope of the Order

The merchandise subject to the order is polyethylene terephthalate film. The product is currently classified under subheading 3920.62.00.90 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS number is provided for convenience and for customs purposes, the written product description, available in the Preliminary Decision Memorandum, remains dispositive.[2]

Methodology

Commerce is conducting this review in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act). Export price and constructed export price are calculated in accordance with section 772 of the Act. Normal value is calculated in accordance with section 773 of the Act.

For a full description of the methodology underlying our preliminary results, *see* the Preliminary Decision Memorandum, which is hereby adopted by this notice.[3] A list of topics included in the Preliminary Decision Memorandum is included as an Appendix to this notice. The Preliminary Decision Memorandum 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 in the Central Records Unit in Room B8024 of the main Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly on the internet at *https://enforcement.trade.gov/frn/.* The signed Preliminary Decision Memorandum and electronic versions of the Preliminary Decision Memorandum are identical in content.

Preliminary Results of Review

As a result of our review, we preliminarily determine the following weighted-average dumping margin for the period November 1, 2016, through October 31, 2017:

Manufacturer/exporter	Weighted-average margin (percent)
JBF RAK LLC	57.33

Disclosure and Public Comment

Commerce intends to disclose the calculations used in our analysis for the preliminary results to parties in this review within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b). Interested parties are invited to comment on the preliminary results of this review. Pursuant to 19 CFR 351.309(c)(1)(ii), interested parties may submit case briefs not later than 30 days after the date of publication of this notice. Rebuttal briefs, limited to issues raised in the case briefs, may not be filed later than five days after the time limit for filing case briefs.[4] Parties who submit case briefs or rebuttal briefs in this review are requested to submit with each brief: (1) A statement of the issue, (2) a brief summary of the argument, and (3) a table of authorities.[5] Executive summaries should be limited to five pages total, including footnotes.[6] All briefs must be filed electronically using ACCESS. An electronically filed document must be received successfully in its entirety by the established deadline.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, or to participate if one is requested, must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS within 30 days after the date of publication of this notice. Requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case briefs. If a hearing is requested, Commerce will notify interested parties of the hearing schedule.

We intend to issue the final results of this administrative review, including the results of our analysis of issues raised by the parties in the written comments, within 120 days of publication of these preliminary results in the **Federal Register**, unless otherwise extended.[7]

Assessment Rates

Upon issuing the final results of the review, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries covered by this review. Commerce intends to issue assessment instructions to CBP 15 days after the date of publication of the final results of review.

For any individually examined respondents whose weighted-average dumping margin is above *de minimis,* we will calculate importer-specific *ad valorem* duty assessment rates based on the ratio of the total amount of dumping calculated for the importer's examined sales to the total entered value of those same sales in accordance with 19 CFR 351.212(b)(1).[8] We will instruct CBP to assess antidumping duties on all appropriate entries covered by this review when the importer-specific assessment rate calculated in the final results of this review is above *de minimis.* Where either the respondent's weighted-average dumping margin is zero or *de minimis,* or an importer-specific assessment rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 83 FR 1329, 1333 (January 11, 2018).

[2] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of Antidumping Duty Administrative Review: Polyethylene Terephthalate Film, Sheet, and Strip from the United Arab Emirates'' (Preliminary Decision Memorandum), dated concurrently with this notice.

[3] *Id.*

[4] *See* 19 CFR 351.309(d)(1).

[5] *See* 19 CFR 351.309(c)(2), (d)(2).

[6] *Id.*

[7] *See* section 751(a)(3)(A) of the Act.

[8] In these preliminary results, Commerce applied the calculation methodology adopted in *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings: Final Modification,* 77 FR 8101 (February 14, 2012).

of this review and for future deposits of estimated duties, where applicable.

Cash Deposit Requirements

The following deposit requirements will be effective upon publication of the final results for all shipments of PET Film from the UAE entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this administrative review, as provided for by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for the companies under review will be the rate established in the final results of this review (except, if the rate is zero or *de minimis,* no cash deposit will be required); (2) for previously reviewed or investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the less-than-fair-value investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 4.05 percent, the all-others rate established in the investigation.[9] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

These preliminary results of administrative review are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213(h)(1).

Dated: November 29, 2018.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix—List of Topics Discussed in the Preliminary Decision Memorandum

1. Summary
2. Background
3. Scope of the Order
4. Date of Sale
5. Discussion of Methodology
6. Product Comparisons
7. Export Price/Constructed Export Price
8. Normal Value
9. Currency Conversions
10. Conclusion

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[9] *See Polyethylene Terephthalate Film, Sheet, and Strip from Brazil, the People's Republic of China and the United Arab Emirates: Antidumping Duty Orders and Amended Final Determination of Sales at Less Than Fair Value for the United Arab Emirates,* 73 FR 66595, 66597 (November 10, 2008).

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–991]

Chlorinated Isocyanurates From the People's Republic of China: Preliminary Results of Countervailing Duty Administrative Review; 2016

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily finds that countervailable subsidies are being provided to producers and exporters of chlorinated isocyanurates (chloro isos) from the People's Republic of China (China) for the period of review (POR) January 1, 2016, through December 31, 2016. Interested parties are invited to comment on these preliminary results.

DATES: Applicable December 7, 2018.

FOR FURTHER INFORMATION CONTACT: Omar Qureshi or Susan Pulongbarit, 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) 482–5307 or (202) 482–4031, respectively.

SUPPLEMENTARY INFORMATION:

Background

Commerce published the notice of initiation of this administrative review on January 11, 2018.[1] This review covers two producer/exporters: (1) Heze Huayi Chemical Co., Ltd. (Huayi); and (2) Juancheng Kangtai Chemical Co. Ltd. (Kangtai). Commerce postponed the preliminary results of this administrative review and the revised deadline is now November 30, 2018.[2] For a complete description of the events that followed the initiation of this administrative review, *see* Preliminary Decision Memorandum.[3]

Scope of the Order

The products covered by the order are chloro isos, which are derivatives are cyanuric acid, described as chlorinated s-triazine triones.[4] Chloro isos are currently classifiable under subheadings 2933.69.6015, 2933.69.6021, 2933.69.6050, 3808.50.4000, 3808.94.5000, and 3808.99.9500 of the Harmonized Tariff Schedule of the United States (HTSUS). The HTSUS subheadings are provided for convenience and customs purposes; the written product description of the scope of the order is dispositive.

Methodology

On November 13, 2014, Commerce published in the **Federal Register** a countervailing duty (CVD) order on chloro isos from China.[5] Commerce is conducting this administrative review in accordance with section 751(a)(1)(A) of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found countervailable, we preliminarily find that there is a subsidy, *i.e.,* a financial contribution from an ''authority'' that gives rise to a benefit to the recipient, and that the subsidy is specific.[6] In making this preliminary finding, Commerce relied, in part, on facts otherwise available, with the application of adverse

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 83 FR 1329 (January 11, 2018).

[2] *See* Memorandum, ''Chlorinated Isocyanurates from the People's Republic of China: Extension of Deadline for Preliminary Results of Third Countervailing Duty Administrative Review,'' dated August 2, 2018; *see also* Memorandum, ''Chlorinated Isocyanurates from the People's Republic of China: Extension of Deadline for Preliminary Results of Third Countervailing Duty Administrative Review,'' dated October 11, 2018.

[3] *See* Memorandum, ''Decision Memorandum for Preliminary Results of Countervailing Duty Administrative Review: Chlorinated Isocyanurates from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[4] For a complete description of the Scope of the Order, *see Countervailing Duty Administrative Review of Chlorinated Isocyanurates from the People's Republic of China: Decision Memorandum for the Preliminary Results,* published concurrently with this notice.

[5] *See Chlorinated Isocyanurates from the People's Republic of China: Countervailing Duty Order,* 79 FR 67424 (November 13, 2014).

[6] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

inferences.[7] For further information, see ''Use of Facts Otherwise Available and Adverse Inferences'' in the accompanying Preliminary Decision Memorandum. For a full description of the methodology underlying our preliminary conclusions, including our reliance, in part, on adverse facts available pursuant to sections 776(a) and (b) of the Act, see the Preliminary Decision Memorandum.[8] 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 *http://access.trade.gov,* and is available 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 electronic versions of the Preliminary Decision Memorandum are identical in content.

Preliminary Results of Review

As a result of this review, we preliminarily determine that the following estimated countervailable subsidy rates exist.

Company	Subsidy rate (percent)
Heze Huayi Chemical Co., Ltd ...	1.71
Juancheng Kangtai Chemical Co., Ltd	1.54

Disclosure and Public Comment

Commerce intends to disclose its calculations and analysis performed to interested parties in these preliminary results within five days of its public announcement, or if there is no public announcement, within five days of the date of this notice in accordance with 19 CFR 351.224(b). 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 results of review. Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than five days after the deadline date for case briefs.[9] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this review 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.

Unless the deadline is extended pursuant to section 751(a)(3)(A) of the Act, we intend to issue the final results of this administrative review, including the results of our analysis of the issues raised by the parties in their comments, within 120 days after issuance of these preliminary results.

Assessment Rates and Cash Deposit Requirement

In accordance with 19 CFR 351.221(b)(4)(i), we preliminarily assigned subsidy rates in the amounts shown above for the producer/exporters shown above. Upon issuance of the final results, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, CVDs on all appropriate entries covered by this review. We intend to issue instructions to CBP 15 days after publication of the final results of review.

Pursuant to section 751(a)(2)(C) of the Act, Commerce also intends to instruct CBP to collect cash deposits of estimated CVDs, in the amounts shown above for each of the respective companies shown above, on shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this review. For all non-reviewed firms, we will instruct CBP to continue to collect cash deposits at the most-recent company-specific or all-others rate applicable to the company, as appropriate. These cash deposit requirements, when imposed, shall remain in effect until further notice.

These preliminary results are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(4).

Dated: November 30, 2018.

Gary Taverman,

Deputy Assistant Secretary, for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Application of CVD Law to Imports From China
IV. Subsidies Valuation
V. Benchmarks
VI. Use of Facts Otherwise Available and Adverse Inferences
VII. Analysis of Programs
VIII. Disclosure and Public Comment
IX. Conclusion

[FR Doc. 2018–26551 Filed 12–6–18; 8:45 am]

BILLING CODE 3510–DS–P

[7] *See* section 776(a) of the Act.

[8] A list of topics discussed in the Preliminary Decision Memorandum can be found at the Appendix to this notice.

[9] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements).

DEPARTMENT OF EDUCATION

[Docket No.: ED–2018–ICCD–0128]

Agency Information Collection Activities; Comment Request; Federal Student Aid (FSA) Feedback System

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension of an existing information collection.

DATES: Interested persons are invited to submit comments on or before February 5, 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–2018–ICCD–0128. 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. *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: Federal Student Aid (FSA) Feedback System.

OMB Control Number: 1845–0141.

Type of Review: An extension of an existing information collection.

Respondents/Affected Public: Individuals or Households.

Total Estimated Number of Annual Responses: 43,200.

Total Estimated Number of Annual Burden Hours: 7,344.

Abstract: This is a request for extension of the current information collection of the FSA Feedback System, OMB Control 1845–0141. On March 10, 2015, the White House issued a Student Aid Bill of Rights. Among the objectives identified was the creation of a centralized complaint system that is now resident and supported via the Federal Student Aid/Customer Engagement Management System. The purpose of the Customer Engagement Management System (CEMS) is to meet the objective: ''Create a Responsive Student Feedback System: The Secretary of Education will create a new website by July 1, 2016, to give students and borrowers a simple and straightforward way to file complaints and provide feedback about federal student loan lenders, servicers, collections agencies, and institutions of higher education. Students and borrowers will be able to ensure that their complaints will be directed to the right party for timely resolution, and the Department of Education will be able to more quickly respond to issues and strengthen its efforts to protect the integrity of the student financial aid programs.''

Dated: December 3, 2018.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2018–26542 Filed 12–6–18; 8:45 am]

BILLING CODE 4000–01–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9042–7]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal, Activities, General Information 202–564–5632 or *https://www.epa.gov/nepa/.*

Weekly receipt of Environmental Impact Statements

Filed 11/26/2018 Through 11/30/2018

Pursuant to 40 CFR 1506.9.

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *https://cdxnodengn.epa.gov/cdx-enepa-public/action/eis/search.*

EIS No. 20180292, Draft, RUS, WI, Cardinal-Hickory Creek 345-kV Transmission Line Project, *Comment Period Ends:* 02/05/2019, *Contact:* Dennis Rankin 202–720–1953.

EIS No. 20180293, Final, BLM, ID, Idaho Greater-Sage Grouse Proposed Resource Management Plan, Amendment and Final Environmental Impact Statement, *Review Period Ends:* 01/07/2019, *Contact:* Jonathan Beck 208–373–3841.

EIS No. 20180294, Final, BLM, NV, Nevada and Northeastern California Greater-Sage Grouse Proposed, Resource Management Plan Amendment and Final Environmental Impact Statement, *Review Period Ends:* 01/07/2019, *Contact:* Matt Magaletti 775–861–6400.

EIS No. 20180295, Final, BLM, WY, Wyoming Greater-Sage Grouse Proposed Resource Management Plan, Amendment and Final Environmental Impact Statement, *Review Period Ends:* 01/07/2019, *Contact:* Jennifer Fleuret 307–775–6329.

EIS No. 20180296, Final, BLM, CO, Northwest Colorado Greater-Sage Grouse Proposed Resource Management Plan, Amendment and Final Environmental Impact Statement, *Review Period Ends:* 01/07/2019, *Contact:* Bridget Clayton 202–244–3045.

EIS No. 20180297, Final, BLM, UT, Utah Greater-Sage Grouse Proposed Resource Management Plan, Amendment and Final Environmental Impact Statement, *Review Period Ends:* 01/07/2019, *Contact:* Quincy Bahr 801–539–4122.

EIS No. 20180298, Final, BLM, OR, Oregon Greater-Sage Grouse Proposed Resource Management Plan, Amendment and Final Environmental Impact Statement, *Review Period Ends:* 01/07/2019, *Contact:* James Regan-Vienop 503–808–6062.

EIS No. 20180299, Draft Supplement, FHWA, GSA, ME, New Madawaska Land Port of Entry and International Bridge Project, *Comment Period Ends:* 01/31/2019, *Contact:* Alexandria Kelly 617–549–8190.

EIS No. 20180300, Final, USACE, CA, Upper Llagas Creek Flood Protection Project, *Review Period Ends:* 01/11/2019, *Contact:* Keith D. Hess 707–443–0855.

EIS No. 20180301, Final Supplement, FTA, CA, Transbay Transit Center Program, *Review Period Ends:* 01/07/2019, *Contact:* Ted Matley 415–734–9468.

EIS No. 20180302, Draft Supplement, NMFS, WA, 10 Salmon and Steelhead Hatchery Programs in the Duwamish-Green River Basin, *Comment Period Ends:* 01/22/2019, *Contact:* Allyson Purcell 503–736–4736.

EIS No. 20180303, Draft, BOEM, MA, Vineyard Wind Offshore Wind Energy Project, *Comment Period Ends:* 01/21/2019, *Contact:* Michelle Morin 703–787–1722.

EIS No. 20180304, Draft, VA, CA, Draft Programmatic Environmental Impact Statement and National Historic Preservation Act Section 106 Consultation, West Los Angeles Medical Center Campus Proposed Master Plan for Improvements and Reconfiguration, *Comment Period Ends:* 01/21/2019, *Contact:* Glenn Elliott 202–632–5879.

EIS No. 20180305, Final, FTA, TX, DART Cotton Belt Corridor Regional Rail Project, *Review Period Ends:* 01/07/2019, *Contact:* Melissa Foreman 817–978–0554.

EIS No. 20180306, Final, Caltrans, CA, SR 710 North Study FEIR/FEIS, *Review Period Ends:* 01/07/2019, *Contact:* Jason Roach 213–897–0357.

Amended Notices

EIS No. 20180244, Draft, USFS, CA, Plumas National Forest Over-Snow Vehicle (OSV) Use Designation, *Comment Period Ends:* 01/24/2019, *Contact:* Katherine Carpenter 530–283–7742, Revision to FR Notice Published 10/26/2018; Extending the Comment Period from 12/10/2018 to 01/24/2019.

Dated: December 3, 2018.

Robert Tomiak,

Director, Office of Federal Activities.

[FR Doc. 2018–26577 Filed 12–6–18; 8:45 am]

BILLING CODE 6560–50–P

FARM CREDIT ADMINISTRATION

Sunshine Act Meeting; Farm Credit Administration Board

AGENCY: Farm Credit Administration.

ACTION: Notice, regular meeting.

SUMMARY: Notice is hereby given, pursuant to the Government in the Sunshine Act, of the regular meeting of the Farm Credit Administration Board (Board).

DATES: The regular meeting of the Board will be held at the offices of the Farm Credit Administration in McLean, Virginia, on December 13, 2018, from 9:00 a.m. until such time as the Board concludes its business.

ADDRESSES: Farm Credit Administration, 1501 Farm Credit Drive, McLean, Virginia 22102–5090. Submit attendance requests via email to *VisitorRequest@FCA.gov.* See **SUPPLEMENTARY INFORMATION** for further information about attendance requests.

FOR FURTHER INFORMATION CONTACT: Dale Aultman, Secretary to the Farm Credit Administration Board, (703) 883–4009, TTY (703) 883–4056.

SUPPLEMENTARY INFORMATION: This meeting of the Board will be open to the public (limited space available). Please send an email to *VisitorRequest@FCA.gov* at least 24 hours before the meeting. In your email include: Name, postal address, entity you are representing (if applicable), and telephone number. You will receive an email confirmation from us. Please be prepared to show a photo identification when you arrive. If you need assistance for accessibility reasons, or if you have any questions, contact Dale Aultman, Secretary to the Farm Credit Administration Board, at (703) 883–4009. The matters to be considered at the meeting are:

Open Session

A. Approval of Minutes

- November 8, 2018

B. Reports

- Quarterly Report on Economic Conditions and FCS Conditions
- Semi-Annual Report on Office of Examination Operations

Closed Session *

- Office of Examination Quarterly Report

Date: December 3, 2018.

Dale Aultman,

Secretary, Farm Credit Administration Board.

[FR Doc. 2018–26718 Filed 12–4–18; 4:15 pm]

BILLING CODE 6705–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Termination of Receiverships

The Federal Deposit Insurance Corporation (FDIC or Receiver), as Receiver for each of the following insured depository institutions, was charged with the duty of winding up the affairs of the former institutions and liquidating all related assets. The Receiver has fulfilled its obligations and made all dividend distributions required by law.

NOTICE OF TERMINATION OF RECEIVERSHIPS

Fund	Receivership name	City	State	Termination date
4637	First National Bank of Keystone	Keystone	WV	12/1/2018
10407	Decatur First Bank	Decatur	GA	12/1/2018
10436	Inter Savings Bank FSB	Maple Grove	MN	12/1/2018
10458	Truman Bank	St. Louis	MO	12/1/2018
10521	The Woodbury Banking Company	Woodbury	GA	12/1/2018

The Receiver has further irrevocably authorized and appointed FDIC-Corporate as its attorney-in-fact to execute and file any and all documents that may be required to be executed by the Receiver which FDIC-Corporate, in its sole discretion, deems necessary, including but not limited to releases, discharges, satisfactions, endorsements, assignments, and deeds. Effective on the termination dates listed above, the Receiverships have been terminated, the Receiver has been discharged, and the Receiverships have ceased to exist as legal entities.

Dated at Washington, DC, on December 3, 2018.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2018–26539 Filed 12–6–18; 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

*Session Closed-Exempt pursuant to 5 U.S.C. 552b(c)(8) and (9).

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)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than January 4, 2019.

A. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. *Amsterdam Bancshares, Inc., Amsterdam, Missouri;* to acquire 100 percent of the voting shares of S.T.D. Investments, Inc., and thereby indirectly acquire Bank of Minden, both of Mindenmines, Missouri.

Board of Governors of the Federal Reserve System, December 3, 2018.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2018–26571 Filed 12–6–18; 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 (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 notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than December 26, 2018.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *David L. Howland and Melanie S. Dart, as trustees of the David L. Howland and Melanie S. Dart Revocable Trust dated May 27, 2015, both of Mason, Michigan, Stephanie Noel Howland of Saginaw, Michigan, and Marc Miilu of DeWitt, Michigan;* to join the Dart Family Control Group and retain voting shares of Dart Financial Corporation, Mason, Michigan, and thereby indirectly retain shares of Dart Bank, Mason, Michigan.

Board of Governors of the Federal Reserve System, December 3, 2018.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2018–26572 Filed 12–6–18; 8:45 am]

BILLING CODE P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0197; Docket No. 2018–0003; Sequence No. 19]

Submission for OMB Review; Use of Products and Services of Kaspersky Lab

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of an existing OMB emergency clearance notice regarding the use of products and services of Kaspersky Labs.

DATES: Submit comments on or before January 7, 2019.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer for GSA, Room 10236, NEOB, Washington, DC 20503. Additionally submit a copy to GSA by any of the following methods:

- *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by searching for the OMB Control number 9000–0197. Select the link ''Comment Now'' that corresponds with ''Information Collection 9000–0197; Use of Products and Services of Kaspersky Lab''. Follow the instructions on the screen. Please include your name, company name (if any), and ''Information Collection 9000–0197; Use of Products and Services of Kaspersky Lab.
- *Mail:* General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW, Washington, DC 20405–0001. ATTN: Ms. Mandell/IC 9000–0197; Use of Products and Services of Kaspersky Lab.

Instructions: Please submit comments only and cite Information Collection 9000–0197; Use of Products and Services of Kaspersky Lab, in all correspondence related to this collection. Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two-to-three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Ms. Camara Francis, Procurement Analyst, at telephone 202–550–0935, or email *camara.francis@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. Purpose

The Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA) provides that an agency generally cannot conduct or sponsor a collection of information, and no person is required to respond to, nor be subject to, a penalty for failure to comply with a collection of information, unless that collection has obtained Office of Management and Budget (OMB) approval and displays a currently valid OMB Control Number.

This information collection requirement supports implementation of Section 1634 of Division A of the National Defense Authorization Act (NDAA) for Fiscal Year 2018 (Pub. L. 115–91). This section of the NDAA prohibits Government use of any hardware, software, or services developed or provided, in whole or in part, by Kaspersky Lab or its related entities. This requirement is implemented in the Federal Acquisition Regulation (FAR) through the clause at FAR 52.204–23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities.

This clearance covers the information contractors must submit to comply with the requirements of FAR 52.204–23,

which requires contractors to report covered products identified during performance of a contract.

DoD, GSA, and NASA request approval of this information collection in order to implement the law. The information will be used by agency personnel to identify and remove prohibited hardware, software, or services from Government use.

B. Annual Reporting Burden

The public reporting burden for this collection of information consists of reports of identified covered articles during contract performance as required by 52.204–23. Reports are estimated to average 1.5 hour per response, including the time for reviewing definitions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the report.

Number of Respondents: 4,882.

Responses per Respondent: 5.

Total Responses: 24,410.

Average Burden Hours per Response: 1.5.

Total Burden Hours: 36,615.

C. Public Comments

A 60-day notice was published in the **Federal Register** at 83 FR 29116 on June 22, 2018. No comments were received.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW, Washington, DC 20405, telephone 202–501–4755. Please cite OMB Control No. 9000–0197, Use of Products and Services of Kaspersky Lab, in all correspondence.

Dated: November 30, 2018.

Janet Fry,

Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2018–26525 Filed 12–6–18; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Head Start Child and Family Experiences Survey (FACES) (OMB #0970–0151)

AGENCY: Office of Planning, Research, and Evaluation; Administration for Children and Families; HHS.

ACTION: Request for public comment.

SUMMARY: The Office of Planning, Research, and Evaluation (OPRE), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is proposing to collect data for a new round of the Head Start Family and Child Experiences Survey (FACES).

DATES: *Comments due within 30 days of publication.* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration for Children and Families.

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *OPREinfocollection@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION: Similar to FACES 2014–2018, in 2019, two parallel studies will commence. FACES 2019 focuses on Head Start Regions I through X (which are geographically based); AI/AN (American Indian and Alaska Native) FACES 2019 focuses on Region XI (which funds Head Start programs that serve federally recognized American Indian and Alaska Native tribes). Both studies will provide data on a set of key indicators for Head Start programs. In fall 2019 and spring 2020, FACES will assess the school readiness skills of 2,400 Head Start children in Regions I–X (FACES 2019) and 800 children in Region XI (AI/AN FACES 2019), survey their parents, and ask their Head Start teachers to rate children's social and emotional skills. This sample will be drawn from 60 programs in Regions I–X and 22 programs in Region XI. In spring 2020, classroom observations of sampled programs will occur. In Regions I–X, the number of programs will increase from the 60 that are used to collect data on children's school readiness outcomes to 180 for the purpose of conducting observations in 720 Head Start classrooms. In Region XI, the program sample will remain at 22, and approximately 80 Head Start classroom observations will take place. Program director, center director, and teacher surveys will also be conducted in spring 2020 in Regions I–XI. In spring 2022, program level data collection will be repeated in Regions I–X only. FACES 2019 also features a ''Core Plus'' design, with the above activities reflecting the Core data, with the potential of ''Plus'' studies to inform emerging programmatic questions. If any Plus studies are conducted, they will be conducted within the Core sample and will be included in a future **Federal Register** notice.

Previous **Federal Register** notices provided the opportunity for public comment on the proposed Head Start program recruitment and center selection process (FR V.82, pg. 48819 10/20/2017; FR V.83, pg. 7480 02/21/2018). This notice describes the planned data collection activities for the FACES 2019 and AI/AN FACES 2019 data collection. Data collection activities include classroom and child sampling information collection, direct child assessments, parent surveys, teacher child reports, and staff surveys.

Sampling of children and classrooms for FACES starts with site visits to 157 Head Start centers (120 for FACES 2019 and 37 for AI/AN FACES 2019) in fall 2019. Field enrollment specialists (FES) will request a list of all Head Start-funded classrooms from Head Start staff. Next, for each selected classroom, the FES will request enrollment information for each child enrolled. Data collection will then start with site visits in fall 2019 to 82 Head Start programs (60 for FACES 2019 and 22 for AI/AN FACES 2019) to directly assess the school readiness skills of 3,200 children (2,400 for FACES 2019 and 800 for AI/AN FACES 2019) sampled for FACES and whose parents agree to participate. Parents of sampled children will complete surveys on the Web or by telephone about their children and family background. Head Start teachers will rate each sampled child (approximately 10 children per classroom) using the Web or paper-and pencil forms. These activities will occur a second time in spring 2020. When the FACES 2019 program sample size increases to 180 programs in the spring, the methods of data collection for this phase will feature classroom sampling and site visitors conducting observations of the quality of classrooms. Head Start program directors, center directors, and teachers will complete surveys about themselves and the services and instruction at Head Start. The purpose of the FACES data collection is to support the 2007

reauthorization of the Head Start program (Pub. L. 110–134), which calls for periodic assessments of Head Start's quality and effectiveness.

Respondents: Head Start children, parents of Head Start children, and Head Start teachers and Head Start staff.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
FACES 2019 Classroom sampling form from Head Start staff	360	120	1	0.17	20
FACES 2019 Child roster form from Head Start staff	120	40	1	0.33	13
FACES 2019 Parent consent form	2,400	800	1	0.17	136
FACES 2019 Head Start parent survey	2,400	800	2	0.42	672
FACES 2019 Head Start child assessment	2,400	800	2	0.75	1,200
FACES 2019 Head Start teacher child report	240	80	20	0.17	272
FACES 2019 Head Start teacher survey	720	240	1	0.50	120
FACES 2019 Head Start program director survey	180	60	1	0.50	30
FACES 2019 Head Start center director survey	360	120	1	0.50	60
AI/AN FACES 2019 Classroom sampling form from Head Start staff	37	13	1	0.17	2
AI/AN FACES 2019 Child roster form from Head Start staff	37	13	1	0.33	4
AI/AN FACES 2019 Parent consent form	800	267	1	0.17	45
AI/AN FACES 2019 Head Start parent survey	800	267	2	0.50	267
AI/AN FACES 2019 Head Start child assessment	800	267	2	0.75	401
AI/AN FACES 2019 Head Start teacher child report	80	27	20	0.17	92
AI/AN FACES 2019 Head Start teacher survey	80	27	1	0.58	16
AI/AN FACES 2019 Head Start program director survey	22	8	1	0.33	3
AI/AN FACES 2019 Head Start center director survey	37	13	1	0.33	4

Estimated Total Annual Burden Hours: 3,357.

Authority: Section 640(a)(2)(D) and section 649 of the Improving Head Start for School Readiness Act of 2007.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2018–26563 Filed 12–6–18; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: OCSE–157 Child Support Enforcement Program Annual Data Report.

OMB No.: 0970–0177.

Description: The information obtained from this form will be used to: (1) Report Child Support Enforcement activities to the Congress as required by law; (2) calculate incentive measures performance and performance indicators utilized in the program; and (3) assist the Office of Child Support Enforcement (OCSE) in monitoring and evaluating State Child Support programs.

OCSE is proposing updates to the OCSE–157 report instructions to update and clarify reporting requirements. Respondents are encouraged to contact the agency to obtain a copy of the revised instructions for review and comment.

Respondents: State, Local or Tribal Government.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
OCSE–157	54	1	7	378

Estimated Total Annual Burden Hours: 378.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201. Attention Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV.* Attn:

Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2018–26535 Filed 12–6–18; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–3380]

Developing and Labeling *In vitro* Companion Diagnostic Devices for a Specific Group or Class of Oncology Therapeutic Products; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Developing and Labeling *In vitro* Companion Diagnostic Devices for a Specific Group or Class of Oncology Therapeutic Products.'' This draft guidance describes considerations for the development and labeling of *in vitro* companion diagnostic devices (referred to as *companion diagnostics* in this document) to support the indicated uses of multiple drug or biologic oncology products (referred to as *therapeutic products* or *oncology therapeutic products* in this document), when appropriate. The draft guidance includes factors for considering when broader labeling (*i.e.,* labeling that is expanded) of a companion diagnostic would be appropriate. Oncology companion diagnostics with broader evidence-based indications will optimally facilitate clinical use.

DATES: Submit either electronic or written comments on the draft guidance by February 5, 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–2018–D–3380 for ''Developing and Labeling *In vitro* Companion Diagnostic Devices for a Specific Group or Class of Oncology Therapeutic Products.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• 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 draft guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002; the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002; or the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. The draft guidance may also be obtained by mail by calling FDA's Center for Biologics Evaluation and Research (CBER) at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911; Reena Philip, Center for

Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5680, Silver Spring, MD 20993–0002, 301–796–6179; or Julie Schneider, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2208, Silver Spring, MD 20993–0002, 240–402–4658.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Developing and Labeling *In vitro* Companion Diagnostic Devices for a Specific Group or Class of Oncology Therapeutic Products.'' This draft guidance describes considerations for the development and labeling of companion diagnostics to support the indicated uses of multiple therapeutic oncology products, when appropriate. This draft guidance expands on existing policy, surrounding broader labeling, which notes that in some cases, if evidence is sufficient to conclude that the companion diagnostic is appropriate for use with a specific group or class of therapeutic products (as discussed in the draft guidance), the companion diagnostic's intended use/indications for use should name the specific group or class of therapeutic products, rather than specific products. To describe FDA's thinking on the topic, the draft guidance discusses a specific example of companion diagnostics for a specific biomarker, disease, and specimen type (specific epidermal growth factor receptor mutations in tumors of patients with nonsmall cell lung cancer in tissue specimens).

Trials designed to support approval of a specific therapeutic product and a specific companion diagnostic have led to companion diagnostic labels that reference only a specific therapeutic product(s). Such specificity in labeling can limit a potentially broader use of a companion diagnostic that may be scientifically appropriate. In clinical practice, an oncologist generally considers the mutation profile of the tumor along with other factors when determining the treatment for a patient, such as the toxicity profile of the therapeutic product, the patient's preference, and formulary options. When a companion diagnostic is labeled for use with a specific therapeutic product, the clinician may need to order a different companion diagnostic (*i.e.,* one that includes other therapeutic products in the labeling), obtain an additional biopsy(ies) from a patient, or both, to have additional therapy treatment options.

The draft guidance describes considerations for when broader labeling may be scientifically appropriate and when it may not. FDA recommends developers of therapeutic oncology products and associated companion diagnostics collaboratively consider development programs that may result in broader labeling of companion diagnostics that are most clinically useful. Developers are encouraged to discuss development programs that could result in broader labeling with the CBER, Center for Devices and Radiological Health (CDRH), or Center for Drug Evaluation and Research, in coordination with the Oncology Center of Excellence, as appropriate, early to determine if the approach described in this guidance is appropriate for consideration. Developers whose approved companion diagnostics may be appropriate for broader labeling are encouraged to contact CDRH or CBER, as appropriate, to discuss.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Developing and Labeling *In vitro* Companion Diagnostic Devices for a Specific Group or Class of Oncology Therapeutic Products.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Other Issues for Consideration

In addition to providing stakeholders an opportunity to comment on the draft guidance, the Agency is interested in responses from stakeholders to the following:

1. Please describe any specific challenges with developing the evidence needed to identify in labeling a companion diagnostic for use with a specific group or class of oncology therapeutic products, rather than a specific therapeutic product. For example, please describe any challenges resulting from industry or business practices, including business agreements. What actions can FDA take to address the challenge(s)?

2. Please describe any specific challenges with submitting a premarket approval (PMA) supplement to FDA to expand the labeling for an approved companion diagnostic for use with a specific group or class of oncology therapeutic products. What actions can FDA take to address the challenge(s)?

3. Please describe any additional actions FDA can take to facilitate or encourage broader, evidence-based labeling that supports the use of a specific group or class of oncology therapeutic products with a companion diagnostic.

4. The guidance notes that variations in defined cut-points established for specific biomarkers for companion diagnostics can lead to challenges in implementing broader labeling for a specific group or class of oncology therapeutic products. Are there actions that FDA, or the broader scientific community, can take to facilitate standardization in this area?

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations and guidance. 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 21 CFR parts 801 and 809 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, subparts A through E, have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 814, subpart H, have been approved under OMB control number 0910–0332; the collections of information in the guidance document ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff'' have been approved under OMB control number 0910–0756; and the collections of information in the guidance ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' have been approved under OMB control number 0910–0844.

IV. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: December 3, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–26554 Filed 12–6–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3458]

Food Handler Antiseptic Drug Products for Over-the-Counter Human Use; Request for Data and Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for data and information.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the establishment of a docket to obtain data, information, and comments that will assist the Agency in assessing the safety and effectiveness of food handler antiseptic drug products (*i.e.,* antiseptic hand washes or rubs intended for use in food handling settings) for over-the-counter (OTC) human use. We are asking manufacturers of food handler antiseptics and other interested parties to submit safety and effectiveness data on OTC food handler antiseptics marketed for use by food handlers in commercial or regulated environments where growth, harvest, production, manufacturing, processing, packaging, transportation, storage, preparation, service, or consumption of food occurs. We also are inviting comments and requesting data on definitions, eligibility, current conditions of use of food handler antiseptics; safety and effectiveness criteria; as well as test methods to demonstrate the effectiveness of food handler antiseptics. In general, we are seeking input on current use conditions of antiseptics used in the food handler setting and recommended testing to establish the effectiveness of OTC food handler antiseptics. This information and data will inform FDA's ongoing review of OTC antiseptic drug products and will specifically inform our review of food handler antiseptic products.

DATES: Submit either electronic or written comments, data, or information by February 5, 2019.

ADDRESSES: You may submit data and comments as follows. For each comment, indicate the specific question to which you are responding. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 5, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 5, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions''). We note however, that the OTC drug monograph process is a public process; and, the Agency intends to consider only non-confidential material that is submitted to the docket in response to this request for information, or that is otherwise publicly available in evaluating if a relevant ingredient is generally recognized as safe and effective (GRAS/GRAE).

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–2018–N–3458 for ''Food Handler Antiseptic Drug Products for Over-the-Counter Human Use; Request for Data and Information.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- 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.

FOR FURTHER INFORMATION CONTACT: Pranvera Ikonomi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5418, Silver Spring, MD 20993–0002, 240–402–0272.

SUPPLEMENTARY INFORMATION:

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I. Introduction

We are seeking public input regarding the safety and effectiveness of food handler antiseptics to inform FDA's ongoing review of OTC antiseptic drug products and the Agency's review of the active ingredients used in these products in the food handler setting. The Agency seeks data and information about these topical antiseptics and how the active ingredients should be tested and evaluated for safety and effectiveness.

This Request for Information (RFI) covers only OTC food handler antiseptics that are intended for use by food handlers in commercial or regulated environments where growth, harvest, production, manufacturing, processing, packaging, transportation, storage, preparation, service, or consumption of food occurs. This RFI does not cover consumer antiseptic washes (78 FR 76444, December 17, 2013; 81 FR 61106, September 6, 2016); health care antiseptics (80 FR 25166, May 1, 2015; 82 FR 60474, December 20, 2017); consumer antiseptic rubs (81 FR 42912, June 30, 2016); or antiseptics identified as ''first aid antiseptics'' in the 1991 First Aid tentative final monograph (TFM) (56 FR 33644, July 22, 1991).

FDA has tentatively concluded that, based on FDA's current categorization of other antiseptic products and considering factors that may include specific microorganisms of concern in food handling environments as well as the safety of repeated-exposure use patterns, food handler antiseptics may differ from antiseptic products addressed in other rulemakings. There has been support from industry and interested parties for an OTC food handler antiseptic category, and some information and data have been submitted in support of establishing such a category. However, we believe more data and information are needed to assist the Agency in evaluating the safety and effectiveness criteria appropriate for food handler antiseptics.

II. Table of Abbreviations/Commonly Used Acronyms in This Document

Abbreviation/acronym	What it means
ANPR	Advance Notice of Proposed Rule.
AOAC	Association of Official Analytical Chemists (now ''AOAC International'').
ASTM	American Society for Testing and Materials (now ''ASTM International'').
ATCC	American Type Culture Collection.
CDC	Centers for Disease Control and Prevention.
FDA	Food and Drug Administration.
FD&C Act	Food Drug and Cosmetic Act.
FR	Federal Register.
GRAS/GRAE	Generally recognized as safe and effective.
HACCP	Hazard analysis and critical control point.
HCCM	Health Care Continuum Model.
MIC	Minimum Inhibitory Concentration Testing.
OTC	Over-the-counter.
PCPC	Personal Care Products Council.
RFI	Request for information.
SDA	Soap and Detergent Association.
TFM	Tentative final monograph.
U.S.C.	United States Code.

III. Background

A. Background on Topical Antiseptics

This RFI is part of FDA's ongoing evaluation of the safety and effectiveness of OTC drug products marketed in the United States on or before May 11, 1972 (OTC Drug Review). The OTC topical antimicrobial rulemaking has had a broad scope, encompassing drug products that may contain the same active ingredients, but that are labeled and marketed for different intended uses. In 1974, the Agency published an advance notice of proposed rulemaking (ANPR) for topical antimicrobial products that encompassed products for both health care and consumer use. The 1974 ANPR covered seven different intended uses for these products: (1) Antimicrobial soap; (2) health care personnel hand wash; (3) patient preoperative skin preparation; (4) skin antiseptic; (5) skin wound cleanser; (6) skin wound protectant; and (7) surgical hand scrub (39 FR 33103 at 33140, September 13, 1974). FDA subsequently identified skin antiseptics, skin wound cleansers, and skin wound protectants as antiseptics used primarily by consumers for first aid use and referred to them collectively as ''first aid antiseptics.'' FDA published a separate TFM covering the first aid antiseptics in the 1991 First Aid TFM (56 FR 33644). The remaining categories of topical antimicrobials were addressed in the 1994 TFM for healthcare antiseptic drug products (59 FR 31402, June 17, 1994). The 1994 TFM covered: (1) Antiseptic hand wash (*i.e.,* consumer hand wash); (2) health care personnel hand wash; (3) patient preoperative skin preparation; and (4) surgical hand scrub (59 FR 31402 at 31442).

The 1994 TFM did not distinguish between consumer antiseptic washes and rubs and health care antiseptic washes and rubs. In the 2013 Consumer Wash Proposed Rule, we proposed that our evaluation of OTC antiseptic drug products be further subdivided into health care antiseptics and consumer antiseptics (78 FR 76444 at 76446). These categories are distinct based on the proposed use setting, target population, and the fact that each setting presents a different level of risk for infection. In the 2013 Consumer Wash Proposed Rule (78 FR 76444 at 76446–76447) and the 2016 Consumer Rub Proposed Rule (81 FR 42912 at 42915–42916), we proposed that our evaluation of OTC consumer antiseptic drug products be further subdivided into consumer washes (products that are rinsed off with water, including hand washes and body washes) and consumer rubs (products that are not rinsed off after use, including hand rubs and antibacterial wipes).

B. Regulatory History on Food Handler Antiseptics

In the 1994 TFM, FDA also identified a new category of antiseptics for use by the food industry, which historically had been marketed for use by food handlers in federally inspected meat and poultry processing plants, and other food handling establishments (59 FR 31402 at 31440). As stated in the 2016 Consumer Wash Final Rule (81 FR 61106 at 61109; September 6, 2016) and the 2017 Health Care Antiseptic Final Rule (82 FR 60474 at 60483, December 20, 2017), we classify the food handler antiseptics as separate and distinct from the other OTC topical antiseptics. Based on FDA's current categorization of other OTC antiseptic products and given the additional issues raised by the public health consequences of foodborne illness, differences in frequency and type of use, and contamination of the hands by dirt, grease and other oils, we believe that a separate evaluation of food handler antiseptics is warranted. Food handler antiseptics include antiseptic products labeled for use in commercial or other regulated settings where food is grown, harvested, manufactured, packed, held, transported, prepared, served, or

consumed. The intended use of these products (the reduction of microorganisms on the skin for the purpose of preventing disease caused by transfer of microorganism from hands to foods) makes them drugs under the provisions of the Federal, Food, Drug, and Cosmetic Act (FD&C Act), which defines a drug to include an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man (section 201(g)(1) of the FD&C Act; 21 U.S.C. 321(g)(1)).

FDA has determined that the safety and effectiveness of active ingredients intended for use in food handler antiseptic products needed to be demonstrated, and we proposed to include an evaluation of the safety and effectiveness of these active ingredients in the rulemaking for OTC topical antimicrobial drug products (59 FR 31402 at 31440). In the 1994 TFM, we requested relevant data and information to assist in characterizing this category of food handler antiseptics (59 FR 31402 at 31440), but we did not discuss what data would be necessary to support a GRAS/GRAE determination. In response to the 1994 TFM, we received public comments pertaining to food handler antiseptic hand washes (see section IV), including an industry proposal, the Health Care Continuum Model (HCCM), which refers to the effectiveness, effectiveness testing requirements, and labeling of antiseptic products discussed in the 1994 TFM, including the antiseptic hand wash products used by food handlers (Refs. 1 and 2). We also received comments in response to the 1994 TFM regarding antiviral testing for antiseptic products used by food handlers (59 FR 31402).

FDA also received comments pertaining to food handler antiseptics in response to the 2013 Consumer Antiseptic Wash proposed rule. One of these comments was submitted from the Personal Care Products Council (PCPC) and American Cleaning Institute in the form of a citizen petition (FDA–1975–N–0012–0493) (Ref. 3) requesting that FDA, among other things, define food handler antiseptic hand washes or rubs as antiseptic products for use in commercial establishments and other regulated settings, establish food handler antiseptic hand washes as a separate category, and consider food handler antiseptic products as professional use products similar to health care antiseptics.

IV. Proposed Effectiveness Models and Indications for Food Handler Antiseptics

In response to the 1994 TFM, FDA received comments pertaining to food handler antiseptic hand washes. The comments that addressed food handler antiseptic hand washes generally agreed that they should be evaluated in the review of antiseptic products. FDA also received comments and a citizen petition proposing an effectiveness model for antiseptic products in general, including food handler antiseptics, as well as a proposal on specific indications for food handler antiseptics (Refs. 1, 2, 33, and 14). We describe and respond to the proposed model and indications in sections IV.A. through IV.D.

A. Health Care Continuum Model

A comment from two trade associations proposed regulating food handler antiseptics as part of the HCCM (Ref. 1). This regulatory model included proposed labeling, final formulation testing requirements, and effectiveness testing criteria. The proposed testing included in vitro and in vivo testing that is modeled after FDA's previously proposed testing for OTC health care antiseptic drug products (Ref. 1). Table 1 summarizes the HCCM's proposed in vitro and in vivo testing and other effectiveness criteria for food handler antiseptics.

TABLE 1—SUMMARY OF INDUSTRY PROPOSED TESTING OF FOOD HANDLER ANTISEPTICS

[Health Care Continuum Model]

Proposed test method	Test organisms (American type culture collection strain number (ATCC))	Efficacy criteria
Establish in vitro spectrum of antimicrobial activity of active ingredient (Minimum inhibitory concentration testing (MIC)).	*Candida albicans.* (ATCC 10231).*	None Stated.
	Enterobacter cloacae. (ATCC 13047).	
	Entercoccus faecalis. (ATCC 19433).	
	Escherichia coli. (ATCC 25922).*	
	Klebsiella pneumoniae (ATCC 10031).	
	Listeria monocytogenes (ATCC 7644).*	
	Proteus mirabilis (ATCC 7002)..	
	Pseudomonas aeruginosa (ATCC 9027)..	
	Pseudomonas stutzeri (ATCC 17588)..	
	Salmonella choleraesuis (ATCC 10708).*	
	Salmonella enteritidis (ATCC 13076).*	
	Salmonella typhi (ATCC 6539).*	
	Salmonella typhimurium (ATCC 11311).*	
	Shigella dysenteraiae (ATCC 13313).	
	Shigella sonnei (ATCC 11060).*	
	Staphylococcus aureus (ATCC 6538).*	
	Streptococcus pyogenes (ATCC 19615).*	
Establish in vitro spectrum of antimicrobial activity of end-use formulation (MIC).	*Escherichia coli* (ATCC 25922).*	None Stated.
	Klebsiella pneumoniae. (ATCC 10031).	
	Listeria monocytogenes. (ATCC 7644).*	
	Pseudomonas stutzeri. (ATCC 17588).	
	Salmonella choleraesuis (ATCC 10708).*	
	Salmonella enteritidis (ATCC 13076).*	
	Salmonella typhi (ATCC 6539).*	
	Salmonella typhimurium (ATCC 11311).*	
	Shigella sonnei (ATCC 11060).*	
	Staphylococcus aureus (ATCC 6538).*	

TABLE 1—SUMMARY OF INDUSTRY PROPOSED TESTING OF FOOD HANDLER ANTISEPTICS—Continued

[Health Care Continuum Model]

Proposed test method	Test organisms (American type culture collection strain number (ATCC))	Efficacy criteria
Establish broad spectrum and fast acting claims for formulations (In vitro Time Kill Test).	*Escherichia coli* (ATCC 11229) *Klebsiella pneumoniae* (ATCC 10031). *Listeria monocytogenes* (ATCC 7644).* *Salmonella typhi* (ATCC 6539).* *Staphylococcus aureus* (ATCC 6538)	1 minute: 1 $\log_{10}$ reduction 5 minutes: 2 $\log_{10}$ reduction Must meet criteria for 4 of 5 strains.
General Use Hand Wash Method (Formulation).	*Serratia marcescens* (ATCC 14756) or *Escherichia coli* (ATCC 11229)	1st wash 1.5 $\log_{10}$ reduction. 5th wash: 2 $\log_{10}$ reduction.
American Society for Testing and Materials International (ASTM) Hand Rub Method (Formulation).	*Serratia marcescens* (ATCC 14756) or *Escherichia coli* (ATCC 11229).	Rubs: 2 $\log_{10}$ reduction.

* Organisms included in the Hazard Analysis and Critical Control Point Principles and Application Guidelines (Ref. 4).

The HCCM proposal explained that the ATCC strains recommended for in vitro testing were chosen to represent a broad spectrum of bacteria that ''present a challenge to antisepsis'' and are the principal foodborne pathogens and contaminants. The model also proposed the use of clinical simulation studies to demonstrate the effectiveness of final formulations that rely on the reduction of the same surrogate organisms that historically have been used to demonstrate the effectiveness of health care personnel and antiseptic hand washes. More specifically, two protocols were proposed for clinical simulation studies: (1) A General Hand Wash Method for the demonstration of fast-acting and persistent activity of products used with water; and (2) an ASTM method for the evaluation of alcohol-based hand rub formulations to demonstrate the fast-acting antimicrobial activity of leave-on products. The proposal also provides log-reduction effectiveness criteria that are similar to the effectiveness criteria for health care personnel hand antiseptics proposed in the 1994 TFM (59 FR 31402 at 31444) (see table 1). The Soap and Detergent Association (SDA) stated that the proposed HCCM ''log reduction and acceptance criteria will demonstrate the appropriate effectiveness of products used in a food handling environment'' (Ref. 5). However, the HCCM did not define the appropriate level of effectiveness or include data to support corresponding effectiveness testing criteria.

The SDA also recommended the continued use of the Association of Official Analytical Chemists (AOAC International) chlorine equivalency test for in vitro effectiveness testing of food handler antiseptics (Ref. 6). The SDA suggested that an antiseptic activity equivalent to 50 parts per million of available chlorine be a strict requirement for food handler antiseptic products (Ref. 5).

B. FDA Comments on the Proposed Health Care Continuum Model

FDA identified several issues in the proposed HCCM. The use conditions of food handler antiseptics vary widely. Heavily soiled items are common in food preparation and food handling settings, and in general, antiseptic products are considered to be less effective in soiled hands (Ref. 7). Studies simulating moderate and heavily soiled hand conditions showed decreased efficacy of antiseptic products, suggesting that the organic load, *i.e.,* the amount of fat, grease, blood, and debris associated with food handling, affects the efficacy of antiseptic products (Ref. 8). The transfer of bacteria from contaminated food items and surfaces to hands may also be affected by the organic load contained in such items (Ref. 9). Use conditions vary in both organic and bacterial load, resulting in moderate to high levels of bacterial contamination. These differences are, in some cases, related to the setting in which a product is used. The differences may be related to other factors as well. The proposed HCCM does not take into consideration the wide-ranging use conditions of food handler antiseptics, and it raises the question of how to best address the broad spectrum of situational challenges stemming from these varied uses.

Contact time is another factor that is expected to impact an antiseptic's effectiveness. The Food Code, a model that represents FDA's advice for a uniform system of provisions that address the safety and protection of food offered at retail and in food service establishments, specifies that a food handler's hand cleaning regimen should last ''at least 20 seconds'' using a cleaning compound in a hand washing sink (Ref. 10). In the method for in vivo efficacy testing proposed in the HCCM, contact times vary from 30 seconds to 5 minutes. These timeframes do not reflect the hand cleaning procedures recommended in the Food Code. The contact times used in effectiveness testing should be appropriately related to reasonable real-life conditions of use, as reflected in product labeling. We are interested in comments on appropriate contact times for in vivo effectiveness testing.

The HCCM proposal also requires the demonstration of an antiseptic's effectiveness after multiple hand washes or rubs and proposes effectiveness criteria that range from 1.5 to 2 $\log_{10}$ reduction of the test organism. Given the manner in which food handler antiseptics are currently used (*i.e.,* short contact times with use of antiseptics, high bacterial loads, and expectations that these products be effective after a single use), the proposed in vivo effectiveness testing does not appear to reflect food handler antiseptic use situations and raises the question of what criteria best demonstrate the effectiveness of food handler antiseptics.

When evaluating food handler antiseptics, it is important to focus on the foodborne pathogens most often known to cause foodborne illness through contamination of food by food employee's hands (Ref. 11). The list of ''*Pathogens Transmitted by Food Contaminated by Infected Person Who Handle Food, and Modes of Transmission of Such Pathogens*'' is available on the Centers for Disease Control and Prevention (CDC) website (*https://www.cdc.gov/foodsafety/pdfs/pathogens-by-food-handlers-508c.pdf*). The in vitro testing proposed in the HCCM includes only bacterial species.

However, in 2014, the CDC reported that bacterial foodborne illness accounted for only 51 percent of food-borne disease outbreaks. Viruses were cited as the second most common cause of disease outbreaks (43 percent). Thus, over one-third of food-borne disease outbreaks included in the CDC report were not caused by bacteria (Ref. 12). Further, norovirus was reported as the most common cause of confirmed, single-etiology outbreaks, accounting for 284 outbreaks (43 percent); its transmission from contaminated hands to food items plays a major role in this foodborne illness. Parasites, including the protozoan species *Giardia lamblia, Cryptosporidium* species, and *Cyclospora cayentanensis,* accounted for a much smaller number of outbreaks, but should also be taken into consideration. These considerations raise questions concerning the antimicrobial spectrum of activity that food handler antiseptic active ingredients should demonstrate to be considered effective and the appropriate in vitro studies to assess such activity (see section IV.C and IV.D.).

In addition, in a 2005 meeting of FDA's Nonprescription Drugs Advisory Committee (Ref. 13) the committee observed that the existing test methods for topical antiseptics used in consumer and professional settings are based on the premise that bacterial reductions translate to a reduced potential for infection. Although bacterial reduction can be demonstrated using tests that simulate conditions of actual use, no corresponding clinical data demonstrate that bacterial reductions of the required magnitude produce a corresponding reduction in infection. For consumer antiseptic wash products, FDA has since recommended clinical outcome studies to demonstrate the products' clinical benefit and their superiority compared to plain soap and water (78 FR 76444, 81 FR 61106). This concern—whether the product's efficacy can be evaluated solely by in vitro tests—remains valid also for food handler antiseptics.

In light of the questions raised by FDA's review of the proposed HCCM, we have concluded that additional public input is needed before a proposed monograph for OTC food handler antiseptics can be developed. Therefore, FDA is seeking comments and requesting submission of data and information relevant to a number of questions related to OTC food handler antiseptics (see section V.)

C. Inclusion of Antiviral Indications in Food Handler Antiseptics

In response to the 1994 TFM, the Agency also received a citizen petition in 2003 from the SDA and Cosmetic Toiletry and Fragrance Association [1] (SDA/PCPC Petition) requesting that the proposed rule be amended to include antiviral indications for OTC consumer, food handler, and health care personnel antiseptics (Ref. 14). The SDA/PCPC Petition proposed labeling, final formulation testing requirements, and effectiveness criteria to demonstrate the antiviral activity of antiseptics (Ref. 15). Table 2 summarizes the SDA/PCPC Petition's proposed testing and other effectiveness criteria for food handler antiseptics.

TABLE 2—SUMMARY OF PETITIONER'S PROPOSED TESTING FOR DEMONSTRATION OF ANTIVIRAL EFFECTIVENESS OF FOOD HANDLER ANTISEPTICS

Proposed test method	Test organisms (ATCC strain No.)	Effectiveness criteria (reduction of viral load)
Establish antiviral activity of active ingredient (None).	Rotavirus Wa (ATCC VR–2018) ..... Rhinovirus Type 37 (ATCC VR–1147) or Rhinovirus Type 13 (ATCC VR–284).	None stated.
Establish antiviral activity of formulation. (ASTM E1838 [1]—fingerpad method). (ASTM E2011 [2]—entire-hand method).	Rotavirus Wa (ATCC VR–2018) ..... Rhinovirus Type 37 (ATCC VR–1147) or Rhinovirus Type 13 (ATCC VR–284).	2 $\log_{10}$. Contact time: Unspecified, should reflect use conditions

[1] ASTM E1838; "Standard Test Method for Determining the Virus-Eliminating Effectiveness of Hygienic Handwash and Handrub Agents using Fingerpads of Adults."
[2] ASTM E2011; "Standard Test Method for Evaluation of Hygienic Handwash and Handrub Formulations for Virus-Eliminating Activity Using the Entire Hand."

The SDA/PCPC Petition included studies and publications in which the antiviral activity of several active ingredients included in the 1994 TFM and their final formulations were assessed by both in vitro test methods and clinical simulation studies (*i.e.,* studies that simulate conditions of use to evaluate a product's efficacy in human subjects).

The SDA/PCPC Petition recommends testing against respiratory and enteric viral pathogens to determine the antiviral activity of the antiseptics: Rhinovirus Type 37 (ATCC VR–1147) or Rhinovirus Type 13 (ATCC VR–284) and Rotavirus Wa (ATCC VR–2018). The rationale for this recommendation is based on the premise that both viruses are important hand-transmitted pathogens, less susceptible to inactivation than enveloped viruses, and are known to survive for a significant period on skin and surfaces commonly contacted by hands. As such, they present an adequate challenge for testing the antiviral activity of antiseptic products.

Regarding the test methods for demonstration of virucidal effectiveness, the SDA/PCPC Petition proposed two specific methods: ASTM E1838 and ASTM E201. Both these methods present simulation models of viral contamination, and both measure the reduction of viral load on fingerpads (ASTM E1838) or on the entire hand (ASTM E201) after the application of the antiseptic test product. The SDA/PCPC Petition also proposed a 2 $\log_{10}$ reduction of the test virus or viruses as the criterion for antiviral effectiveness. Although several in vitro tests such as the carrier method (Ref. 16) and suspension tests (Ref. 17) are presented in the submission, there is no recommendation with regard to in vitro test methods for demonstration of

[1] In 2007, the CTFA changed its name to the Personal Care Products Council (PCPC).

virucidal activity of antiseptic products and/or their active ingredients.

Lastly, the SDA/PCPC Petition suggested a two-step approach for antibacterial and antiviral labeling: Providing that the antibacterial criteria as laid out in the rulemaking have been met, the antiviral labeling would be optional for products that in addition to antibacterial criteria, meet the antiviral criteria.

D. FDA Response to the Proposed Model for Antiviral Indications of the Antiseptic Products

FDA responded to the SDA/PCPC Petition on March 26, 2010, and denied the petition's request that FDA amend the 1994 TFM (Ref. 18). The submitted data were reviewed by FDA, and the following points were addressed:

In vitro data included in the SDA/PCPC Petition do not clearly demonstrate the effectiveness of the antiseptic active ingredients or product formulations against viruses. Primarily, the in vitro results obtained may not predict the antiseptic's effectiveness against viruses on human skin. An evaluation of effectiveness against viruses on human skin would need to be supported by adequate in vivo studies. In most of the studies, the test conditions and results vary considerably. Also, most studies lacked vehicle and neutralization controls; this undermines the validity of the data and makes it difficult to evaluate the contribution of the antiseptic product in the reduction of the viral concentration.

Clinical simulation studies included in the SDA/PCPC Petition were not adequately controlled to distinguish the antiviral effectiveness of the antiseptic and eliminate bias. These studies lacked proper controls and adequate statistical analyses. Most studies lacked either vehicle or placebo controls such as washing with plain soap and water. In the few studies in which a vehicle control was included, the advantage of the antiseptic product use was not demonstrated. Moreover, the use of plain soap and water was often found to be as or more effective than using the test antiseptic. Most studies also lacked proper documentation of neutralization and they were not randomized or blinded. Overall, the lack of adequate comparison controls rendered the submitted studies insufficient to demonstrate antiviral effectiveness.

The SDA/PCPC Petition proposed using an enteric pathogen, Rotavirus Wa Type 30, and a respiratory pathogen, Rhinovirus Type 37, for testing antiseptic viral activity. After reviewing submitted data and current publications, FDA determined that viruses vary significantly in their susceptibility to antiseptics and that this variability makes it difficult to extrapolate the effectiveness results obtained from the proposed viruses to a broader range of viruses (Ref. 19).

The SDA/PCPC Petition's proposed 2 $\log_{10}$ reduction of viral contamination as the criterion for determination of effectiveness is inadequate; viruses vary in their infectivity titers, and 2 $\log_{10}$ titer reduction achieved in the proposed viruses may be irrelevant to other viral pathogens. We currently have no data to evaluate the significance of 2 $\log_{10}$ reduction of test viruses and how such reduction would relate to a reduced risk of viral infections. In addition, the 2 $\log_{10}$ reduction of viral titers was achieved in alcohol-based products, but in studies where soap and water were used, the virus reduction was in the range of 1 $\log_{10}$. In conclusion, FDA determined that given these large variations, the clinical relevance of the proposed criterion for antiviral effectiveness was not supported by the data and may not be applicable to many viral pathogens. The surrogate measure of antiviral effectiveness would need to be validated and its significance should be supported by clinical data.

FDA found the test methods proposed in the SDA/PCPC Petition inadequate to support a general antiviral indication; the proposed ASTM methods do not account for data variability, nor do they provide guidance on adequate study size and data analysis. Moreover, the studies submitted in support of the proposed methods are insufficient to demonstrate comparable results between the two ASTM methods proposed due to the small study size.

In short, data reviewed by FDA are insufficient to support general antiviral labeling for antiseptic products including food handler antiseptics. Additional data that adequately demonstrate the antiviral effectiveness of antiseptic active ingredients and their product formulations are needed to properly address the antiviral activity of food handler antiseptics.

V. Data

Data to support the effectiveness of several antiseptic active ingredients were also submitted to the FDA–1975–N–0012–0494 docket by the PCPC in response to the Consumer Wash Proposed Rule (Ref. 20). Comments received from the PCPC asserted that the data provided demonstrated effectiveness based on the industry's proposed standard of effectiveness for food handler antiseptic products. However, because FDA currently has insufficient information to determine what constitutes an adequate demonstration of effectiveness of antiseptic active ingredients intended for use in the food handler setting, an evaluation of the submitted data would be premature.

VI. Questions for Public Input

Based on the history of food handler antiseptics and a review of our records and data received, we have determined that additional new data and information are needed to inform FDA on the safety and effectiveness of the active ingredients used in food handler antiseptics and drug products containing them. Thus, we are soliciting data and information that will help address the questions that follow.

A. Definition of Food Handler Antiseptics

As discussed in section III, we view food handler antiseptics as a category that includes antiseptic products used in regulated settings where food is grown, harvested, produced, manufactured, processed, packed, transported, prepared, served, or consumed.

In response to the questions that follow, FDA is seeking data and other information on defining food handler antiseptic products and any other information relevant to their definition.

- What are the categories of workers who might use the food handler antiseptic products?
- In what settings are food handler antiseptics used? What should be the boundaries (*e.g.,* growth, harvest, production, manufacturing, processing, packaging, transportation, storage, preparation, service, and consumption) of regulated use of food handler antiseptics? Are there any additional details and information to be considered related to scope-of-use settings of food handler antiseptics?
- What types of antiseptic products are used by food handlers and what terms are used in the food industry to describe such products (*e.g.,* wash, or leave-on products)?
- How frequently are food handler antiseptics used?

B. Active Ingredients for Food Handler Antiseptic Products

An OTC drug is eligible for the OTC Drug Review if its conditions of use existed in the OTC drug marketplace on or before May 11, 1972 (37 FR 9464), or if drug products with the same conditions of use have been marketed for a material time and extent such that they meet the requirements for eligibility under FDA's time and extent application regulation (§ 330.14 (21 CFR

330.14)). Conditions of use include, among others, active ingredient, dosage form and strength, route of administration, and specific OTC use or indication of the product (§ 330.14(a)).

To determine eligibility for the OTC Drug Review, FDA typically must have actual product labeling or a facsimile of labeling that documents the conditions of marketing of a product prior to May 1972 (21 CFR 330.10(a)(2)). FDA considers a drug that is ineligible for inclusion in the OTC monograph system to be a new drug that will require FDA approval under a new drug application (NDA) or an abbreviated new drug application (ANDA). Also, an active ingredient's ineligibility for evaluation under the OTC Drug Review for a specific indication does not affect its eligibility for evaluation for other indications under the OTC Drug Review.

FDA's recognition of the potential eligibility of food handler antiseptic products for evaluation under the OTC Drug Review is relatively new. We expect that many of the antiseptic active ingredients found in products currently used by food handlers may not have been on the U.S. market when the OTC Drug Review was first established, or that it may be difficult to establish eligibility based on use at that time. It may be possible, however, that some of the active ingredients currently used in these products have been in use in or outside of the United States for a material time and extent such that they meet the requirements for eligibility under FDA's time and extent application regulation (§ 330.14). We are, therefore, seeking information about food handler antiseptic active ingredients and the products in which they are found.

For the active ingredients used in food handler antiseptics, we ask for submission of the following information:

- What are the active ingredients currently used in food handler antiseptic products?
- How long and to what extent (*e.g.,* number of units or volume sold) have currently marketed active ingredients been in the marketplace inside and/or outside of the U.S. market?
- What active ingredients were in products on the market for food handler use prior to 1972, and what evidence of eligibility for evaluation for use in food handler antiseptic products under the OTC Drug Review is available for these active ingredients?
- What other information relevant to the eligibility of active ingredients for use in food handler antiseptic products is available?

C. Safety

In the consumer antiseptic wash and rubs, and in the health care antiseptics rulemakings for OTC topical antiseptic active ingredients, the following data are required to determine the safety of these active ingredients as part of the risk-to-benefit evaluation of the product's use (81 FR 61106 at 61117, 81 FR 42912, 80 FR 25166):

- Animal toxicology data
- Carcinogenicity
  - Dermal and Oral Exposure
- Absorption, Distribution, Metabolism & Excretion
  - Dermal and Oral Exposure
- Developmental & Reproductive Toxicology
- Hormonal Effects
- Human absorption data from a Maximal Usage Trial
- Development of Antimicrobial Resistance

To better assess the criteria for a determination of the safety of active ingredients used in food handler antiseptics, we welcome information to answer the following questions and any other issues related to evaluating the safety of these products:

- Should the data required to demonstrate the safety of active ingredients intended for use in food handler antiseptic products be the same as the safety criteria for active ingredients intended for use in consumer antiseptic and health care antiseptic products?
- If antiseptic hand rubs or leave-on products are used, the presence of residual antiseptic products on the hands of food handler professionals may result in indirect consumer exposure (*i.e.,* ingestion of residual antiseptic due to transfer of such residues from food handlers to food contact surfaces and/or food). Are additional studies required to address this concern?
- If additional studies are required to address indirect consumer exposure to antiseptic ingredients, what should they be?
- On a daily basis, how frequently do food handlers use food handler antiseptic products in the workplace? Are there any requirements related to the frequency of using food handler antiseptics in the workplaces where food is handled (*e.g.,* produce safety standards)?
- What data are available to support the long-term safety of the active ingredients of these products (*e.g.,* oral and dermal carcinogenicity studies)?
- How should the potential for antimicrobial resistance to these active ingredients be assessed?
- What data are available regarding antimicrobial resistance for these products, and how should the potential of food handler antiseptics' use with potential emergence of antimicrobial resistance be assessed?
- What other issues should be taken into consideration to support evaluation of the safety of food handler antiseptic products?

D. Effectiveness

New information on potential risks posed by the long-term use of certain antiseptic active ingredients prompted us to reconsider the data necessary to determine that active ingredients used in consumer or health care antiseptic products are generally recognized as safe and effective for their intended use. Based on new data as well as on input provided during the Nonprescription Drugs Advisory Committee meeting of March 2005, we have reevaluated the effectiveness data needed for consumer and health care antiseptic active ingredients (78 FR 76444, 81 FR 42912, 80 FR 25166).

For topical antiseptics used both in consumer and health care settings, the following studies in table 3 are required or proposed to be required to demonstrate effectiveness.

TABLE 3—EFFECTIVENESS DATA REQUIREMENTS FOR OTC CONSUMER AND HEALTH CARE ANTISEPTICS

Required tests	In vitro	In vivo
Consumer Antiseptic Washes	• Time-kill Assay*	• Clinical Outcome Studies ○ Evaluates the effect of antiseptic use in decreasing the incidence of infections.
Consumer Antiseptic Rubs	• Minimal Bactericidal Concentration*. • Time-kill Assay*.	• Clinical Simulation Studies ○ Measures the reduction of bacteria on skin due to antiseptic use.

TABLE 3—EFFECTIVENESS DATA REQUIREMENTS FOR OTC CONSUMER AND HEALTH CARE ANTISEPTICS—Continued

Required tests	In vitro	In vivo
Health Care Antiseptics	• Minimal Bactericidal Concentration**. • Time-kill Assay**.	• Clinical Simulation Studies ○ Measures reduction of bacteria on skin due to antiseptic use ○ Evaluates the persistence of bactericidal activity by measuring bacteria on skin 6 hours post product application for surgical hand scrub and patient preoperative skin preparation antiseptic products.

*Test organisms are representative of infections occurring in consumer settings.
**Test organisms are representative of infections occurring in health care settings.

To assess the effectiveness criteria for food handler antiseptic active ingredients, as well as the testing methods necessary to demonstrate effectiveness, we are interested in gathering information on the following questions related to in vivo testing:

• What studies should be used for a demonstration of efficacy in vivo?

• Should effectiveness be established through clinical outcome study (*e.g.,* show a statistically significant reduction in food-borne illness associated with the use of a food handler antiseptic in comparison to vehicle or washing with plain soap and water)?

• Do the data support use of a simulation model as a surrogate for effectiveness, such as bacterial log reduction on the hands of a food handler or on food following use of the product? What data can be used to link a simulation model to clinical outcomes related to food-borne illness (*i.e.,* model validation)?

• If the bacterial log reduction method for assessing effectiveness is used, what should be the required log reduction criteria for food handler antiseptics and what are the data that support such log reduction criteria?

• Are there any other criteria, such as reduction of transmission of microorganisms after use of food handler antiseptics that should be considered to determine the effectiveness of food-handler antiseptics?

• The Health Care Antiseptics Final Rule requires that for surgical hand scrub and patient preoperative skin preparation indications, the antiseptic activity of the product must be both immediate and persistent (82 FR 60474 at 60488). The effectiveness criteria for such products require that, in addition to the immediate antibacterial activity demonstrated by log reduction, bacterial growth is also suppressed for 6 hours after product use. Should food handler antiseptics' action be persistent?

• How are food handler antiseptics used in food handler settings? Are they used according to the manufacturer's directions of use or according to establishment-based standard operating procedures?

• Given the importance of a consistently effective product, should the dose of a food handler antiseptic vary with the product or should a standard dose be required?

• For the same reasons noted earlier, should the recommended length of time and/or frequency of use of the antiseptic product be consistent and standardized for all food handler antiseptics?

We would also like information as it relates to the following questions on in vitro testing:

• How should the products demonstrate effectiveness in vitro?

• What in vitro test methods should be used, *e.g.,* minimal bactericidal concentration and Time-kill Assay?

• What organisms should food handler antiseptics be required to demonstrate effectiveness against? Should viruses and other organisms (*e.g.,* protozoa) be tested as well as bacteria?

• Should the test methods address the effects of organic load (*i.e.,* high fat content, blood, or other materials) and dirt or soil on the effectiveness of food handler antiseptics?

• What other variables could impact the effectiveness of food handler antiseptics besides organic load, and how should the effect of such variables be taken into consideration during testing?

• How quickly must these products demonstrate effectiveness?

• At what specific time point(s) should effectiveness be measured?

VII. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

*1. Comment submitted in Docket No. FDA–1975–N–0012–0111, Volume 1 of 4, Part A. Available at *https://www.regulations.gov/document?D=FDA-1975-N-0012-0111.*

*2. Comment submitted in Docket No. FDA–1975–N–0012–0085. Available at *https://www.regulations.gov/document?D=FDA-1975-N-0012-0085.*

*3. Comment submitted in Docket No: FDA–1975–N–0012–0493. Available at *https://www.regulations.gov/document?D=FDA-1975-N-0012-0493.*

*4. FDA, ''HACCP Principles & Application Guidelines.'' Available at *https://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006801.htm.* Accessed on May 15, 2018.

*5. Comment submitted in Docket No. FDA–1975–N–0012–0081. Available at *https://www.regulations.gov/document?D=FDA-1975-N-0012-0081.*

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*10. FDA, Food Code 2017 2–301.12. Available at *https://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/UCM595140.pdf.* Accessed on May 15, 2018.
*11. ''Diseases Transmitted through the Food Supply: Pathogens Transmitted by Food Contaminated by Infected Person Who Handle Food, and Modes of Transmission of Such Pathogens.'' Available at *https://www.cdc.gov/foodsafety/pdfs/pathogens-by-food-handlers-508c.pdf.*
*12. Gould, H., et al. ''Surveillance for Foodborne Disease Outbreaks-United States 1998–2008,'' *Morbidity and Mortality Weekly Report,* Surveillance Summaries 62 (2).
*13. Transcript of the October 20, 2005, Nonprescription Drugs Advisory Committee Meeting. Available at *http://wayback.archive-it.org/7993/20170404055923/https:/www.fda.gov/ohrms/dockets/ac/05/transcripts/2005-4184T1.pdf.* Accessed May 15, 2018
*14. Comment submitted in Docket No. FDA–1975–N–0012–0037. Available at *https://www.regulations.gov/searchResults?rpp=25&po=0&s=FDA-1975-N-0012-0037&fp=true&ns=true.* Accessed May 15, 2018.
*15. Comment submitted in Docket No. FDA–1975–N–0012–0038. Available at *https://www.regulations.gov/searchResults?rpp=25&po=0&s=FDA-1975-N-0012-0038&fp=true&ns=true.*
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*18. Petition Denial Response Letter from FDA to PCPC and SDA. No. FDA–1975–0012–0042. Available at *https://www.regulations.gov/document?D=FDA-1975-N-0012-0042.* Accessed on May 15, 2018.
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Dated: December 3, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–26561 Filed 12–6–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–2126]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food and Drug Administration's Research and Evaluation Survey for the Public Education Campaign on Tobacco Among the Lesbian Gay Bisexual Transgender Community

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by January 7, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0808. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Food and Drug Administration's (FDA's) Research and Evaluation Survey for the Public Education Campaign on Tobacco (RESPECT) Among the LGBT Community

OMB Control Number 0910–0808—Extension

The 2009 Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to grant FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health and to reduce tobacco use by minors. Section 1003(d)(2)(D) of the FD&C Act (21 U.S.C. 393(d)(2)(D)) supports the development and implementation of FDA public education campaigns related to tobacco use. In May 2016, FDA began implementing a public education campaign to help prevent and reduce tobacco use among Lesbian, Gay, Bisexual, and Transgender (LGBT) young adults and thereby reduce the public health burden of tobacco. The campaign continues to be implemented in 12 U.S. cities and features events, television and radio and print advertisements, digital communications, including videos, social media, and other forms of media. For the purpose of this notice, these campaign elements will be referred to as ''advertisements'' or ''ads.''

In support of the provisions of the Tobacco Control Act that require FDA to protect the public health and to reduce tobacco use, FDA requests OMB approval to collect information needed to evaluate FDA's campaign to reduce tobacco use among LGBT young adults. Comprehensive evaluation of FDA's public education campaigns is needed to ensure campaign messages are effectively received, understood, and accepted by those for whom they are intended. Evaluation is an essential organizational practice in public health and a systematic way to account for and improve public health actions.

To evaluate the effectiveness of FDA's RESPECT at reducing tobacco use among LGBT young adults aged 18 to 24, FDA contracted with RTI International to conduct Web-based surveys with the target population in the 12 campaign cities and 12 comparison cities. The surveys include measures of tobacco-related knowledge, attitudes, beliefs, intentions, and use as well as measures of audience awareness of and exposure to campaign events and advertisements. The voluntary surveys also collect information on demographic variables, including sexual orientation, age, sex, race/ethnicity, education, and

primary language. Baseline data collection for RESPECT was conducted between February and May 2016. Four subsequent waves of data collection were conducted with new (cross-sectional) and returning (longitudinal) respondents. This design facilitated analysis of relationships between individuals' exposure to campaign activities and baseline to followup changes in outcomes of interest between campaign and comparison cities. Information collection for baseline and the first four followups was reviewed and approved by OMB.

FDA will continue to implement RESPECT in 12 U.S. cities through April 2019. To complete the evaluation of RESPECT, FDA is requesting an extension of the previously approved information collection in order to conduct two additional waves of data collection with the target population. The proposed sixth and seventh waves of data collection (*i.e.,* fifth and sixth followups after baseline) will coincide with the official end of the campaign, and will serve as an assessment of the campaign at completion. Continued evaluation is necessary in order to determine the campaign's impact on outcomes of interest.

As in previous waves, new and returning survey respondents will be invited to complete the online questionnaire. New (or cross-sectional) respondents will be recruited at LGBT social venues and via social media (*i.e.,* Facebook and Twitter). In-person recruitment will take place in a variety of LGBT venues. The owners or managers of potential recruitment sites will be asked a series of questions to determine the appropriateness of its clientele for participation in the study. For the fifth and sixth followups, an estimated 60 new venues (20 annualized) will be assessed at 5 minutes per assessment, for an additional 5 hours (1.67 annualized). A total of 1,980 venues (660 annualized) will be assessed during the evaluation study, for a total of 165 hours (55 annualized).

Our goal is to recruit 75 percent of the sample via intercept interviews and 25 percent via social media. To obtain the target number of completed fifth and sixth followup questionnaires, an additional 11,904 adults (3,968 annualized) recruited in person and 2,736 adults (912 annualized) recruited via social media will complete screening questionnaires. For the entire evaluation study, a total of 33,717 adults (11,239 annualized) recruited in person will complete screening questionnaires along with 10,617 adults (3,539 annualized) recruited via social media. The estimated burden to complete the screening questionnaire is 5 minutes (0.083 hour), for a total of 2,799 hours (933 annualized) for in-person recruits and 881 hours (294 annualized) for social media recruits.

Based on analysis of response rates from prior waves of data collection, we expect 65 percent of intercept respondents will be deemed eligible and 50 percent of those will complete the fifth followup questionnaire. We expect 30 percent of those recruited via social media will be deemed eligible and complete the fifth followup questionnaire. Lastly, we expect 50 percent of returning (or longitudinal) respondents to complete the fifth and sixth followup questionnaires. We estimate that approximately 2,100 new respondents (700 annualized) and 6,678 returning (2,226 annualized) respondents will complete the fifth and sixth followup questionnaires, for a total of 8,778 responses (2,926 annualized).

OMB previously approved 3,156 (1,052 annualized) respondents recruited via social media and 9,456 (3,152 annualized) respondents recruited in person to complete the first four followup questionnaires. Adding the fifth and sixth followups brings the total estimated number of followup questionnaires completed by social media recruits to 5,256 (1,752 annualized) and by in-person recruits to 16,134 (5,378 annualized). At 40 minutes per completed questionnaire, the total burden is 3,507 hours (1,169 annualized) for social media respondents and 10,761 hours (3,587 annualized) for in-person respondents.

OMB also previously approved 393 hours (approximately 132 annualized) for social media respondents and 1,182 hours (394 annualized) for in-person respondents to complete baseline questionnaires. OMB also approved the pilot test of procedures in bars (6 hours (2 annualized)). As these study components are complete, the corresponding burden will not change. Lastly, the original study design included a media tracking component, which included a burden of 414 hours (138 annualized) for completing a 5-minute screening questionnaire and 999 hours (333 annualized) for completing the media tracking questionnaire. However, this component was dropped from the study; hence, the related burden has been deducted from the total study burden.

In the **Federal Register** of August 2, 2018 (83 FR 37817), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received a total of nine comments from the public, of which five were PRA-related.

(Comment) Two commenters indicated support for FDA's efforts to evaluate media campaigns targeting smoking within the LGBT community.

(Response) FDA appreciates the public's support of its efforts to meet its mission to promote and protect public health.

(Comment) One commenter questioned the need for further data collection on this topic.

(Response) FDA disagrees. This collection of information is necessary for FDA to meet its mission to promote and protect public, and in its implementation of the Tobacco Control Act.

(Comment) One commenter questioned whether the evaluation is collecting sufficient data on the campaign's impact on the target population's thinking about smoking.

(Response) The campaign is intended to influence the target population's attitude towards smoking. To evaluate the effectiveness of the campaign, FDA is asking questions about the target population's tobacco use-related knowledge, attitudes, beliefs, and intentions before and after seeing the campaign's ads to test whether those have changed over time as a result of exposure to the campaign.

(Comment) One commenter questioned the utility of collecting data on smoking among LGBT young adults without first gathering information on smoking rates in this population, and also suggested specific modes for participant recruitment.

(Response) Multiple peer-reviewed studies have found that LGBT populations of all age groups are significantly more likely to smoke cigarettes and use other tobacco products compared to non-LGBT populations. FDA appreciates the detailed review of the evaluation's recruitment approach. Consistent with the commenter's recommendation, this information collection recruits participants both online via social media platforms and in person at LGBT social venues. This information collection does not recruit on the street or advertise via television.

(Comment) Several comments raised questions about the appropriateness of the target population and implementation approach of the public education campaigns being conducted by FDA.

(Response) FDA notes that these comments address the content, focus, or implementation of an existing public education campaign, and are therefore outside the scope of this information

collection, which is being conducted to evaluate the campaign.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Respondent type and activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Venue Owners and Managers	660	1	660	0.083 (5 minutes)	55
General Population: Pilot test of Procedures in Bars.	27	1	27	0.083 (5 minutes)	2
General population—outcome screener (in person).	11,239	1	11,239	0.083 (5 minutes)	933
General population—outcome screener (social media).	3,539	1	3,539	0.083 (5 minutes)	294
LGBT young adults outcome baseline (social media).	263	1	263	0.5 (30 minutes)	132
LGBT young adults outcome baseline (in person).	788	1	788	0.5 (30 minutes)	394
LGBT young adults outcome followup questionnaire (social media).	1,752	1	1,752	0.667 (40 minutes)	1,169
LGBT young adults outcome followup questionnaire (in person).	5,378	1	5,378	0.667 (40 minutes)	3,587
Totals					6,566

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

To accommodate the additional waves of data collection, FDA requests approval to increase the number of burden hours under the existing control number. The previous number of approved responses was 53,967 (17,989 annualized), and the previous burden was 14,031 hours (4,677 annualized). The fifth and sixth followups add 23,478 responses (7,826 annualized), which include responses to new venues assessments, screening questionnaires, and the followup questionnaires, for a total of 7,074 additional burden hours (2,357 annualized). Removing the media tracking component deducts 6,507 responses (2,169 annualized) and 1,413 burden hours (471 annualized). The totals for the entire evaluation study are increasing by 16,971 responses (5,657 annualized) and 5,661 hours (1,887 annualized) for a new total of 70,938 responses (23,646 annualized) and 19,692 burden hours (approximately 6,566 annualized).

Dated: November 30, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–26555 Filed 12–6–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–4000]

Framework for a Real-World Evidence Program; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is establishing a public docket to collect comments on a framework created by the Center for Drug Evaluation and Research and the Center for Biologic Evaluation and Research for implementing a program to evaluate the potential use of real-world evidence (RWE) in regulatory decision making. This framework is entitled ''Framework for the Real-World Evidence Program.'' The 21st Century Cures Act (Cures Act) was enacted on December 13, 2016, and requires that FDA establish a framework for implementing a program to evaluate the potential use of RWE to help support the approval of a new indication for a drug approved under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and to help support or satisfy postapproval study requirements. FDA has created this framework to satisfy the Cures Act mandate and is establishing a docket to receive public comments.

DATES: Submit either electronic or written comments on the draft document by February 5, 2019 to ensure that the Agency considers your comment before it begins work to implement the program.

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–2018–N–4000 for ''Framework for a Real-World Evidence Program; Availability.'' 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.

FOR FURTHER INFORMATION CONTACT: Dianne Paraoan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3326, Silver Spring, MD 20993–0002, 301–796–2500, *dianne.paraoan@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911, *stephen.ripley@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is establishing a public docket to collect comments on its ''Framework for a Real-World Evidence Program.'' Section 3022 of the Cures Act amended the FD&C Act to add section 505F, Utilizing real world evidence (21 U.S.C. 355g). This section requires the establishment of a program to evaluate the potential use of RWE to help support the approval of a new indication for a drug approved under section 505(c) of the FD&C Act (21 U.S.C. 355(c)) and to help to support or satisfy postapproval study requirements. This section also requires FDA publish a framework for that program. In addition to drug and biological products approved under section 505(c) of the FD&C Act, FDA is also applying this framework to biological products licensed under section 351 of the Public Health Service Act (42 U.S.C. 262).

The statute directs that the framework for the RWE program include information describing sources of RWE, gaps in data collection activities, standards and methodologies for collecting and analyzing RWE, and priority areas, remaining challenges, and potential pilot opportunities to address the overarching Cures Act requirements. To help meet a requirement in the Cures Act for consultation in developing the program framework, on September 13, 2017, through its cooperative agreement with the Duke Margolis Center for Health Policy, FDA convened a public meeting that explored the use of RWE for regulatory decisions. Representatives from industry, academia, and patient advocacy groups discussed, among other things, opportunities and challenges associated with applying real-world data and RWE, the evidence derived from that data, to demonstrate product effectiveness, including data acquisition, study design, and analytic methods necessary to establish causal inference. The workshop helped to inform FDA's RWE framework. FDA will continue to consult stakeholders through public-private partnerships, public workshops, and demonstration projects as it implements its RWE program.

II. Electronic Access

Persons with access to the internet may obtain the ''Framework for the Real-World Evidence Program'' at *https://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/SignificantAmendmentstotheFDCAct/21stCenturyCuresAct/ucm562475.htm.*

Dated: November 30, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–26546 Filed 12–6–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0961]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Environmental Impact Considerations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by January 7, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0322. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD

20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Environmental Impact Considerations

OMB Control Number 0910–0322—Extension

I. Background

FDA is requesting OMB approval for the reporting requirements contained in the FDA collection of information ''Environmental Impact Considerations.'' The National Environmental Policy Act (NEPA) (42 U.S.C. 4321–4347) states national environmental objectives and imposes upon each Federal Agency the duty to consider the environmental effects of its actions. Section 102(2)(C) of NEPA requires the preparation of an environmental impact statement (EIS) for every major Federal action that will significantly affect the quality of the human environment.

FDA's NEPA regulations are in part 25 (21 CFR part 25). All applications or petitions requesting Agency action require the submission of a claim for categorical exclusion or an environmental assessment (EA). A categorical exclusion applies to certain classes of FDA-regulated actions that usually have little or no potential to cause significant environmental effects and are excluded from the requirements to prepare an EA or EIS. Section 25.15(a) and (d) specifies the procedures for submitting to FDA a claim for a categorical exclusion. Extraordinary circumstances (§ 25.21), which may result in significant environmental impacts, may exist for some actions that are usually categorically excluded. An EA provides information that is used to determine whether an FDA action could result in a significant environmental impact. Section 25.40(a) and (c) specifies the content requirements for EAs for non-excluded actions.

This collection of information is used by FDA to assess the environmental impact of Agency actions and to ensure that the public is informed of environmental analyses. Firms wishing to manufacture and market substances regulated under statutes for which FDA is responsible must, in most instances, submit applications requesting approval. Environmental information must be included in such applications for the purpose of determining whether the proposed action may have a significant impact on the environment. Where significant adverse events cannot be avoided, the Agency uses the submitted information as the basis for preparing and circulating to the public an EIS, made available through a **Federal Register** document also filed for comment at the Environmental Protection Agency. The final EIS, including the comments received, is reviewed by the Agency to weigh environmental costs and benefits in determining whether to pursue the proposed action or some alternative that would reduce expected environmental impact.

Any final EIS would contain additional information gathered by the Agency after the publication of the draft EIS, a copy or a summary of the comments received on the draft EIS, and the Agency's responses to the comments, including any revisions resulting from the comments or other information. When the Agency finds that no significant environmental effects are expected, the Agency prepares a finding of no significant impact.

In the **Federal Register** of June 7, 2018 (83 FR 26477), FDA published a 60-day notice requesting public comment on the proposed collection of information. One PRA related comment was received.

(Comment) One commenter requested that FDA should categorically exclude all categories of SE applications from the EA requirement.

(Response) FDA appreciates this comment. We note, however, that any action to establish a categorial exclusion would need to be undertaken through a notice and comment rulemaking procedure.

FDA estimates the burden of this collection of information as follows:

II. Estimated Annual Reporting Burden for Human Drugs (Including Biologics in the Center for Drug Evaluation and Research)

Under §§ 312.23(a)(7)(iv)(e), 314.50(d)(1)(iii), and 314.94(a)(9)(i) (21 CFR 312.23(a)(7)(iv)(e), 314.50(d)(1)(iii), and 314.94(a)(9)(i)), each investigational new drug application (IND), new drug application (NDA), and abbreviated new drug application (ANDA) must contain a claim for categorical exclusion under § 25.30 or § 25.31, or an EA under § 25.40. Annually, FDA receives approximately 3,687 INDs from 2,456 sponsors; 140 NDAs from 116 applicants; 3,192 supplements to NDAs from 443 applicants; 28 biologic license applications (BLAs) from 22 applicants; 464 supplements to BLAs from 52 applicants; 1,152 ANDAs from 248 applicants; and 6,774 supplements to ANDAs from 384 applicants. FDA estimates that it receives approximately 15,437 claims for categorical exclusions as required under § 25.15(a) and (d) and 10 EAs as required under § 25.40(a) and (c). Based on information provided by the pharmaceutical industry, FDA estimates that it takes sponsors or applicants approximately 8 hours to prepare a claim for a categorical exclusion and approximately 3,400 hours to prepare an EA.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN FOR HUMAN DRUGS [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
25.15(a) and (d)	3,724	4.1453	15,437	8	123,496
25.40(a) and (c)	10	1	10	3,400	34,000
Total					157,496

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

III. Estimated Annual Reporting Burden for Medical Devices

Under § 814.20(b)(11) (21 CFR 814.20(b)(11)), premarket approvals (PMAs) (original PMAs and supplements) must contain a claim for categorical exclusion under § 25.30 or § 25.34 or an EA under § 25.40. In 2017, FDA received an average of 50 claims (original PMAs and supplements) for categorical exclusions as required under § 25.15(a) and (d), and 0 EAs as required under § 25.40(a) and (c). FDA estimates that approximately 50 respondents will submit an average of 1 application for

categorical exclusion annually. Based on information provided by sponsors, FDA estimates that it takes approximately 6 hours to prepare a claim for a categorical exclusion.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN FOR MEDICAL DEVICES [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
25.15(a) and (d)	50	1	50	6	300

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

IV. Estimated Annual Reporting Burden for Biological Products, Drugs, and Medical Devices in the Center for Biologics Evaluation and Research

Under 21 CFR 601.2(a), BLAs as well as INDs (§ 312.23), NDAs (§ 314.50), ANDAs (§ 314.94), and PMAs (§ 814.20) must contain either a claim of categorical exclusion under § 25.30 or § 25.32 or an EA under § 25.40. Annually, FDA receives approximately 34 BLAs from 18 applicants, 801 BLA supplements to license applications from 156 applicants, 345 INDs from 256 sponsors, 1 NDA from 1 applicant, 26 supplements to NDAs from 8 applicants, 1 ANDA from 1 applicant, 1 supplement to ANDAs from 1 applicant, 8 PMAs from 3 applicants, and 33 PMA supplements from 16 applicants. FDA estimates that approximately 10 percent of these supplements would be submitted with a claim for categorical exclusion or an EA.

FDA has received approximately 481 claims for categorical exclusion as required under § 25.15(a) and (d) annually and 2 EAs as required under § 25.40(a) and (c) annually. Therefore, FDA estimates that approximately 247 respondents will submit an average of 2 applications for categorical exclusion and 2 respondents will submit an average of 1 EA. Based on information provided by industry, FDA estimates that it takes sponsors and applicants approximately 8 hours to prepare a claim of categorical exclusion and approximately 3,400 hours to prepare an EA for a biological product.

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN FOR BIOLOGICAL PRODUCTS [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
25.15(a) and (d)	247	2	494	8	3,952
25.40(a) and (c)	2	1	2	3,400	6,800
Total					10,752

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

V. Estimated Annual Reporting Burden for Animal Drugs

Under 21 CFR 514.1(b)(14), new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs); 21 CFR 514.8(a)(1) supplemental NADAs and ANADAs; 21 CFR 511.1(b)(10) investigational new animal drug applications (INADs) and generic investigational new animal drug applications (JINADs), and 21 CFR 571.1(c) food additive petitions must contain a claim for categorical exclusion under § 25.30 or § 25.32 or an EA under § 25.40. Annually, FDA's Center for Veterinary Medicine has received approximately 810 claims for categorical exclusion as required under § 25.15(a) and (d) and 22 EAs as required under § 25.40(a) and (c). Assuming an average of 10 claims per respondent, FDA estimates that approximately 81 respondents will submit an average of 10 claims for categorical exclusion. FDA further estimates that 22 respondents will submit an average of 1 EA. FDA estimates that it takes sponsors/applicants approximately 3 hours to prepare a claim of categorical exclusion and an average of 2,160 hours to prepare an EA.

TABLE 4—ESTIMATED ANNUAL REPORTING BURDEN FOR ANIMAL DRUGS [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
25.15(a) and (d)	81	10	810	3	2,430
25.40(a) and (c)	22	1	22	2,160	47,520
Total					49,950

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

VI. Estimated Annual Reporting Burden for Tobacco Products

Under sections 905, 910, and 911 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387e, 387j, and 387k), product applications and supplements (PMTAs), SEs, Exemption from SEs, and modified risk tobacco products must contain a claim for categorical exclusion or an EA. After further review, the agency has concluded that the majority of the EA burden for tobacco products

is covered under already existing information collections. To avoid double counting, the agency has removed the burden which is approved under other FDA information collections. The burden for SEs are currently approved under OMB control number 0910–0673; the burden for PMTAs are currently approved under OMB control number 0910–0768; the burden for SE exemptions are currently approved under OMB control number 0910–0684.

FDA's estimates are based on actual report data from fiscal year (FY) 2015 to FY 2017, on average FDA estimated it received approximately 27 modified risk tobacco product applications (MRTPAs) from 27 respondents. Based on updated data for this collection, FDA estimates 27 EAs from 27 respondents. A total of 27 respondents will submit an average of 1 application for environmental assessment. Based on FDA's experience, previous information provided by potential sponsors and knowledge that part of the EA information has already been produced in one of the tobacco product applications, FDA estimates that it takes approximately 80 hours to prepare an EA.

TABLE 5—ESTIMATED ANNUAL REPORTING BURDEN FOR TOBACCO PRODUCTS [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
25.40(a) and (c)	27	1	27	80	2,160

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The Estimated Annual Reporting Burden for Human Foods is no longer a part of this information collection. The burden has now been incorporated into OMB control number 0910–0541.

Our estimated burden for the information collection reflects an overall decrease of 10,566 hours (currently approved 231,224) and a corresponding decrease of 11,364 annual responses (currently approved 15,527). The new estimated totals are 220,658 hours and 4,163 annual responses. We attribute this adjustment to the removal of the majority tobacco burden from this collection, and the number of EA submissions we received since the last extension.

Dated: November 30, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–26556 Filed 12–6–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Information Collection Request Title: Family-to-Family Health Information Center Feedback Surveys, OMB Number: 0906–xxxx–New

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR must be received no later than January 7, 2019.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference, in compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995.

Information Collection Request Title: Family-to-Family Health Information Center Feedback Surveys, *OMB Control Number:* 0906–xxxx–New.

Abstract: The Family-to-Family Health Information Center (F2F HIC) program is authorized by the Social Security Act, Title V, § 501(c) (42 U.S.C. 701(c)), as amended by § 50501 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123). The goal of the F2F HIC program is to promote optimal health for children and youth with special health care needs (CYSHCN) by facilitating their access to an effective health delivery system and by meeting the health information and support needs of families of CYSHCN and the professionals who serve them. F2F HICs are staffed by families of CYSHCN who have first-hand knowledge using health care services and programs. With this experience, these staff are uniquely positioned to provide support to other CYSHCN families and help other families like theirs navigate an often complex and confusing health care and social service system. They also serve as mentors and as a reliable source of health care information to other families.

During Fiscal Years (FY) 2003 to 2017, HRSA's Maternal and Child Health Bureau (MCHB) awarded approximately $4.9 million per FY in grants to support 51 F2F HICs in each of the 50 states and the District of Columbia. In FY 2017, 49 centers that reported data served and trained over 184,000 families and approximately 85,500 health professionals. For FYs 2018 and 2019, HRSA MCHB will award approximately $6 million per FY to support 59 F2F HICs: One each in the 50 states and the District of Columbia, 1 each in the 5 U.S. Territories (American Samoa, Guam, Puerto Rico, the Northern Mariana Islands and the U.S. Virgin Islands), and 3 to serve American Indians/Alaska Natives.

HRSA has developed feedback surveys to determine the extent to which F2F HICs provide service to families of CYSHCN and health professionals who serve such families. Each F2F HIC will administer the surveys and report data back to HRSA. Survey respondents will be asked to answer questions about how useful they found the information, assistance, or resources received from the F2F HICs. The purpose of this notice is to solicit comments regarding the proposed feedback surveys and the F2F HIC grant recipient activity instructions form.

Need and Proposed Use of the Information: Data from the feedback surveys will provide mechanisms to capture consistent performance data from F2F HIC grant recipients. The data will also allow F2F HICs to evaluate the effectiveness of their interventions and improve services provided to families and the providers who serve CYSHCN families.

Likely Respondents: Likely respondents are users of F2F HIC services, which include family members of CYSHCN and health professionals who serve such families.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information; to process and maintain information; to disclose and provide information; to train personnel to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information.

The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
F2F HIC Feedback Survey	1,147	1	1,147	0.15	172
F2F HIC Grant Recipient Activity	59	1	59	89	5,251
Total	1,206		1,206		5,423

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2018–26524 Filed 12–6–18; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Presidential Advisory Council on HIV/AIDS

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health.

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 a meeting and will discuss recommendations regarding programs, policies, and research to promote effective, prevention, treatment and cure of HIV disease and AIDS. The meeting will be open to the public.

DATES: The Council meeting is scheduled to convene on March 14–15, 2019 from 9:00 a.m. to approximately 5:00 p.m. (ET) on March 14 and from 9:00 a.m. to 1:00 p.m. (ET) on March 15. Please note that on March 14, the meeting will include a closed session from 9:00 a.m. to 12:00 p.m. This portion of the meeting will be closed for administrative briefings to be presented to the new Council members. The meeting will be open to the public from 1:00 p.m. to 5:00 p.m. on March 14 and from 9:00 a.m.–1:00 p.m. (ET) on March 15.

ADDRESSES: 200 Independence Avenue SW, Washington, DC 20201 in the Penthouse (eighth floor), Room 800.

FOR FURTHER INFORMATION CONTACT: Ms. Caroline Talev, 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.* More detailed information about PACHA 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 the upcoming meeting will be posted on the *HIV.gov* website 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 on Thursday, March 7, 2019. Members of the public will have the opportunity to provide comments during the meeting. Comments will be limited to two 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 on Thursday, March 7, 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. Public comment will be limited to two minutes per speaker. 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 Thursday, March 7, 2019.

Dated: November 27, 2018.

B. Kaye Hayes,

Executive Director, Presidential Advisory Council on HIV/AIDS.

[FR Doc. 2018–26568 Filed 12–6–18; 8:45 am]

BILLING CODE 4150–43–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Laboratory Animal Welfare: Draft Report on Recommendations To Reduce Administrative Burden on Researchers

AGENCY: National Institutes of Health, HHS.

ACTION: Notice; request for comments.

SUMMARY: The National Institutes of Health (NIH) is seeking input on the draft report by the 21st Century Cures Act Working Group on Reducing Administrative Burden to Researchers for Animal Care and Use in Research. The draft report is a coordinated effort of the Director of the National Institutes of Health, in collaboration with the Secretary of Agriculture and the Commissioner of Food and Drugs. It describes the proposed actions that the working group has identified to reduce administrative burden on investigators while maintaining the integrity and credibility of research findings and protection of research animals.

DATES: The Request for Information regarding the proposed actions that the working group has identified is open for public comment for a period of 60 days. Comments must be submitted electronically at *https://grants.nih.gov/grants/rfi/rfi.cfm?ID=83* and must be received by February 5, 2019 to ensure consideration.

FOR FURTHER INFORMATION CONTACT: Patricia Brown, Office of Laboratory Animal Welfare (OLAW), Office of Extramural Research, National Institutes of Health, Suite 2500, 6700B Rockledge Drive, Bethesda, MD 20892–6910, phone: 301–496–7163, email: *olaw@od.nih.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

This request for information is a coordinated effort of the Director of the National Institutes of Health, in collaboration with the Secretary of Agriculture and the Commissioner of Food and Drugs, to seek input on the draft report by the 21st Century Cures Act, Section 2034(d) Working Group on Reducing Administrative Burden to Researchers for Animal Care and Use in Research.

Section 2034(d) of the 21st Century Cures Act (Pub. L. 114–255) was enacted December 13, 2016 and requires that the NIH, in collaboration with the United States Department of Agriculture (USDA) and the Food and Drug Administration (FDA), complete a review of applicable regulations and policies for the care and use of laboratory animals and make revisions to reduce administrative burden on investigators. NIH OLAW, USDA, and FDA formed a Working Group to: (1) Identify overlapping regulations and policies; (2) take steps to reduce such identified regulations and policies; and (3) take actions to improve coordination, as directed by the U.S. Congress. Input is sought on the draft report of the Working Group and others within the federal government and the proposed recommendations to reduce the administrative burden associated with research activities with laboratory animals while maintaining appropriate protections and scientific integrity. The draft report is available at *https://olaw.nih.gov/sites/default/files/21CCA_draft_report.pdf.*

Dated: November 16, 2018.

Francis S. Collins,

Director, National Institutes of Health.

[FR Doc. 2018–26557 Filed 12–6–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

[Docket No. BOEM–2018–0069]

Notice of Availability of a Draft Environmental Impact Statement for Vineyard Wind LLC's Proposed Wind Energy Facility Offshore Massachusetts

AGENCY: Bureau of Ocean Energy Management, Interior.

ACTION: Notice of availability of a Draft Environmental Impact Statement.

SUMMARY: Consistent with the regulations implementing the National Environmental Policy Act (NEPA), the Bureau of Ocean Energy Management (BOEM) is announcing the availability of a Draft Environmental Impact Statement (EIS) for the Construction and Operation Plan (COP) submitted by Vineyard Wind LLC (Vineyard Wind). The Draft EIS analyzes the potential environmental impacts of the proposed action described in the Vineyard Wind COP and reasonable alternatives to the proposed action. This Notice of Availability (NOA) announces the start of the public review and comment period, as well as the dates and locations of public hearings on the Draft EIS. After BOEM holds the public hearings and addresses comments on the Draft EIS, BOEM will prepare a Final EIS.

DATES: Comments should be submitted no later than January 22, 2019. BOEM's public hearings will be held at the following dates and times. Please see the **ADDRESSES** section for the specific locations.

- New Bedford, Massachusetts: Tuesday, January 8, 2019
- Narragansett, Rhode Island: Wednesday: January 9, 2019
- Hyannis, Massachusetts: Tuesday, January 15, 2019
- Nantucket, Massachusetts: Wednesday, January 16, 2019
- Vineyard Haven, Massachusetts: Thursday, January 17, 2019

ADDRESSES: The Draft EIS and detailed information about the proposed wind energy facility, including the COP, can be found on BOEM's website at: *https://www.boem.gov/Vineyard-Wind/.* Comments can be submitted in any of the following ways:

- In written form, delivered by hand or by mail, enclosed in an envelope labeled ''Vineyard Wind COP Draft EIS'' and addressed to Program Manager, Office of Renewable Energy, Bureau of Ocean Energy Management, 45600 Woodland Road, Sterling, Virginia 20166. Comments must be received or postmarked no later than January 22, 2019; or
- Through the *regulations.gov* web portal: Navigate to *htttp://www.regulations.gov* and search for Docket No. BOEM–2018–0069. Click on the ''Comment Now!'' button to the right of the document link. Enter your information and comment, then click ''Submit.''

BOEM will hold public hearings for the Draft EIS for the Vineyard Wind COP at the following places and times:

- New Bedford, Massachusetts: Tuesday, January 8, 2019; New Bedford Whaling Museum, 18 Johnny Cake Hill, New Bedford, Massachusetts 02740; Open House 5:00–8:00 p.m.; Presentation and Q&A 6:00 p.m.
- Narragansett, Rhode Island: Wednesday: January 9, 2019; Narragansett Town Hall, 25 5th Avenue, Narragansett, Rhode Island 02882; Open

House 5:00–8:00 p.m.; Presentation and Q&A 6:00 p.m.

- Hyannis, Massachusetts: Tuesday, January 15, 2019; Double Tree Hotel, Cape Cod Room, 287 Iyannough Road, Hyannis, Massachusetts 02601; Open House 5:00–8:00 p.m.; Presentation and Q&A 6:00 p.m.
- Nantucket, Massachusetts: Wednesday, January 16, 2019; Nantucket Atheneum, 1 India Street, Nantucket, Massachusetts 02554; Open House 5:00 p.m.–7:30 p.m.; Presentation and Q&A 6:00 p.m.
- Vineyard Haven, Massachusetts: Thursday, January 17, 2019; Martha's Vineyard Hebrew Center, 130 Center Street, Vineyard Haven, Massachusetts 02568; Open House 5:00–8:00 p.m.; Presentation and Q&A 6:00 p.m.

FOR FURTHER INFORMATION CONTACT: For information on the Vineyard Wind COP EIS, the submission of comments, or BOEM's policies associated with this notice, please contact Michelle Morin, BOEM Office of Renewable Energy Programs, 45600 Woodland Road, Sterling, Virginia 20166, (703) 787–1722 or *michelle.morin@boem.gov*

SUPPLEMENTARY INFORMATION:

Proposed Action: The proposed action is approval of the construction and operation of a wind energy facility as described in the COP submitted by Vineyard Wind on Lease Area OCS–A 0501. The COP proposes to construct, operate, maintain, and eventually decommission an up to 800 MW wind energy facility on the OCS offshore Massachusetts within the proposed Project area. Vineyard Wind's COP proposes installing up to 100 wind turbine generators, each with a capacity of between 8 and 10 MW. Foundations would be 100 monopiles or up to 10 jacket foundations and the remainder monopiles. The proposed facility would also include one or two offshore substations or electrical service platforms. The Vineyard Wind COP also proposes an export cable from the wind energy facility to shore that would occur within the range of design parameters outlined in the COP. Vineyard Wind has identified two potential export cable landfalls: One near the town of Yarmouth and one near the town of Barnstable, both in the Commonwealth of Massachusetts. Onshore construction and staging would take place at the New Bedford Marine Commerce Terminal facility. At its nearest point, the project area is approximately 12 nautical miles from the southeast corner of Martha's Vineyard and a similar distance from the southwest side of Nantucket. The turbines would be located in water depths ranging from approximately 37 to 49 meters (approximately 121 to 161 feet).

Alternatives: In preparing the Draft EIS and in consideration of scoping comments, BOEM conducted an initial evaluation of a full range of alternatives. BOEM eliminated from further consideration alternatives that were technically or economically infeasible, did not provide environmental benefits, or otherwise did not meet BOEM's purpose and need. BOEM's Draft EIS carries forward for full evaluation a reasonable range of alternatives to the proposed action. The alternatives include the proposed action, a different cable landfall location, a reduction in project size, several options for modified wind turbine layouts, and a no-action alternative to disapprove the COP. This Draft EIS analyzes each alternative in detail, including direct, indirect, and cumulative environmental effects. The Draft EIS also considers proposed mitigation measures that BOEM may select. Compliance with existing laws and regulations by Vineyard Wind and BOEM may require additional measures or modifications to the measures described in the Draft EIS.

Once BOEM completes the Final EIS and associated consultations, BOEM will decide whether to approve, approve with modification, or disapprove the Vineyard Wind COP. If BOEM approves the COP and the proposed facility is constructed, the lessee must submit a plan to decommission the facilities before the lease term ends.

Availability of the Draft EIS: The Draft EIS, Vineyard Wind COP, and associated information are available on BOEM's website at: *https://www.boem.gov/Vineyard-Wind/*. BOEM will distribute digital copies of the Draft EIS to interested parties upon request. If you require a paper copy, BOEM will provide one upon request, as long as copies are available. You may request a CD, paper copy, or the location of a library with a paper copy of the Draft EIS by calling (703) 787–1346.

Cooperating Agencies: On March 30, 2018, BOEM published in the **Federal Register** a Notice of Intent to prepare the Draft EIS. Nine agencies are participating as cooperating agencies in the preparation of the Draft EIS: The Bureau of Safety and Environmental Enforcement, the U.S. Environmental Protection Agency, the National Oceanic and Atmospheric Administration, the U.S. Army Corps of Engineers, the U.S. Coast Guard, the Massachusetts Office of Coastal Zone Management, the Rhode Island Department of Environmental Management, the Rhode Island Coastal Resource Management Council, and the Narragansett Indian Tribe.

BOEM does not consider anonymous comments. Please include your name and address as part of your submittal. BOEM makes all comments, including the name and addresses of respondents, available for public review during regular business hours. Individual respondents may request that BOEM withhold their names or addresses from the public record; however, BOEM cannot guarantee that it will be able to do so. If you wish your name or address to be withheld, you must state your preference prominently at the beginning of your comment. 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 inspection in their entirety.

Authority: This NOA was prepared pursuant to NEPA and implementing regulations at 40 CFR 1506.6 and 43 CFR 46.435.

Dated: December 3, 2018.

William Yancey Brown,

Chief Environmental Officer, Bureau of Ocean Energy Management.

[FR Doc. 2018–26573 Filed 12–6–18; 8:45 am]

BILLING CODE 4310–MR–P

INTERNATIONAL TRADE COMMISSION

[USITC SE–18–059]

Change of Date of Government in the Sunshine Act Meeting; Issuance of Revised Agenda for Meeting of December 7, 2018 at 11:00 a.m.

AGENCY HOLDING THE MEETING: United States International Trade Commission.

ORIGINAL TIME AND DATE: December 5, 2018 at 11:00 a.m.

NEW DATE: December 7, 2018 at 11:00 a.m.

PLACE: Room 100, 500 E Street SW, Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public.

In accordance with 19 CFR 201.35 (d)(2)(i), the Commission hereby gives notice that the Commission has determined to change the date of the meeting originally scheduled for December 5, 2018 at 11:00 a.m. to December 7, 2018 at 11:00 a.m. to consider Inv. Nos. 701–TA–591 and 731–TA–1399 (Final) (Common Alloy Aluminum Sheet from China).

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the

following meeting. Earlier notification of this change was not possible.

The revised agenda of December 7, 2018 at 11:00 a.m. is as follows:

1. Agendas for future meetings: None.
2. Minutes.
3. Ratification List.
4. Vote on Inv. Nos. 701–TA–614 and 731–TA–1431 (Preliminary)(Magnesium from Israel). The Commission is currently scheduled to complete and file its determinations on December 11, 2018; views of the Commission are currently scheduled to be completed and filed on December 18, 2018.
5. Vote on Inv. Nos. 701–TA–591 and 731–TA–1399 (Final)(Common Alloy Aluminum Sheet from China). The Commission is currently scheduled to complete and file its determinations and views of the Commission by January 2, 2019.
6. Outstanding action jackets: None.

By order of the Commission.

Issued: December 3, 2018.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2018–26608 Filed 12–4–18; 11:15 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1057]

Certain Robotic Vacuum Cleaning Devices and Components Thereof Such as Spare Parts; Notice of the Commission's Final Determination Finding a Violation of Section 337; Issuance of a Limited Exclusion Order and Cease and Desist Orders; Termination of the Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has found a violation of section 337 of the Tariff Act of 1930, in this investigation. The Commission has issued a limited exclusion order prohibiting the unlicensed entry of certain vacuum cleaning devices and components thereof, such as spare parts, that infringe certain claims of U.S. Patent No. 9,038,233. The Commission has also issued cease and desist orders prohibiting the sale and distribution within the United States of articles that infringe certain claims of that patent against Hoover, Inc. of Glenwillow, Ohio; Royal Appliance Manufacturing Co., Inc. d/b/a TTI Floor Care North America, Inc. of Glenwillow, Ohio; bObsweep, Inc. of Toronto, Canada; and bObsweep USA of Henderson, Nevada. The investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Lucy Grace D. Noyola, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone 202–205–3438. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone 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 this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, on May 23, 2017, based on a complaint filed by iRobot Corporation of Bedford, Massachusetts (''iRobot''). 82 FR 23592 (May 23, 2017). The complaint alleges a violation of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain vacuum cleaning devices and components thereof, such as spare parts, by reason of infringement of certain claims of U.S. Patent Nos. 6,809,490 (''the '490 patent''), 7,155,308 (''the '308 patent''), 8,474,090 (''the '090 patent''), 8,600,553 (''the '553 patent''), 9,038,233 (''the '233 patent''), and 9,486,924 (''the '924 patent''). The Notice of Investigation names as respondents Bissell Homecare, Inc. of Grand Rapids, Michigan (''Bissell''); Hoover, Inc. of Glenwillow, Ohio and Royal Appliance Manufacturing Co., Inc. d/b/a TTI Floor Care North America, Inc. of Glenwillow, Ohio (collectively, ''Hoover''); bObsweep, Inc. of Toronto, Canada and bObsweep USA of Henderson, Nevada (collectively, ''bObsweep''); The Black & Decker Corporation of Towson, Maryland and Black & Decker (U.S.) Inc. of Towson, Maryland (collectively, ''Black & Decker''); Shenzhen ZhiYi Technology Co., Ltd., d/b/a iLife of Shenzhen, China (''iLife''); Matsutek Enterprises Co., Ltd. of Taipei City, Taiwan (''Matsutek''); Suzhou Real Power Electric Appliance Co., Ltd. of Suzhou, China (''Suzhou''); and Shenzhen Silver Star Intelligent Technology Co., Ltd. of Shenzhen, China (''SSSIT''). The Office of Unfair Import Investigations is not a party in this investigation.

The investigation has been terminated with respect to respondents Suzhou, Black & Decker, Bissell, and Matsutek. Notice (Oct. 18, 2017) (determining not to review Order No. 23 (Sept. 26, 2017)); Notice (Jan. 31, 2018) (determining not to review Order No. 31 (Jan. 9, 2018)); Notice (Feb. 16, 2018) (determining not to review Order No. 34 (Jan. 25, 2018)). The investigation has also been terminated with respect to the '924 and the '308 patents. Notice (Jan. 16, 2018) (determining not to review Order No. 29 (Dec. 14, 2017)); Notice (Mar. 15, 2018) (determining not to review Order No. 40 (Feb. 21, 2018)).

On June 25, 2018, the presiding administrative law judge (''ALJ'') issued a final initial determination (''ID''), finding a violation of section 337 with respect to the '553 and '233 patents and no violation with respect to the '490 and '090 patents. Specifically, with respect to the '553 patent, the ID found that: (1) iLife directly infringes claims 1 and 4, but not claims 11, 12, 13, and 22; (2) iLife has not induced or contributed to infringement of the patent; (3) iRobot has satisfied the technical prong of the domestic industry requirement; (4) claim 1, but not claims 11 and 12, is invalid for anticipation; and (5) claims 4, 12, 13, and 22 are not invalid for obviousness. With respect to the '490 patent, the ID found that: (1) iLife and bObsweep directly infringe claim 42, but not claims 1 and 12, and Hoover directly infringes claim 42; (2) iLife, Hoover, bObsweep, and SSSIT have not induced or contributed to infringement of the patent; (3) iRobot has satisfied the technical prong of the domestic industry requirement; (4) claim 1, but not claim 12, is invalid for anticipation: (5) claims 12 and 42 are invalid for obviousness; and (6) claims 1 and 42 are not invalid for indefiniteness. With respect to the '090 patent, the ID found that: (1) iLife, Hoover, SSSIT, and bObsweep directly infringe claims 1, 2, 3, 5, 7, and 10, but not claim 17; (2) iLife, Hoover, bObsweep, and SSSIT have not induced or contributed to infringement of the patent; (3) iRobot has satisfied the technical prong of the domestic industry requirement; (4) claims 1, 5, 7, 10, and 17 are not invalid for anticipation; and (5) claims 1, 2, 3, 4, 5, 7, 10, and 17 are invalid for obviousness in view of certain prior art combinations, but not others. With respect to the '233 patent,

the ID found that: (1) iLife and bObsweep directly infringe claims 1, 10, 11, 14, 15, and 16 and Hoover directly infringes the same claims with respect to the Hoover Quest 1000 products, but not the Hoover Rogue/Y1 and Hoover Y2 products; (2) iLife, Hoover, bObsweep, and SSSIT have not induced or contributed to infringement of the patent; (3) iRobot has satisfied the technical prong of the domestic industry requirement; and (4) claims 1, 10, 11, 14, 15, and 16 of the '233 patent are not invalid for anticipation, obviousness, nor lack of written description. The ID found that iRobot has satisfied the economic prong of the domestic industry requirement under 19 U.S.C. 1337(a)(3)(C) with respect to all asserted patents.

The ALJ also issued a Recommended Determination on Remedy and Bond (''RD''), recommending, if the Commission finds a section 337 violation, the issuance of (1) a limited exclusion order against certain robotic vacuum cleaning devices and components thereof that are imported, sold for importation, and/or sold after importation by Hoover, bObsweep, SSSIT, and iLife, (2) cease and desist orders against Hoover and iLife, and (3) imposition of a bond of 18.89 percent of the entered value for iLife products, 48.65 percent for bObsweep products, and 41.35 percent for Hoover products that are imported during the period of Presidential review.

On July 9, 2018, iRobot and Respondents each filed a petition for review challenging various findings in the final ID. On July 17, 2018, iRobot and Respondents each filed responses to the petitions for review.

On July 16, 2018, the Commission determined that iRobot satisfied the economic prong of the domestic industry requirement under 19 U.S.C. 1337(a)(3)(B). Notice (July 16, 2018) (determining to affirm with modifications Order No. 39 (Feb. 13, 2018)).

On July 25, 2018, iRobot filed post-RD statements on the public interest under Commission Rule 210.50(a)(4). The Commission did not receive any post-RD public interest comments from any respondent pursuant to Commission Rule 210.50(a)(4). The Commission did not receive comments from the public in response to the Commission notice issued on July 10, 2018 soliciting public interest comments. 83 FR 31977 (July 10, 2018).

On September 12, 2018, the Commission determined to review in part the final ID. 83 FR 47188 (Sept. 18, 2018). Specifically, the Commission determined to review the ID's findings on: (1) Induced and contributory infringement with respect to the '553, '490, '090, and '233 patents; (2) anticipation with respect to the asserted claims of the '553 patent; (3) obviousness with respect to the asserted claims of the '553 patent; (4) direct infringement of the '090 patent by iLife, Hoover, bObsweep, and SSSIT; (5) anticipation with respect to the asserted claims of the '090 patent; (6) obviousness with respect to the asserted claims of the '090 patent; (7) anticipation with respect to the asserted claims of the '233 patent; and (8) consideration of U.S. Patent No. 6,594,844 as prior art under 35 U.S.C. 102(a) and 35 U.S.C. 103 with respect to the '233 patent. The Commission also requested briefing from the parties on certain issues under review and briefing from the parties, interested government agencies, and interested persons on the issues of remedy, the public interest, and bonding.

On September 19, 2018, iRobot filed an unopposed motion to terminate the investigation as to iLife based on a settlement agreement and, because the '553 patent is asserted against iLife only, all claims asserted under the '553 patent for mootness. On October 2, 2018, the Commission determined to grant that motion. Notice (Oct. 2, 2018). Thus, the respondents remaining in this investigation are Hoover, bObsweep, and SSSIT, and the remaining asserted patents are the '490, '090, and '233 patents.

On September 24, 2018, iRobot and the remaining respondents filed initial written submissions addressing the Commission's questions and the issues of remedy, the public interest, and bonding. On October 1, 2018, the parties filed response briefs. No comments were received from the public.

Having examined the record of this investigation, including the ID and the parties' submissions, the Commission has determined to affirm, on modified grounds, the ID's finding of a violation as to the '233 patent and no violation as to the '490 and '090 patents. Specifically, the Commission has determined that Hoover, bObsweep, and SSSIT have not induced or contributed to infringement of the '490, '090, and '233 patents. With respect to the '090 patent, the Commission has determined that the Hoover, SSSIT, and bObsweep bObi products meet all limitations of claims 1, 2, 3, 5, 7, 10, and 17, and that the asserted claims are invalid for obviousness, but not invalid for anticipation. With respect to the '233 patent, the Commission has determined that claims 1, 10, 11, 14, 15, and 16 are not invalid for anticipation nor obviousness. The Commission has determined to adopt all findings and conclusions in the final ID that are not inconsistent with the Commission's opinion issued herewith.

The Commission has determined the appropriate remedy is a limited exclusion order prohibiting Hoover, bObsweep, and SSSIT from importing certain vacuum cleaning devices and components thereof, such as spare parts, that infringe one or more of claims 1, 10, 11, 14, 15, and 16 of the '233 patent, as well as cease and desist orders against Hoover and bObsweep prohibiting them from, *inter alia,* selling or distributing within the United States such products. The Commission has determined the public interest factors enumerated in section 337(d)(1) and (f)(1) do not preclude issuance of the limited exclusion order or cease and desist orders.

The Commission has also determined to set a bond in the following percentages of the entered value of the respondents' infringing products during the period of Presidential review (19 U.S.C. 1337(j)): 48.65 percent for products that are manufactured by or on behalf of bObsweep; 41.35 percent for products that are manufactured by or on behalf of Hoover; and zero percent (no bond) for products that are manufactured by SSSIT on behalf of entities other than Hoover and bObsweep, as well as products that are manufactured on behalf of SSSIT. The Commission's orders and opinion were delivered to the President and to the United States Trade Representative on the day of their issuance.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: November 30, 2018.

Jessica Mullan,

Attorney Advisor.

[FR Doc. 2018–26522 Filed 12–6–18; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 731–TA–873–875, 878–880, and 882 (Third Review)]

Steel Concrete Reinforcing Bar From Belarus, China, Indonesia, Latvia, Moldova, Poland, and Ukraine

Determinations

On the basis of the record [1] developed in the 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 antidumping duty orders on steel concrete reinforcing bar from Belarus, China, Indonesia, Latvia, Moldova, Poland, and Ukraine 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 June 1, 2018 (83 FR 25490) and determined on September 4, 2018 that it would conduct expedited reviews (83 FR 48651, September 26, 2018).

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 November 30, 2018. The views of the Commission are contained in USITC Publication 4838 (November 2018), entitled *Steel Concrete Reinforcing Bar from Belarus, China, Indonesia, Latvia, Moldova, Poland, and Ukraine: Investigation Nos. 731–TA–873–875, 878–880, and 882 (Third Review).*

By order of the Commission.

Issued: December 3, 2018.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2018–26541 Filed 12–6–18; 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] Commissioner Meredith M. Broadbent dissenting with respect to the antidumping duty orders on steel concrete reinforcing bar from Indonesia, Latvia, and Poland.

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Reemployment Services and Eligibility Assessments (RESEA) Program Implementation Study; New Collection

AGENCY: Office of the Assistant Secretary for Policy, Chief Evaluation Office, Department of Labor.

ACTION: Notice of information collection; request for comment.

SUMMARY: The Department of Labor (DOL), as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95). This program helps to ensure that 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 on respondents is properly assessed. Currently, the Department of Labor is soliciting comments concerning the collection of data for the Reemployment Services and Eligibility Assessments (RESEA) Program Implementation Study. A copy of the proposed Information Collection Request (ICR) can be obtained by contacting the office listed below in the addressee section of this notice.

DATES: Written comments must be submitted to the office listed in the addressee section below on or before February 5, 2019.

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

Email: ChiefEvaluationOffice@dol.gov; *Mail or Courier:* Megan Lizik, Chief Evaluation Office, OASP, U.S. Department of Labor, Room S–2312, 200 Constitution Avenue NW, Washington, DC 20210. *Instructions:* Please submit one copy of your comments by only one method. All submissions received must include the agency name and OMB Control Number identified above for this information collection. Comments, including any personal information provided, become a matter of public record. They will also be summarized and/or included in the request for OMB approval of the information collection request.

FOR FURTHER INFORMATION CONTACT: Megan Lizik by email at *ChiefEvaluationOffice@dol.gov* or by phone at (202) 430–1255.

SUPPLEMENTARY INFORMATION:

I. Background: DOL funds RESEA programs across all 50 states, DC, Puerto Rico, and the Virgin Islands. States and territories use these funds to address the reemployment services needs of Unemployment Insurance (UI) claimants and to prevent and detect UI improper payments (Unemployment Insurance Program Letter 8–18). The Bipartisan Budget Act of 2018 (Pub. L. 115–123) contains requirements to ''establish and expand the use of evidence-based interventions'' in states' RESEA programs. To help meet this requirement and build evidence about RESEA, DOL is conducting an implementation study that will provide in-depth understanding of RESEA programs and their components as implemented, and how states plan to meet the requirement for evidence-based programs (including building needed evidence).

This **Federal Register** Notice provides the opportunity to comment on two new proposed information collection activities that will be used for the implementation study.

- *Semi-structured telephone interview protocols.* The evaluation team will conduct calls to RESEA state leadership in approximately 24 states to systematically gather information about RESEA program operations not available in existing documents. This includes detail on how reemployment services are provided, interactions with federal workforce programs, how eligibility assessment and enforcement are carried out, and any current and planned evaluation activities.
- *Semi-structured in-person interview protocols.* Based on the phone discussions, the evaluation team will choose approximately 10 states for three-day site visits. Each site visit will examine the population served by the RESEA programs, the structure and service components of the programs, and evaluation efforts and perspectives on Bipartisan Budget Act of 2019. These visits will involve a day of interviews with relevant RESEA state officials and a day in each of two American Job Centers (AJCs) in two separate Workforce Development Board (WDB) areas.

A separate information collection activity request will be submitted in the future for a web survey of all RESEA programs. This web survey will provide the data needed to systematically understand RESEA program operations and state plans across all RESEA grantees nationwide.

II. Desired Focus of Comments: Currently, the Department of Labor is soliciting comments concerning the

above data collection for the Evaluation to Advance Reemployment Services and Eligibility Assessments Program Evidence. DOL is particularly interested in comments that do the following:

○ 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—for example, permitting electronic submission of responses.

III. Current Actions: At this time, the Department of Labor is requesting clearance for the semi-structured interview protocols for calls and site visits affiliated with the evaluation.

Type of Review: New information collection request.

OMB Control Number: 1290—0NEW.

Affected Public: State employees of state UI agencies and staff of local Workforce Development Boards (WDBs) and staff working in AJCs.

Comments submitted in response to this request will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

ESTIMATED ANNUAL BURDEN HOURS

Type of instrument	Number of respondents [a]	Number of responses per respondent	Total number of responses	Average burden time per response (hours)	Estimated Burden Hours
Semi-structured telephone interview protocol for State RESEA administrator	[b] 8	1	8	2	16
Semi-structured in-person interview protocol for State UI staff	[c] 17	1	17	1	17
Semi-structured in-person interview protocol for Local WDB administrators	[d] 13	1	13	1	13
Semi-structured in-person interview protocol for AJC staff	[e] 40	1	40	1	40
Total	78	.....	78	.....	86

[a] We are seeking a clearance period of three years

[b] Assumes approximately 1 semi-structured interview participant on each call to approximately 24 state Unemployment Insurance agencies over the three-year clearance period (rounding to an average of 8 per year).

[c] Assumes approximately 5 semi-structured interview participants during each site visit to approximately 10 state Unemployment Insurance agencies over the three-year clearance period (rounding to an average of 17 per year).

[d] Assumes approximately 4 semi-structured interview participants during each site visit to approximately 10 local workforce boards (WDBs) over the three-year clearance period (rounding to an average of 13 per year).

[e] Assumes approximately 6 semi-structured interview participants during each site visit to approximately 20 American Jobs Centers (AJCs) over the three-year clearance period, an average of 40 per year.

Molly Irwin,

Chief Evaluation Officer, U.S. Department of Labor.

[FR Doc. 2018–26574 Filed 12–6–18; 8:45 am]

BILLING CODE 4510–HX–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards; Procedures for Meetings

Background

This notice describes procedures to be followed with respect to meetings conducted by the U.S. Nuclear Regulatory Commission's (NRC's) Advisory Committee on Reactor Safeguards (ACRS) pursuant to the Federal Advisory Committee Act (FACA). These procedures are set forth so that they may be incorporated by reference in future notices for individual meetings.

The ACRS is a statutory advisory Committee established by Congress to review and report on nuclear safety matters and applications for the licensing of nuclear facilities. The Committee's reports become a part of the public record.

The ACRS meetings are conducted in accordance with FACA; they are normally open to the public and provide opportunities for oral or written statements from members of the public to be considered as part of the Committee's information gathering process. ACRS reviews do not normally encompass matters pertaining to environmental impacts other than those related to radiological safety.

The ACRS meetings are not adjudicatory hearings such as those conducted by the NRC's Atomic Safety and Licensing Board Panel as part of the Commission's licensing process.

General Rules Regarding ACRS Full Committee Meetings

An agenda will be published in the **Federal Register** for each full committee meeting. There may be a need to make changes to the agenda to facilitate the conduct of the meeting. The Chairman of the Committee is empowered to conduct the meeting in a manner that, in his/her judgment will facilitate the orderly conduct of business, including making provisions to continue the discussion of matters not completed on the scheduled day on another day of the same meeting. Persons planning to attend the meeting may contact the Designated Federal Officer (DFO) specified in the **Federal Register** notice prior to the meeting to be advised of any changes to the agenda that may have occurred.

The following requirements shall apply to public participation in ACRS Full Committee meetings:

(a) Persons who plan to submit written comments at the meeting should provide 35 copies to the DFO at the beginning of the meeting. Persons who cannot attend the meeting, but wish to submit written comments regarding the agenda items may do so by sending a readily reproducible copy addressed to the DFO specified in the **Federal Register** notice, care of the Advisory Committee on Reactor Safeguards, U.S.

Nuclear Regulatory Commission, Washington, DC 20555–0001. Comments should be limited to items being considered by the Committee. Comments should be in the possession of the DFO 5 days prior to the meeting to allow time for reproduction and distribution.

(b) Persons desiring to make oral statements at the meeting should make a request to do so to the DFO; if possible, the request should be made 5 days before the meeting, identifying the topic(s) on which oral statements will be made and the amount of time needed for presentation so that orderly arrangements can be made. The Committee will hear oral statements on topics being reviewed at an appropriate time during the meeting as scheduled by the Chairman.

(c) Information regarding topics to be discussed, changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained by contacting the DFO.

(d) The use of still, motion picture, and television cameras will be permitted at the discretion of the Chairman and subject to the condition that the use of such equipment will not interfere with the conduct of the meeting. The DFO will have to be notified prior to the meeting and will authorize the use of such equipment after consultation with the Chairman. The use of such equipment will be restricted as is necessary to protect proprietary or privileged information that may be in documents, folders, etc., in the meeting room. Electronic recordings will be permitted only during those portions of the meeting that are open to the public.

(e) A transcript will be kept for certain open portions of the meeting and will be available in the NRC Public Document Room (PDR), One White Flint North, Room O–1F21, 11555 Rockville Pike, Rockville, Maryland 20852–2738. A copy of the certified minutes of the meeting will be available at the same location 3 months following the meeting. Copies may be obtained upon payment of appropriate reproduction charges. ACRS meeting agendas, transcripts, and letter reports are available at *pdr@nrc.gov,* or by calling the PDR at 1–800–397–4209, or from Agencywide Documents Access and Management System (ADAMS) which is accessible from the NRC website at *http://www.nrc.gov/reading-rm/adams.html* or *http://www.nrc.gov/reading-rm/doc-collections/ACRS/agenda/.*

(f) Video teleconferencing service may be available for observing open sessions of ACRS meetings. Those wishing to use this service for observing ACRS meetings should contact the ACRS Audio Visual Office, telephone: 301–415–6702, between 7:30 a.m. and 3:45 p.m. Eastern Time at least 10 days before the meeting to ensure the availability of this service. Individuals or organizations requesting this service will be responsible for telephone line charges and for providing the equipment and facilities that they use to establish the video teleconferencing link. The availability of video teleconferencing services is not guaranteed.

ACRS Subcommittee Meetings

In accordance with the revised FACA, the agency is no longer required to apply the FACA requirements to meetings conducted by the Subcommittees of the NRC Advisory Committees, if the Subcommittee's recommendations would be independently reviewed by its parent Committee.

The ACRS, however, chose to conduct its subcommittee meetings in accordance with the procedures noted above for ACRS Full Committee meetings, as appropriate, to facilitate public participation, and to provide a forum for stakeholders to express their views on regulatory matters being considered by the ACRS. When subcommittee meetings are held at locations other than at NRC facilities, reproduction facilities may not be available at a reasonable cost. Accordingly, 50 copies of the materials to be used during the meeting should be provided for distribution at such meetings.

Special Provisions When Proprietary Sessions Are To Be Held

If it is necessary to hold closed sessions for the purpose of discussing matters involving proprietary information, persons with agreements permitting access to such information may attend those portions of the ACRS meetings where this material is being discussed upon confirmation that such agreements are effective and related to the material being discussed.

The DFO should be informed of such an agreement at least five working days prior to the meeting so that it can be confirmed, and a determination can be made regarding the applicability of the agreement to the material that will be discussed during the meeting. The minimum information provided should include information regarding the date of the agreement, the scope of material included in the agreement, the project or projects involved, and the names and titles of the persons signing the agreement. Additional information may be requested to identify the specific agreement involved. A copy of the executed agreement should be provided to the DFO prior to the beginning of the meeting for admittance to the closed session.

Dated: November 30, 2018.

Russell E. Chazell,

Federal Advisory Committee Management Officer, Office of the Secretary.

[FR Doc. 2018–26506 Filed 12–6–18; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting; Cancellation

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: 83 FR 62396, 3 Dec. 2018.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: Wednesday, December 5, 2018 at 10:00 a.m.

CHANGES IN THE MEETING: The Open Meeting scheduled for Wednesday, December 5, 2018 at 10:00 a.m., has been cancelled.

CONTACT PERSON FOR MORE INFORMATION: For further information, please contact Brent J. Fields of the Office of the Secretary at (202) 551–5400.

Dated: December 4, 2018.

Brent J. Fields,

Secretary.

[FR Doc. 2018–26656 Filed 12–4–18; 4:15 pm]

BILLING CODE 8011–01–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36246]

St. Paul & Pacific Northwest Railroad Company, LLC—Change in Operators Exemption—Kettle Falls International Railway, LLC

St. Paul & Pacific Northwest Railroad Company, LLC (SPN), a noncarrier, has filed a verified notice of exemption under 49 CFR 1150.31 to assume operations over approximately 83 miles of rail lines owned by BNSF Railway Company. The lines originate at milepost 60.5 in Chewelah, Wash., extending to milepost 0.0 at Kettle Falls, Wash., where the line diverges into two branches (the Lines). The West Branch continues northwest from Kettle Falls to milepost 4.7 at West Kettle Falls, Wash. The East Branch continues northeast to the United States-Canada border at milepost 139.7 and across the border at milepost 139.7 to Columbia Gardens,

B.C., Canada.[1] The verified notice indicates that the Lines are currently operated by Kettle Falls International Railway LLC (KFR), and that as a result of this transaction, SPN will become a Class III carrier and replace KFR as the Line's exclusive lessee and operator.

This transaction is related to a concurrently filed verified notice of exemption in *Progressive Rail Incorporated—Continuance in Control Exemption—St. Paul & Pacific Northwest Railroad Company,* Docket No. FD 36254, in which Progressive Rail Incorporated seeks to continue in control of SPN upon SPN's becoming a Class III rail carrier.

SPN certifies that the underlying lease and operation agreement does not contain an interchange commitment. SPN also certifies that its projected revenues as a result of this proposed transaction will not exceed those that would result in the creation of a Class II or Class I rail carrier but notes that they will exceed $5 million. PGR filed the certification of notice to employees required under 49 CFR 1150.42(e) on November 1, 2018. Further, under 49 CFR 1150.32(b), a change in operator requires that notice be given to shippers. SPN certifies that notice of the change in operator was served on all known shippers on the Lines.

The earliest this transaction may be consummated is December 31, 2018, the effective date of the exemption (60 days after the Section 1150.42(e) certification was filed). SPN states that it expects to consummate the underlying transaction on receipt of all regulatory approvals, anticipated to be no later than January 1, 2019.

If the notice contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than December 24, 2018 (at least seven days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 36246, must be filed with the Surface Transportation Board, 395 E Street SW, Washington, DC 20423. In addition, one copy of each pleading must be served on Bradon J. Smith, Fletcher & Sippel LLC, 29 North Wacker Drive, Suite 800, Chicago, Ill. 60606.

Board decisions and notices are available on our website at *www.stb.gov.*

Decided: December 3, 2018.

By the Board, Scott M. Zimmerman, Acting Director, Office of Proceedings.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2018–26581 Filed 12–6–18; 8:45 am]

BILLING CODE 4915–01–P

[1] SPN clarifies, for Board jurisdictional purposes, that the relevant distance of the East Branch from Chewelah to the international border is approximately 79 miles. It further states that the additional four miles of West Branch track it will lease makes the total to be leased by SPN approximately 83 miles of track.

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36254]

Progressive Rail Incorporated—Continuance in Control Exemption—St. Paul & Pacific Northwest Railroad Company, LLC

Progressive Rail Incorporated (PGR), a Class III rail carrier, has filed a verified notice of exemption under 49 CFR 1180.2(d)(2) to continue in control of St. Paul & Pacific Northwest Railroad Company, LLC (SPN), upon SPN's becoming a Class III rail carrier.

This transaction is related to a concurrently filed verified notice of exemption in *St. Paul & Pacific Northwest Railroad Company, LLC—Change in Operators Exemption—Kettle Falls International Railway LLC,* Docket No. FD 36246. In that proceeding, SPN seeks to assume operations over approximately 83 miles of rail line owned by BNSF Railway Company, that extends north from Chewelah, Wash., to Kettle Falls, Wash., where the line branches; the West Branch continues northwest to West Kettle Falls, Wash., and the East Branch continues northeast across the United States-Canada border at milepost 139.7 and on to Columbia Gardens, B.C., Canada. PGR states that SPN is a new entity established by PGR to lease and operate those lines.

The earliest this transaction may be consummated is December 20, 2018, the effective date of the exemption (30 days after the verified notice was filed). PGR states that it intends to consummate the transaction concurrently with SPN's commencement of operations pursuant to Docket No. FD 36246, on or about January 1, 2019.

PGR will continue in control of SPN upon SPN's becoming a Class III rail carrier, while remaining in control of eight other Class III carriers: Airlake Terminal Railway Company, LLC; Central Midland Railway Company; Iowa Traction Railway Company; Iowa Southern Railway Company; Piedmont & Northern Railroad, LLC; Chicago Junction Railway Company; St. Paul & Pacific Railroad Company, LLC; and Clackamas Valley Railway Company, LLC.

PGR verifies that: (1) The rail lines do not connect with the lines of PGR or of the lines of any of the other eight Class III rail carriers controlled by PGR; (2) this continuance in control transaction is not part of a series of anticipated transactions that would result in such a connection; and (3) the transaction does not involve a Class I rail carrier. Therefore, the transaction is exempt from the prior approval requirements of 49 U.S.C. 11323. *See* 49 CFR 1180.2(d)(2).

Under 49 U.S.C. 10502(g), the Board may not use its exemption authority to relieve a rail carrier of its statutory obligation to protect the interests of its employees. Section 11326(c), however, does not provide for labor protection for transactions under sections 11324 and 11325 that involve only Class III rail carriers. Accordingly, the Board may not impose labor protective conditions here because all the carriers involved are Class III carriers.

If the notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than December 13, 2018 (at least seven days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 36254, must be filed with the Surface Transportation Board, 395 E Street SW, Washington, DC 20423. In addition, one copy of each pleading must be served on Bradon J. Smith, Fletcher & Sippel LLC, 29 North Wacker Drive, Suite 800, Chicago, Ill. 60606.

Board decisions and notices are available on our website at *www.stb.gov.*

Decided: December 3, 2018.

By the Board, Scott M. Zimmerman, Acting Director, Office of Proceedings.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2018–26582 Filed 12–6–18; 8:45 am]

BILLING CODE 4915–01–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36252]

North Carolina & Virginia Railroad Company, L.L.C., Chesapeake & Albemarle Railroad Division—Lease Amendment and Operation Exemption Including Interchange Commitment—Norfolk Southern Railway Company

Chesapeake & Albemarle Railroad (CA), a Class III railroad and division of North Carolina & Virginia Railroad Company, L.L.C. (NCVA), has filed a verified notice of exemption under 49 U.S.C. 10902 to enter into a superseding and replacement lease with Norfolk Southern Railway Company (NSR) and operate lines of railroad between (1) milepost NS 4.00 at Providence Junction, Va., and milepost NS 8.00 at Butts, Va., (2) milepost NS 8.00 at Butts, Va., and milepost NS 73.59 at Edenton, N.C., and (3) milepost WK 0.00 at Elizabeth City, N.C., and milepost WK 7.48 at Weeksville, N.C. (collectively, the Line). The Line totals approximately 77.07 miles.

CA and NSR entered into a lease in 1990, which covered lines between (1) milepost NS 8.00, and milepost NS 74.00, and (2) milepost WK 0.00, and milepost WK 7.48 (Original Lease).[1] A 2003 amendment added a line between milepost NS 4.00, and milepost NS 8.00.[2] In 2004 and 2007, the Board issued abandonment and discontinuance of service exemptions for line included in the Original Lease between (1) milepost NS 73.67 and milepost NS 74.00 at Edenton, N.C.,[3] and (2) milepost NS 73.59 and milepost NS 73.67 at Edenton, N.C.[4] In 2011, CA and NSR added an amendment to extend the term of the Original Lease and strike all provisions relating to the option to purchase.[5] Now, CA explains that the Original Lease has expired, and CA and NSR have reached a new Lease Agreement (New Lease). CA and NSR intend the New Lease to supersede and replace the Original Lease and extend the term for an additional 10 years. CA declares that it currently operates the Line pursuant to the Original Lease and will continue to operate the Line under the New Lease.[6]

According to CA, the New Lease includes an interchange commitment that is similar in structure to the interchange commitment included in the Original Lease. As required under 49 CFR 1150.43(h)(1), CA provided additional information regarding the interchange commitment.

CA does not project that this transaction will result in annual revenues significant enough to establish a Class I or Class II rail carrier. Additionally, CA confirms that its total revenues will not exceed $5 million after the transaction; however, CA states that NCVA, of which CA is a division, will have revenues over $5 million following the transaction. Accordingly, CA is required by Board regulations to send notice of the transaction to the national offices of the labor unions with employees on the affected lines at least 60 days before this exemption is to become effective, to post a copy of the notice at the workplace of the employees on the affected lines, and to certify to the Board that it has done so. 49 CFR 1150.42(e).

CA requests a waiver of the 60-day advance labor notice requirement under 49 CFR 1150.42(e). In that request, CA argues that: (1) No employees of the transferring carrier, NSR, will be affected by the lease and no employees of NSR have worked on any part of the Line since 2003 and therefore, posting notices would be futile because no NSR employees work on the Line and (2) there will be no operational changes and no CA employees will be affected by the lease. CA's waiver request will be addressed in a separate decision.

CA states that it expects to consummate the transaction on the effective date of this exemption. The Board will establish the effective date in its separate decision on the waiver request.

If the notice contains false or misleading information, the exemption is void *ab initio*. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed at least seven days before the exemption becomes effective.

An original and 10 copies of all pleadings, referring to Docket No. FD 36252, must be filed with the Surface Transportation Board, 395 E Street SW, Washington, DC 20423–0001. In addition, a copy of each pleading must be served on Eric M. Hocky, Clark Hill PLC, One Commerce Square, 2005 Market Street, Suite 1000, Philadelphia, PA 19103.

Board decisions and notices are available on our website at *www.stb.gov*.

Decided: December 3, 2018.

By the Board, Scott M. Zimmerman, Acting Director, Office of Proceedings.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2018–26575 Filed 12–6–18; 8:45 am]

BILLING CODE 4915–01–P

[1] *Chesapeake & Albemarle R.R.—Lease, Acquis. & Operation Exemption—S. Ry.,* FD 31617 (ICC served Apr. 17, 1990).

[2] *N.C. & Va. R.R.—Lease & Operation Exemption—Norfolk S. Ry.,* FD 34272 (STB served Jan. 22, 2003).

[3] *Norfolk S. Ry.—Aban. Exemption—in Chowan Cty., N.C.,* AB 290 (Sub-No. 251X) et al. (STB served July 16, 2004). NSR consummated the abandonment between milepost NS 73.67 and milepost NS 74.00.

[4] The verified notices filed by NSR and CA describe the line to be abandoned and discontinued as between milepost NS 73.59 and milepost NS 73.67. Likewise, NSR consummated the abandonment between milepost NS 73.59 and milepost NS 73.67. Therefore, it appears this milepost was erroneously stated as 73.50 in the published notice. *See Norfolk S. Ry.—Aban. Exemption—in Chowan Cty., N.C.,* AB 290 (Sub-No. 295X) et al. (STB served Aug. 9, 2007).

[5] *N.C. & Va. R.R., Chesapeake & Albemarle R.R. Div.—Lease Amendment Exemption—Norfolk S. Ry.,* FD 35564 (Sub-No. 1) (STB served Dec. 16, 2011).

[6] The Original Lease, as amended in 2011, appears to have included line from mileposts NS 73.59 to NS 74.00, which had been abandoned prior to the 2011 lease amendment. CA does not state whether it continued to operate over that abandoned line after the 2011 renewal.

TENNESSEE VALLEY AUTHORITY

Environmental Impact Statement for Gallatin Fossil Plant Surface Impoundment Closure and Restoration Project

AGENCY: Tennessee Valley Authority.

ACTION: Notice of intent.

SUMMARY: The Tennessee Valley Authority (TVA) intends to prepare an Environmental Impact Statement (EIS) to address the potential environmental effects associated with management of coal combustion residual (CCR) material at the Gallatin Fossil Plant (GAF) located near Gallatin in Sumner County, Tennessee. The purpose of the EIS is to address the final disposition of CCR onsite at GAF, support TVA's goal to eliminate wet CCR storage at its plants, and assist TVA in complying with the U.S. Environmental Protection Agency's (EPA's) CCR Rule. The proposed actions would also provide long-term on-site landfill space for operations and/or storage of CCR. TVA will develop and evaluate various alternatives for these actions, including the No Action Alternative. Public comments are invited concerning both the scope of the review and environmental issues that should be addressed.

DATES: Comments on the scope of the EIS must be received on or before January 11, 2019.

ADDRESSES: Comments may be submitted in writing to Ashley Farless, NEPA Specialist, 1101 Market Street, BR4A–C, Chattanooga, TN, 37402. Comments may also be submitted online

at: *https://www.tva.gov/nepa* or by email to *CCR@tva.gov.*

FOR FURTHER INFORMATION CONTACT: Other related questions should be sent to Tennessee Valley Authority, Ashley Farless, NEPA Specialist, 1101 Market Street, BR4A–C, Chattanooga, TN, 37402, Phone 423.751.2361 or *arfarless@tva.gov.*

SUPPLEMENTARY INFORMATION: This notice is provided in accordance with the Council on Environmental Quality's regulations (40 CFR parts 1500 to 1508) for implementing the National Environmental Policy Act (NEPA), TVA's procedures for implementing NEPA, and Section 106 of the National Historic Preservation Act (NHPA) and its implementing regulations (36 CFR part 800).

TVA Power System and CCR Management

TVA is a corporate agency and instrumentality of the United States created by and existing pursuant to the TVA Act of 1933 that provides electricity for business customers and local power distributors. TVA serves more than 9 million people in parts of seven southeastern states. TVA receives no taxpayer funding, deriving virtually all of its revenues from sales of electricity. In addition to operating and investing its revenues in its electric system, TVA provides flood control, navigation and land management for the Tennessee River system and assists local power companies and state and local governments with economic development and job creation.

The GAF is located in Sumner County, Tennessee, on 1,950 acres of land on the north bank of the Cumberland River. The plant has four turbo-generating units with a combined summer net generating capacity of 976 megawatts. The plant consumes an average of 3.5 million tons of coal per year which results in the annual production of approximately 255,000 tons of CCR. This CCR is the byproduct produced from burning coal and includes fly ash, bottom ash, boiler slag, and flue gas desulfurization materials. Historically, GAF stored CCR wet in onsite surface impoundments (commonly referred to as ash ponds). Bottom ash and boiler slag are the only remaining CCRs currently sent to the ponds. Newly installed air emission controls at GAF allow the majority of CCR to be stored dry in the North Rail Loop Landfill located at GAF, a state-of-the-art lined and state permitted facility. When the construction of a new bottom ash dewatering facility is finished in 2020, the plant will have completed its transition from wet CCR handling to dry handling of all CCR.

Background

In July 2009, the TVA Board of Directors passed a resolution for staff to review TVA practices for storing CCRs at its generating facilities, including GAF, which resulted in a recommendation to convert the wet ash management system at GAF to a dry storage system. On April 17, 2015, the EPA published the final Disposal of CCRs from Electric Utilities rule, also known as the CCR Rule.

In June 2016, TVA issued a Final Programmatic Environmental Impact Statement (PEIS) that analyzed methods for closing CCR impoundments at TVA fossil plants and identified specific screening and evaluation factors to help frame its evaluation of closures at its other facilities. A Record of Decision was released in July 2016 that would allow future environmental reviews of qualifying CCR impoundment closures to tier from the PEIS. This PEIS can be found at *www.tva.com/nepa.*

Alternatives

The EIS will examine closure of the following surface impoundments: Ash Pond A, Ash Pond E, Middle Pond A and a Non-Registered Site. In addition, TVA will examine removal of CCR from on-site Stilling Ponds and permanent disposition of CCR from the Bottom Ash Pond at Gallatin. TVA is performing a separate NEPA review for a project at Gallatin that could result in a temporary stockpile of CCR from the Bottom Ash Pond in the on-site landfill (North Rail Loop Landfill). The Bottom Ash Pond CCR would be temporarily stockpiled to make the most efficient use of property at GAF. Whether the Bottom Ash Pond CCR remains in its current location onsite at GAF or is temporarily stockpiled to allow TVA to make use of real estate available onsite, the final disposition of the Bottom Ash Pond CCR will be addressed in this EIS. Construction of a new on-site landfill will be examined as well as construction of a CCR beneficial re-use facility.

In addition to a No Action Alternative, this EIS will address alternatives that meet the purpose and need for the project. One alternative identified by TVA is closure of all surface impoundments and stilling ponds via closure-by-removal with construction of a new on-site landfill. The CCR material removed in this closure-by-removal alternative would be disposed of in a new on-site landfill and/or a beneficial re-use facility. Another alternative identified by TVA is closure of all surface impoundments and stilling ponds via closure-in-place with construction of a new on-site landfill that would be used to support ongoing long-term plant operations. TVA could also consider a combination closure-in-place and closure-by-removal alternative(s).

No decision has been made about CCR storage at GAF beyond the current operations. TVA is preparing this EIS to inform decision makers, other agencies and the public about the potential for environmental impacts associated with management of CCR at GAF.

Proposed Resources and Issues To Be Considered

This EIS will identify the purpose and need of the project and will contain descriptions of the existing environmental and socioeconomic resources within the area that could be affected by management of CCR at GAF. Evaluation of potential environmental impacts to these resources will include, but not be limited to, water quality, aquatic and terrestrial ecology, threatened and endangered species, wetlands, land use, historic and archaeological resources, solid and hazardous waste, safety, and socioeconomic and environmental justice issues. The final range of issues to be addressed in the environmental review will be determined, in part, from scoping comments received. The preliminary identification of reasonable alternatives and environmental issues in this notice is not meant to be exhaustive or final.

Public Participation

TVA is interested in an open process and wants to hear from the community. The public is invited to submit comments on the scope of this EIS no later than the date identified in the ''Dates'' section of this notice. Federal, state, local agencies and Native American Tribes are invited to provide comments.

After consideration of comments received during the scoping period, TVA will develop and distribute a scoping document that will summarize public and agency comments that were received and identify the schedule for completing the EIS process. Following analysis of the issues, TVA will prepare a draft EIS for public review and comment. In making its final decision, TVA will consider the analyses in this EIS and substantive comments that it receives. A final decision on proceeding with the management and storage of CCRs at GAF will depend on a number of factors. These include results of the EIS, requirements of the CCR Rule,

relevant state law requirements, engineering and risk evaluations, financial considerations, as well as the resolution of ongoing litigation concerning Gallatin.

TVA anticipates holding a community meeting near the plant after releasing the Draft EIS. Meeting details will be posted on TVA's website. TVA expects to release the Draft EIS in the Fall 2019.

Authority: 40 CFR 1501.7.

M. Susan Smelley,

Director, Environmental Compliance and Operations.

[FR Doc. 2018–26531 Filed 12–6–18; 8:45 am]

BILLING CODE 8120–08–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Dockets No. FMCSA–2017–0243, FMCSA–2017–0296, FMCSA–2017–0337, FMCSA–2017–0340, FMCSA–2017–0342, FMCSA–2017–0356, FMCSA–2017–0361, FMCSA–2017–0373, FMCSA–2018–0003, FMCSA–2017–0336]

Hours of Service (HOS) of Drivers; Applications for Exemption From the Electronic Logging Device Rule

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of final disposition; denial of applications for exemption.

SUMMARY: As required by statute, FMCSA announces denials of 10 applications for exemptions from the hours-of service (HOS) electronic logging device (ELD) rule. The applicants are as follows: Power and Construction Contractors Association; Western Equipment Dealers Association; Association of Energy Service Companies; Cudd Energy Services, Inc.; SikhsPAC and North American Punjabi Trucker Association; Owner- Operator Independent Drivers Association, Inc.; American Disposal Service; Towing and Recovery Association of America; National Electrical Contractors Association; and the Agricultural Retailers Association. The Agency reviewed each application and any comments received and rendered each decision based upon the merits of the application.

DATES: On June 16, 2018, FMCSA denied 9 applications for exemption and on July 26, 2018, the Agency denied the application of the Agricultural Retailers Association.

FOR FURTHER INFORMATION CONTACT: Ms. Pearlie Robinson, FMCSA Driver and Carrier Operations Division; Office of Carrier, Driver and Vehicle Safety Standards; Telephone: 202–366–4325. Email: *MCPSD@dot.gov.*

SUPPLEMENTARY INFORMATION:

Background

FMCSA has authority under 49 U.S.C. 31136(e) and 31315 to grant exemptions from certain parts of the Federal Motor Carrier Safety Regulations. FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including any safety analyses that have been conducted. The Agency must provide an opportunity for public comment on the request.

The Agency reviews safety analyses and public comments submitted and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305). The decision of the Agency must be published in the **Federal Register** (49 CFR 381.315(b)) with the reasons for denying or granting the application and, if granted, the name of the person or class of persons receiving the exemption, and the regulatory provision from which the exemption is granted. In the case of denials, 49 U.S.C. 31315 explicitly states that the Agency may meet the requirements by periodically publishing in the **Federal Register** the names of persons denied exemptions and the reasons for the denials.

Applications for Exemption

The current hours-of-service (HOS) regulations in 49 CFR 395.8(a) require motor carriers subject to the regulation to ensure their drivers use ELDs in place of written logs to record their duty status for each 24-hour period. Additionally, Part 395 lists certain ELD exceptions for short-haul operations within a 100 air-mile radius and agricultural operations within a 150 air-mile radius.

The 10 applicants cited below applied for an exemption from the requirement to use an ELD to record HOS for drivers subject to the regulation for various reasons. FMCSA published **Federal Register** notices requesting public comment on each application. Each notice established a docket to provide the public an opportunity to inspect the application and other docketed information, such as comments of others submitted to the docket. Details of the Agency's analysis follows.

Power and Construction Association (PCCA)

The PCCA requested that motor carriers and drivers operating commercial motor vehicles (CMVs) in the power and communication construction industry be allowed to use paper records of duty status (RODS) instead of ELDs. PCCA noted that construction contractors spend considerable time off-road on varying jobsites; a single CMV may have several different drivers over the course of a day, moving the vehicle short distances around the jobsite. Due to the limited time that their drivers spend driving on public roads within a workday, PCCA states that the ELD and RODS requirements for drivers in its industries do not result in a significant safety benefit.

FMCSA reviewed the application and the 259 public comments submitted. On June 16, 2018, FMCSA denied PCCA's application for exemption because the Agency could not ensure that the exemption would provide the requisite level of safety. A copy of the denial letter is available for review in the docket (FMCSA–2017–0243).

Western Equipment Dealers Association (WEDA)

WEDA requested this exemption from ELD use on behalf of several organizations and their members. Effectively, the requested exemption would eliminate the requirement for agricultural equipment dealers to install ELDs on their CMVs. WEDA stated that equipment dealer operations in agriculture present unique circumstances that warrant the requested exemption and that the failure to grant it would pose an undue burden on equipment dealers and their customers without a measurable safety benefit.

FMCSA reviewed the application and the 125 public comments submitted. On June 16, 2018, FMCSA denied WEDA's application for exemption because the Agency could not ensure that the exemption would provide the requisite level of safety. A copy of the denial letter is available for review in the docket (FMCSA–2017–0296).

Association of Energy Service Companies (AESC)

AESC requested this exemption to allow all drivers of well service rigs to complete paper RODS instead of using an ELD whenever the drivers exceeded the requirements of the short-haul exception. According to AESC, complying with the ELD requirement would be overly burdensome for well

service rig contractors without providing any measurable safety benefit. AESC further explained that well service rig drivers spend very little time on public roads, in contrast to long-haul truck drivers who spend most of their on-duty hours driving on public roads.

FMCSA reviewed the application and the 8 public comments submitted. On June 16, 2018, FMCSA denied AESC's application for exemption because the Agency could not ensure that the exemption would provide the requisite level of safety. A copy of the denial letter is available for review in the docket (FMCSA–2017–0337).

Cudd Energy Services, Inc. (CES)

CES requested an exemption from the ELD requirements for its specially trained drivers of specially constructed CMVs used in oilfield operations to allow drivers of these infrequently driven CMVs to complete paper RODS instead of using an ELD. FMCSA regulations prohibit these drivers from using the short-haul exceptions to the HOS rules. CES believes that the exemption would not have any adverse impacts on operational safety because drivers would remain subject to the HOS regulations as well as the requirements to maintain paper RODS.

FMCSA reviewed the application and the 8 comments submitted. None of the comments supported the exemption. On June 16, 2018, FMCSA denied AESC's application for exemption because the Agency could not ensure that the exemption would provide the requisite level of safety. A copy of the denial letter is available for review in the docket (FMCSA–2017–0340).

SikhsPAC and North American Punjabi Trucker Association (Applicants)

These applicants requested an exemption from the ELD requirements on behalf of their members (fresh produce shippers and small truck businesses). According to the applicants, many of their members were not fully prepared to meet the December 18, 2017, compliance date. The exemption would allow members involved in segments of America's agricultural transportation industry to delay using ELDs for one year. The applicants asserted that the exemption, if granted, would give the marketplace time necessary to develop cost-effective and practical solutions for the specific needs of impacted stakeholders and would allow FMCSA time to address training programs with compliant ELD options.

FMCSA reviewed the application and the 41 comments submitted. On June 16, 2018, FMCSA denied the application. The information provided by the applicants failed to distinguish the drivers who would be included under the exemption. The applicants failed to indicate how they could ensure that the exemption would achieve a level of safety equivalent to, or greater than, the level of safety that would be obtained by compliance with the HOS regulation. A copy of the denial letter is available for review in the docket (FMCSA–2017–0342).

Owner-Operator Independent Drivers Association, Inc. (OOIDA)

OOIDA requested a five-year exemption from the ELD rule for certain motor carriers considered to be a small transportation trucking business under 13 CFR 121.201. If granted, the exemption would cover small trucking businesses that do not have a carrier safety rating of ''unsatisfactory,'' and that can document a proven history of safety performance with no attributable at-fault crashes.

FMCSA reviewed the application and approximately 4,090 comments submitted. An estimated 96 percent of the comments were from owner-operators in favor of the exemption. Approximately 4 percent of the comments were in opposition to the proposed exemption. On June 16, 2018, FMCSA denied the application. FMCSA noted that most of the content of the application challenges the basis of the ELD rule itself, rather than justifying an exemption for a specific segment of drivers under applicable statutory standards. FMCSA noted further that the application provided no consideration of the significant difficulty that would be encountered in trying to identify and validate drivers who meet the proposed exemption criteria, especially during roadside inspections. A copy of the denial letter is available for review in the docket (FMCSA–2017–0356).

American Disposal Service (ADS)

ADS is a trash hauling and recycling company operating in four States, with over 300 drivers who hold CDLs. ADS has been using the multiple stop rule, ''treating all the stops in a village, town or city as one.'' ADS operations fall under the 100 air-mile short haul exemption in Section 395.1(e)(1). When drivers exceed the 12-hour limitation more than 8 times in any 30 consecutive days, ADS is required to install and use ELDs in its CMVs.

ADS applied for the exemption from the ELD and paper RODS requirements because the company does not believe ELDs can accurately record driving time when the CMV makes constant short movements with the driver often exiting the vehicle. FMCSA reviewed the application and the 10 comments submitted. On June 16, 2018, FMCSA denied the application. FMCSA concluded that ADS had not clearly explained how its non-use of ELDs and its discontinued use of paper RODS would reach the current level of safety that compliance with the HOS rules provides. A copy of the denial letter is available for review in the docket (FMCSA–2017–0361).

Towing and Recovery Association of America (TRAA)

TRAA is the national towing association representing more than 35,000 towing companies in all 50 states. TRAA has requested a 5-year exemption for all operators of CMVs owned or leased to providers of motor vehicle towing, recovery, and roadside repair services while providing such services. TRAA states that towing industry operations represent a unique and vital segment of the overall transportation industry in America that warrants exemption from the ELD regulations. TRAA believes that failure to grant the exemption will cause confusion and create an overly complex regulatory framework that will pose an undue burden on towers and their customers without any measurable benefit to public safety.

FMCSA reviewed the application and the 250 comments submitted. On June 16, 2018, FMCSA denied the application. FMCSA concluded that TRAA's plan for the continued use of paper RODS and the process for reviewing the RODS to verify accuracy would be comparable to the level of safety provided by paper RODS prior to the implementation of the ELD rule but would not achieve the equivalent level of safety that would be achieved by the use of ELDs. A copy of the denial letter is available for review in the docket (FMCSA–2017–0373).

National Electrical Contractors Association (NECA)

NECA requested an exemption from the requirement to use an ELD on CMVs used by 4,000 contractor members who install, repair, and maintain the infrastructure of electrical utilities. NECA believes the ELD requirement burdens its members' operations unnecessarily. It proposed to continue to use paper logs to record their HOS.

FMCSA reviewed the application and the 275 comments submitted. Many of the comments were form letters in support of the application. On June 16, 2018, FMCSA denied the application. FMCSA was unable to determine from

the application and the public comments whether operations under the requested exemption would provide a requisite level of safety. A copy of the denial letter is available for review in the docket (FMCSA–2018–0003).

Agricultural Retailers Association (ARA)

ARA applied for exemption from the ELD requirement on behalf of its members who are retailers and distributors of farm-related products and services. ARA members rely on CMVs to deliver their products and services to farms. ARA asserted that its members were not prepared to meet the December 18, 2017 deadline for complying with the ELD rule and sought to obtain postponement of the deadline.

FMCSA reviewed the application and the 117 comments submitted. On July 26, 2018, FMCSA denied the application. FMCSA was unable to determine from the application and the public comments whether operations under the requested exemption would provide a requisite level of safety. A copy of the denial letter is available for review in the docket (FMCSA–2017–0336).

Conclusion

FMCSA has reviewed these applications carefully and the comments received and has concluded that each application lacks sufficient merit to justify the exemptions sought. Accordingly, FMCSA denies each application.

Issued on: November 30, 2018.

Raymond A. Martinez,

Administrator.

[FR Doc. 2018–26597 Filed 12–6–18; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

U.S. Merchant Marine Academy Board of Visitors

AGENCY: Maritime Administration, DOT.

ACTION: Notice of U.S. Merchant Marine Academy Board Public Meeting.

SUMMARY: The U.S. Department of Transportation, Maritime Administration (MARAD) announces that the following U.S. Merchant Marine Academy (Academy) Board of Visitors (BOV) meeting will take place:

1. *Date:* December 14, 2018.
2. *Time:* 9:00 a.m.–3:00 p.m.
3. *Location:* U.S. Merchant Marine Academy, Kings Point, NY, Crabtree Room, Schuyler Otis Bland Memorial Library.
4. *Purpose of the Meeting:* The purpose of this meeting is to:

(a) Introduce the new Academy Superintendent and Academic Dean/Provost.

(b) Provide a briefing on the Critical Infrastructure Plan, the infrastructure spending plan and ongoing capital improvements.

(c) Provide an update on the general state of the Academy, Class of 2022 performance, and status of incoming class of 2023.

(d) Provide an update on the Sexual Assault/Sexual Harassment program progress.

(e) Provide an update on the status of implementing the 5-year Strategic Plan.

(f) Establish the meeting schedule for CY 2019.

5. *Public Access to the Meeting:* This meeting is open to the public. Seating is on a first-come basis. Members of the public wishing to attend the meeting will need to show photo identification to gain access to the meeting location.

FOR FURTHER INFORMATION CONTACT: The BOV's Designated Federal Officer and Point of Contact Brian Blower, 202–366–2765 or *Brian.Blower@dot.gov*.

SUPPLEMENTARY INFORMATION: Any member of the public is permitted to file a written statement with the Academy BOV. Written statements should be sent to the Designated Federal Officer at: Brian Blower; 1200 New Jersey Ave. SE W28–314, Washington, DC 20590 or via email at *Brian.Blower@Dot.gov*. (Please contact the Designated Federal Officer for information on submitting comments via fax.) Written statements must be received no later than three working days prior to the meeting in order to provide time for member consideration. Only written statements will be considered by the BOV, no member of the public will be allowed to present questions from the floor or speak to any issue under consideration by the BOV unless requested to do so by a member of the Board.

(Authority: 46 U.S.C. 51312; 5 U.S.C. app. 552b; 41 CFR parts 102–3.140 through 102–3.165).

Dated: December 3, 2018.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2018–26529 Filed 12–6–18; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

[Docket No. PHMSA–2018–0100; Notice No. 2018–22]

Hazardous Materials: Emergency Waiver No. 11

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Notice of emergency waiver order.

SUMMARY: PHMSA is issuing an emergency waiver order to persons conducting operations under the direction of Environmental Protection Agency (EPA) Region 10 or United States Coast Guard (USCG) Seventeenth District within the emergency area affected by the November 30, 2018 Alaska earthquake. The Waiver is granted to support the EPA and USCG in taking appropriate actions to prepare for, respond to, and recover from a threat to public health, welfare, or the environment caused by actual or potential oil and hazardous materials incidents resulting from the Alaska earthquake. This Waiver Order is effective immediately and shall remain in effect for 30 days from the date of issuance.

FOR FURTHER INFORMATION CONTACT: Adam Horsley, Deputy Assistant Chief Counsel for Hazardous Materials Safety, Pipeline and Hazardous Materials Safety Administration, telephone: (202) 366–4400.

SUPPLEMENTARY INFORMATION: In accordance with the provisions of 49 U.S.C. 5103(c), the Administrator for PHMSA hereby declares that an emergency exists that warrants issuance of a Waiver of the Hazardous Materials Regulations (HMR, 49 CFR parts 171–180) to persons conducting operations under the direction of EPA Region 10 or USCG Seventeenth District within the emergency area affected by the November 30, 2018 Alaska earthquake. The Waiver is granted to support the EPA and USCG in taking appropriate actions to prepare for, respond to, and recover from a threat to public health, welfare, or the environment caused by actual or potential oil and hazardous materials incidents resulting from the Alaska earthquake.

On November 30, 2018, the President issued an Emergency Declaration for the Alaska earthquake (EM–3410) for Anchorage Municipality, Kenai Peninsula Borough, and Matanuska-Susitna Borough. This Waiver Order

covers all areas identified in the declaration, as amended. Pursuant to 49 U.S.C. 5103(c), PHMSA has authority delegated by the Secretary (49 CFR 1.97(b)(3)) to waive compliance with any part of the HMR provided that the grant of the waiver is: (1) In the public interest; (2) not inconsistent with the safety of transporting hazardous materials; and (3) necessary to facilitate the safe movement of hazardous materials into, from, and within an area of a major disaster or emergency that has been declared under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 *et seq.*).

Given the continuing impacts caused by the Alaska earthquake, PHMSA's Administrator has determined that regulatory relief is in the public interest and necessary to ensure the safe transportation in commerce of hazardous materials while the EPA and USCG execute their recovery and cleanup efforts in Alaska. Specifically, PHMSA's Administrator finds that issuing this Waiver Order will allow the EPA and USCG to conduct their Emergency Support Function #10 response activities under the National Response Framework to safely remove, transport, and dispose of hazardous materials. By execution of this Waiver Order, persons conducting operations under the direction of EPA Region 10 or USCG Seventeenth District within the Alaska earthquake emergency area are authorized to offer and transport non-radioactive hazardous materials under alternative safety requirements imposed by EPA Region 10 or USCG Seventeenth District when compliance with the HMR is not practicable. Under this Waiver Order, non-radioactive hazardous materials may be transported to staging areas within 50 miles of the point of origin. Further transportation of the hazardous materials from staging areas must be in full compliance with the HMR.

This Waiver Order is effective immediately and shall remain in effect for 30 days from the date of issuance.

Issued in Washington, DC, on December 3, 2018.

Howard R. Elliott,

Administrator, Pipeline and Hazardous Materials Safety Administration.

[FR Doc. 2018–26527 Filed 12–6–18; 8:45 am]

BILLING CODE 4910–60–P

FEDERAL REGISTER

Vol. 83 Friday,

No. 235 December 7, 2018

Part II

Department of the Treasury

Internal Revenue Service

26 CFR Part 1

Guidance Related to the Foreign Tax Credit, Including Guidance Implementing Changes Made by the Tax Cuts and Jobs Act; Proposed Rule

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–105600–18]

RIN 1545–BO62

Guidance Related to the Foreign Tax Credit, Including Guidance Implementing Changes Made by the Tax Cuts and Jobs Act

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations that provide guidance relating to the determination of the foreign tax credit under the Internal Revenue Code (the ''Code''). The guidance relates to changes made to the applicable law by the Tax Cuts and Jobs Act (the ''Act''), which was enacted on December 22, 2017. Guidance on other foreign tax credit issues, including in relation to pre-Act statutory amendments, is also included in this document. The proposed regulations provide guidance needed to comply with statutory changes and affect individuals and corporations claiming foreign tax credits.

DATES: Written or electronic comments and requests for a public hearing must be received by February 5, 2019.

ADDRESSES: Send submissions to CC:PA:LPD:PR (REG–105600–18), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20224. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–105600–18), Courier's desk, Internal Revenue Service, 1111 Constitution Avenue NW, Washington, DC 20044, or sent electronically, via the Federal eRulemaking Portal at *www.regulations.gov* (indicate IRS and REG–105600–18).

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations under §§ 1.861–8 through 1.861–13, 1.861–17, and 1.904(b)–3, Jeffrey P. Cowan, (202) 317–4924; concerning the proposed regulations under §§ 1.901(j)–1, 1.904–1 through 1.904–6, 1.904(f)–12, and 1.954–1, Jeffrey L. Parry, (202) 317–4916, and Larry R. Pounders, (202) 317–5465; concerning §§ 1.78–1 and 1.960–1 through 1.960–7, Suzanne M. Walsh, (202) 317–4908; concerning §§ 1.965–5 and 1.965–7, Karen J. Cate, (202) 317–4667; concerning submissions of comments and requests for a public hearing, Regina Johnson, (202) 317–6901 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

The Act made several significant changes to the Internal Revenue Code with respect to the foreign tax credit rules and related rules for allocating and apportioning expenses for purposes of determining the foreign tax credit limitation. In particular, the Act repealed the fair market value method of asset valuation for purposes of allocating and apportioning interest expense under section 864(e)(2), added section 904(b)(4), added two foreign tax credit limitation categories in section 904(d), amended section 960(a) through (c), added section 960(d) through (f), and repealed section 902 along with making other conforming changes. The Act also added section 951A, which requires a United States shareholder of a controlled foreign corporation (''CFC'') to include certain amounts in income (a ''global intangible low-taxed income inclusion'' or ''GILTI inclusion'').

This document contains proposed regulations (the ''proposed regulations'') addressing (1) the allocation and apportionment of deductions under sections 861 through 865 and adjustments to the foreign tax credit limitation under section 904(b)(4); (2) transition rules for overall foreign loss, separate limitation loss, and overall domestic loss accounts under section 904(f) and (g), and for the carryover and carryback of unused foreign taxes under section 904(c); (3) the addition of separate categories under section 904(d) and other necessary updates to the regulations under section 904, including revisions to the look-through rules and other updates to reflect pre-Act statutory amendments; (4) the calculation of the exception from subpart F income for high-taxed income under section 954(b)(4); (5) the determination of deemed paid credits under section 960 and the gross up under section 78; and (6) the application of the election under section 965(n).

Explanation of Provisions

I. Allocation and Apportionment of Deductions and the Calculation of Taxable Income for Purposes of Section 904(a)

The foreign tax credit limitation under section 904 is determined, in part, based on a taxpayer's taxable income from sources without the United States. Regulations under sections 861 through 865 provide rules for allocating and apportioning deductions to determine, among other things, a taxpayer's taxable income from sources without the United States for purposes of applying section 904. Section 904(b)(4) makes certain adjustments to both the taxpayer's taxable income from sources without the United States and the taxpayer's entire taxable income for purposes of computing the applicable foreign tax credit limitation. Proposed §§ 1.861–8 through 1.861–13 and 1.861–17 amend existing regulations to clarify how deductions are allocated and apportioned in general, and provide new rules to account for the specific changes made to sections 864(e) and 904 by the Act. Proposed § 1.904(b)–3 provides rules regarding the application of section 904(b)(4) for purposes of determining a taxpayer's foreign tax credit limitation.

The Department of the Treasury (''Treasury Department'') and the Internal Revenue Service (''IRS'') have received comments suggesting that section 951A, in combination with section 904(d)(1)(A) (the ''section 951A category''), was intended to provide that the income of a United States shareholder derived through the CFC would be subject to additional U.S. tax if the foreign effective tax rate is below a particular rate, and should be effectively exempt from U.S. tax if the foreign effective tax rate is at or above that rate. These comments generally cite language in H.R. Rep. 115–466 (2017) (the ''Conference Report'') illustrating that no U.S. ''residual tax'' applies to foreign earnings subject to a foreign effective tax rate of 13.125 percent or more.

Allocated expenses may reduce the amount of section 951A category income included in U.S. taxable income below the amount of the foreign base on which the CFC paid at least a 13.125 percent foreign effective tax rate, with the effect that the United States shareholder's foreign taxes deemed paid may exceed the pre-credit U.S. tax on its section 951A category income, resulting in excess credits that may not offset U.S. tax on other income. This result flows from the fact that the foreign tax credit limitation under section 904 is calculated with respect to the pre-credit U.S. tax on the shareholder's net foreign source taxable income in each separate category. The comments nevertheless suggest that taxpayers' inability to reduce U.S. tax on non-section 951A category income (such as U.S. source income) with the excess credits is tantamount to imposing U.S. ''residual tax'' on section 951A category income, even though the actual U.S. tax liability on that income, as reduced by foreign tax credits, is zero. The comments suggest that in order to assure full

utilization of foreign tax credits associated with section 951A category income that is subject to a foreign effective tax rate of 13.125 percent or greater, no expenses should be allocated and apportioned to the section 951A category income.

The Treasury Department and the IRS have determined that the Act is not consistent with this view of how the section 904 limitation should apply to the section 951A category. Congress added a new separate category under section 904(d)(1) for amounts includible under section 951A and amended section 904(c) to disallow carryovers of excess foreign tax credits in that category, but did not modify the existing rules under section 904 or sections 861 through 865 to provide for special treatment of expenses allocable to the section 951A category. Other provisions added in the Act are inconsistent with the notion described by comments that Congress intended effectively to exempt section 951A category income that was subject to a certain foreign effective tax rate from U.S. tax, since those provisions may result in U.S. tax being imposed on income derived through a CFC even if the foreign effective tax rate on the income exceeds 13.125 percent. See, for example, sections 59A (limiting the benefits of foreign tax credits) and 250(a)(2)(B)(ii) (limiting the deduction under section 250 in certain cases). In addition, numerous provisions in the Code that were unamended by the Act apply by their terms to section 951A category income, also indicating that Congress did not intend to eliminate generally-applicable limitations on foreign tax credits associated with foreign earnings of a CFC even if such earnings were subject to a certain foreign effective tax rate. For example, the Act did not amend provisions that limit the availability of foreign tax credits (such as sections 901(j), (k), (l), or (m)) or that reduce (or increase) the foreign tax credit limitation in the section 951A category based on U.S. or foreign losses in other separate categories or losses in other years (sections 904(f) and (g)). These provisions apply to a GILTI inclusion and related taxes under section 960(d), and as applied the provisions are not consistent with the policy of determining allowable foreign tax credits based solely on a CFC's foreign effective tax rate because they may reduce the amount of taxes that may be credited without regard to the foreign effective tax rate of the CFC. The Act did, however, add section 904(b)(4)(B), which disregards certain deductions other than those that are ''properly allocable or apportioned to'' amounts includible under sections 951A(a) or 951(a)(1) and stock that produces amounts includible under section 951A(a) or 951(a)(1). This new provision plainly contemplates that deductions will be allocated and apportioned to the section 951A category.

Accordingly, the proposed regulations generally apply the existing approach of the expense allocation rules to determine taxable income in the section 951A category, as well as the new foreign branch category described in section 904(d)(1)(B). However, as discussed in Part I.A of this Explanation of Provisions, the proposed regulations also provide for exempt income and exempt asset treatment with respect to income in the section 951A category that is offset by the deduction allowed under section 250(a)(1) for inclusions under section 951A(a) and a corresponding percentage of the stock of CFCs that generates such income. This will generally have the effect of reducing the amount of expenses apportioned to the section 951A category.

The Treasury Department and the IRS recognize that in light of the significant reduction in the corporate tax rate and the enactment of section 951A, the foreign tax credit limitation and the related expense allocation rules will have a broader impact on taxpayers than before the Act. In particular, although all U.S. taxpayers claiming foreign tax credits were subject to the foreign tax credit limitation under section 904, many taxpayers were not significantly affected by the limitation so long as the U.S. corporate tax rate was higher than the effective foreign tax rate. In addition, the pre-Act deferral system that taxed non-passive income earned through foreign subsidiaries (and allowed deemed paid foreign tax credits) only upon repatriation allowed taxpayers to manage their foreign tax credit limitation by timing repatriations. However, the Act's reduction in the U.S. corporate tax rate, limitations on deferral, and introduction of a participation exemption regime without deemed paid credits has limited the benefits of this type of planning. The Treasury Department and the IRS welcome comments on the proposed approach and anticipated impacts.

Many of the existing expense allocation rules have not been significantly modified since 1988. Furthermore, for taxable years beginning after December 31, 2020, a worldwide affiliated group will be able to elect to allocate and apportion interest expense on a worldwide basis. *See* section 864(f). The Treasury Department and the IRS expect the implementation of section 864(f) will have a significant impact on the effect of interest expense apportionment and will necessitate a reexamination of the existing expense allocation rules.

Therefore, the Treasury Department and the IRS expect to reexamine the existing approaches for allocating and apportioning expenses, including in particular the apportionment of interest, research and experimentation (''R&E''), stewardship, and general & administrative expenses, as well as to reexamine the ''CFC netting rule'' in § 1.861–10(e). The Treasury Department and the IRS request comments with respect to specific revisions to the regulations that should be made in connection with this review.

Part I.A of this Explanation of Provisions describes proposed changes to the rules addressing exempt income and assets, including the application of those rules in the context of the deduction under section 250. Part I.B of this Explanation of Provisions describes rules to address the allocation and apportionment of the deduction under section 250 and clarifying changes to the allocation and apportionment of certain other deductions. Part I.C of this Explanation of Provisions describes a new rule addressing loans to partnerships by certain partners and their affiliates. Part I.D of this Explanation of Provisions describes a revision to the CFC netting rule. Part I.E of this Explanation of Provisions describes rules for the valuation of assets, including stock, for purposes of allocating and apportioning deductions. Part I.F of this Explanation of Provisions describes rules for characterizing the stock of certain foreign corporations for purposes of allocating and apportioning deductions. Part I.G of this Explanation of Provisions describes rules for certain elections relating to the allocation and apportionment of R&E expenditures. Part I.H of this Explanation of Provisions describes rules for applying section 904(b)(4).

A. Changes and Clarifications to Definitions of Exempt Income and Exempt Asset

Section 864(e)(3) provides that, for purposes of allocating and apportioning any deductible expense, any tax-exempt asset (and any income from the asset) is not taken into account. Section 864(e)(3) also provides that a similar rule applies for the portion of any dividend equal to the deduction allowable under section 243 or 245(a) with respect to the dividend and the like portion of any stock the dividends on which would be

so deductible. Section 864(e)(3) was not modified by the Act.

The Treasury Department and the IRS are aware that some taxpayers have taken the position that under § 1.861–8T(d)(2)(ii) assets or income that are partially exempt, excluded, or eliminated may be treated as entirely exempt. This interpretation is inconsistent with section 864(e)(3). The proposed regulations revise the definitions of exempt income and exempt asset to clarify that income or assets are treated as exempt (or partially exempt) under section 864(e)(3) only to the extent that the income or the income from the assets are, or are treated as, exempt, excluded, or eliminated. Proposed § 1.861–8(d)(2)(ii)(A).

New section 250(a)(1) allows a domestic corporate shareholder a deduction (the ''section 250 deduction'') equal to portions of its foreign-derived intangible income (''FDII''), GILTI inclusion, and the amount treated as a dividend under section 78 that is attributable to its GILTI inclusion. Because the section 250 deduction effectively exempts a portion of certain income, the proposed regulations provide that for purposes of applying the expense allocation and apportionment rules, the gross income offset by the section 250 deduction is treated as exempt income, and the stock or other asset giving rise to that income is treated as a partially exempt asset. *See* Senate Committee on Finance, Explanation of the Bill, S. Prt. 115–20, at 376 n.1210 (November 22, 2017) (''The Committee intends that the deduction allowed by new Code section 250 be treated as exempting the deducted income from tax.''). This rule does not apply for purposes of determining the amount of the foreign derived intangible income in applying section 250 as the operative section. No inference is intended regarding whether the section 250 deduction is treated as giving rise to exempt income or assets for any other purpose of the Code other than for purposes of the allocation and apportionment of deductions under §§ 1.861–8 through 1.861–17.

Under proposed § 1.861–8(d)(2)(ii)(C)(*1*), a portion of a domestic corporation's gross income that is FDII or results from a GILTI inclusion (and the corresponding section 78 gross up) is treated as exempt income based on the amount of the section 250 deduction allowed to the United States shareholder under section 250(a)(1). Similarly, the value of a domestic corporation's assets that produce FDII or GILTI is reduced to reflect the fact that the income from the assets is treated in part as exempt. Proposed § 1.861–8(d)(2)(ii)(C)(*2*).

The amount of the section 250 deduction used to determine the amount of gross income that is exempt is reduced to the extent section 250(a)(2)(B) requires a reduction to the amount of the deduction. Therefore, proposed § 1.861–8(d)(2)(ii)(C) does not apply to treat income or assets as exempt if the domestic corporation is not allowed a deduction under section 250(a)(2), even though the domestic corporation may have FDII or a GILTI inclusion.

A special rule is provided in proposed § 1.861–8(d)(2)(ii)(C)(*2*)(*ii*) to determine the portion of CFC stock that gives rise to a GILTI inclusion that is treated as exempt. The rule provides that a portion of CFC stock owned by a domestic corporation that is a United States shareholder of the CFC is treated as exempt based on a fraction equal to the amount of the section 250 deduction allowed to the domestic corporation under section 250(a)(1)(B)(i) (taking into account the reduction, if any, required under section 250(a)(2)(B)(ii)), divided by the domestic corporation's GILTI inclusion. In general, the fraction is applied to the portion of the CFC stock that is treated as giving rise to a GILTI inclusion and that is not assigned to a section 245A subgroup, as determined under the rules in proposed § 1.861–13. *See* Part I.F.1 and I.H of this Explanation of Provisions. To the extent the domestic corporation is allowed a section 250 deduction for an amount under section 250(a)(1)(B) (because the domestic corporation has a GILTI inclusion), the proposed regulations treat a portion of the stock of a CFC with respect to which the domestic corporation is a United States shareholder as exempt even if the CFC has a tested loss for the taxable year.

Section 245A(a) allows domestic corporate shareholders a deduction equal to the foreign-source portion of dividends received from certain foreign corporations (the ''section 245A deduction''), subject to certain limitations described in section 246. Although section 864(e)(3) contemplates that dividends described in sections 243 and 245(a) are treated similarly to exempt income to the extent of the deductions allowed under those sections, section 864(e)(3) does not apply to the dividend income reduced by the section 245A deduction. Instead, section 904(b)(4) provides for alternative adjustments. *See* Part I.H.2 of this Explanation of Provisions for a discussion of the different approaches under section 864(e)(3) and 904(b)(4). Proposed § 1.861–8(d)(2)(iii)(C) clarifies that the section 245A deduction does not give rise to exempt income. Similarly, no asset is treated as an exempt asset by reason of the section 245A deduction. Different treatment is provided under § 1.861–8T(d)(2)(ii)(B) for dividends received deductions under sections 243 and 245 because section 864(e)(3) specifically provides that similar rules to the exempt asset and income rules apply to those deductions.

Finally, the proposed regulations confirm in proposed § 1.861–8(d)(2)(iv) that earnings and profits excluded from income under section 959 (''previously taxed earnings and profits'') do not result in any portion of the stock in a CFC being treated as an exempt asset. Under §§ 1.861–12 and 1.861–12T, stock in a CFC is characterized by reference to the income generated each year by the CFC's assets. Previously taxed earnings and profits are not a type of income that is generated during the taxable year by a CFC's assets; rather, the CFC's assets, whether acquired with previously taxed or non-previously taxed earnings and profits or with another source of funds, generate income used to characterize the stock. For the avoidance of doubt, proposed § 1.861–8(d)(2)(iv) confirms that the fact that a CFC has previously taxed earnings and profits does not result in any portion of the CFC's stock being treated as an exempt asset under section 864(e)(3).

B. Allocation and Apportionment of Foreign Income Taxes, the Section 250 Deduction, and a Distributive Share of Partnership Deductions

Section 1.861–8(e) provides rules for allocating and apportioning certain deductions. Section 1.861–8(e)(6) provides rules for the allocation and apportionment of deductions for state, local, and foreign income, war profits and excess profits taxes. In the case of deductions for foreign income, war profits and excess profits taxes, the allocation and apportionment rules under § 1.861–8(e) are intended to be consistent with the principles of § 1.904–6. The proposed regulations clarify this result by expressly incorporating the principles of § 1.904–6(a)(1)(i), (ii), and (iv) in allocating and apportioning taxes to the relevant statutory and residual groupings (and not just to separate categories of income for purposes of determining the foreign tax credit limitation).

The proposed regulations include rules for allocating and apportioning the section 250 deduction. For these purposes, although the section 250 deduction is a single deduction that equals the sum of the amounts specified

in section 250(a)(1)(A) and (B), the proposed regulations provide separate rules with respect to (i) the portion of the section 250 deduction for FDII and (ii) the portion of the section 250 deduction for the GILTI inclusion and the amount of the section 78 gross up attributable to foreign taxes deemed paid with respect to the GILTI inclusion. The amount of each portion of the section 250 deduction to be allocated and apportioned takes into account any reductions required under section 250(a)(2)(B).

Under proposed § 1.861–8(e)(13), the portion of the section 250 deduction for FDII is treated as definitely related and allocable to the specific class of gross income that is included in the taxpayer's foreign-derived deduction eligible income (as defined in section 250(b)(4)). Although foreign-derived deduction eligible income is an amount net of expenses, the class is determined based solely on the gross income that is used to calculate foreign-derived deduction eligible income. In cases where the income is allocated to a class that contains multiple categories under section 904(d) or U.S. source income, the deduction is apportioned ratably based on the relative amounts of gross income in the different income groupings.

Proposed § 1.861–8(e)(14) provides a similar rule for the portion of the section 250 deduction allowed for the GILTI inclusion and the corresponding section 78 gross up. In certain cases, gross income from the GILTI inclusion could be in a grouping other than the grouping for section 951A category income (for example, because it is U.S. source or passive category income). In such cases, the deduction for the GILTI inclusion and the section 78 gross up is apportioned ratably based on the relative amounts of gross income in the different income groupings.

The proposed regulations also clarify the general rule for allocating and apportioning a taxpayer's distributive share of partnership deductions. Proposed § 1.861–8(e)(15) provides that if a taxpayer is a partner in a partnership, the taxpayer's deductions that are allocated and apportioned include the taxpayer's distributive share of the partnership's deductions.

C. Special Rule for Specified Partnership Loans

The Treasury Department and the IRS are aware that certain loans made to a partnership by a United States person, or a member of its affiliated group, that owns an interest (directly or indirectly) in the partnership can result in a distortion in the determination of the foreign tax credit limitation under section 904 when the same person takes into account both a distributive share of the interest expense and the interest income with respect to the same loan. This result occurs due to differences in the rules that govern the source and separate category of the interest income and those that govern the allocation and apportionment of interest expense. To prevent the distortive effect of these differences, proposed § 1.861–9(e)(8)(ii) generally provides that, to the extent the lender in a specified partnership loan transaction takes into account both interest expense and interest income with respect to the same loan, the interest income is assigned to the same statutory and residual groupings as those groupings from which the interest expense is deducted, as determined under the allocation and apportionment rules in §§ 1.861–9 through 1.861–13. Additionally, proposed § 1.861–9(e)(8)(i) provides that, for purposes of applying the allocation and apportionment rules, a portion of the loan is not taken into account as an asset of the lender based on the ratio of the portion of the interest income included by the lender that is subject to this matching rule to the total amount of interest income included by the lender with respect to the loan in the taxable year. The proposed regulations include anti-avoidance rules to extend these provisions to certain back-to-back loans or loans made through CFCs. *See* proposed § 1.861–9(e)(8)(iii) and (iv). The proposed regulations also apply the specified partnership loan rules to transactions that are not loans but that give rise to deductions that are allocated and apportioned in the same manner as interest expense under § 1.861–9T(b). Proposed § 1.861–9(e)(8)(v).

D. Revision to CFC Netting Rule Relating to Hybrid Debt

Section 1.861–10(e)(8)(vi) provides that for purposes of applying the CFC netting rule of § 1.861–10(e), certain related party hybrid debt is treated as related group indebtedness, but the income derived from the hybrid debt is not treated as interest income derived from related group indebtedness. As a result, no interest expense is generally allocated to income from the hybrid debt, but the debt may nevertheless increase the amount of allocable related group indebtedness for which a reduction in assets is required under § 1.861–10(e)(7). This has a distortive effect on the general allocation and apportionment of other interest expense under § 1.861–9. The proposed regulations revise § 1.861–10(e)(8)(vi) to provide that hybrid debt is not treated as related group indebtedness for purposes of the CFC netting rule. Proposed § 1.861–10(e)(8)(vi) also provides that hybrid debt is not treated as related group indebtedness for purposes of determining the foreign base period ratio, which is based on the average of related group debt-to-asset ratios in the five prior taxable years, even if the hybrid debt was otherwise properly treated as related group indebtedness in a prior year. This is necessary to prevent distortions that would otherwise arise in comparing the ratio in a year in which the hybrid debt was treated as related group indebtedness to the ratio in a year in which the hybrid debt is not treated as related group indebtedness.

E. Valuation of Assets for Purposes of Apportioning Interest Expense and Other Deductions

1. Repeal of Fair Market Value Method and Transition Relief

Section 864(e)(2) requires taxpayers to apportion interest expense on the basis of assets rather than income. Under the asset method, a taxpayer apportions interest expense to the various statutory groupings based on the average total value of assets within each grouping for the taxable year as determined under the asset valuation rules of § 1.861–9T(g). Before the Act, taxpayers could elect to determine the value of their assets under the tax book value, alternative tax book value, or the fair market value method, and were required to obtain the Commissioner's approval to switch from the fair market value method to the tax book or alternative tax book value methods. *See* § 1.861–8T(c)(2). In light of the Act's repeal of the fair market value method for apportioning interest for taxable years beginning after December 31, 2017, taxpayers using the fair market value method must switch to the tax book or alternative tax book value method for purposes of apportioning interest expense for the taxpayer's first taxable year beginning after December 31, 2017. Proposed §§ 1.861–8(c)(2) and 1.861–9(i)(2) provide that the Commissioner's approval is not required for this change.

For purposes of determining asset values, an average of values within each statutory grouping is computed for the year on the basis of the values of assets at the beginning and end of the year. *See* § 1.861–9T(g)(2)(i)(A). The Treasury Department and the IRS understand that taxpayers previously using the fair market value method may not have had an independent reason to calculate the adjusted tax basis of their assets as of the beginning of their first post-2017

taxable year as required by the tax book value and alternative tax book value methods. To provide transitional relief, the proposed regulations provide in § 1.861–9(g)(2)(i) that for the first taxable year beginning after December 31, 2017, a taxpayer that had been using the fair market value method may choose to determine asset values using an average of the end of the first quarter and the year-end values of its assets, provided that all the members of an affiliated group (as defined in § 1.861–11T(d)) make the same choice and no substantial distortion would result.

The amendments made to section 864(e)(2) by the Act repealed the fair market value method only for purposes of allocating and apportioning interest expense. Accordingly, the fair market value method and the rules in § 1.861–9(h) remain applicable for non-interest expenses that are properly apportioned on the basis of the relative fair market values of assets.

2. Clarification of Rules for Adjusting Stock Basis in Nonaffiliated 10 Percent Owned Corporations for Earnings and Profits

Under section 864(e)(4)(A) and § 1.861–12(c)(2)(i)(A), for purposes of apportioning expenses on the basis of the tax book value of assets, certain adjustments are made to the adjusted basis of stock in a 10 percent owned corporation based on the earnings and profits (or deficits in earnings and profits) of the corporation attributable to the stock. The Treasury Department and the IRS are aware that some taxpayers have taken the position that the adjustment to basis for earnings and profits under § 1.861–12T(c)(2) does not include previously taxed earnings and profits. This interpretation is inconsistent with the text and purpose of section 864(e)(4) and § 1.861–12(c)(2). The adjustment under section 864(e)(4) is intended to better approximate the value of stock. *See* Joint Committee on Tax'n, General Explanation of the Tax Reform Act of 1986 (Pub. L. 99–514) (May 4, 1987), JCS–10–87, at p.87. Whether or not certain earnings and profits are reclassified from earnings described in section 959(c)(3) to previously taxed earnings and profits has no bearing on the value of the stock. Therefore, the proposed regulations confirm that previously taxed earnings and profits are taken into account for purposes of the adjustment described in § 1.861–12(c)(2). In addition, the proposed regulations clarify that the reference to the ''rules of section 1248'' in § 1.861–12T(c)(2)(i)(B) is intended to provide rules for determining the pro rata share of earnings and profits attributable to the taxpayer's shares, and is not relevant to determining the amount of the foreign corporation's earnings and profits subject to the adjustment, which is governed by the rules in sections 964(a) and 986. Proposed § 1.861–12(c)(2)(i)(B)(*2*).

The Treasury Department and the IRS are also aware that taxpayers have expressed uncertainty as to which values are used for averaging beginning and year-end values in the case of 10 percent owned corporations whose stock basis is adjusted under § 1.861–12(c)(2) (including rules described in § 1.861–12T(c)(2)), which, in general, first eliminates any additions to basis on account of previously taxed earnings and profits made under sections 961 and 1293(d), and then increases or decreases adjusted basis by the shareholder's pro rata share of total earnings and profits. The proposed regulations clarify in proposed § 1.861–9(g)(2)(i)(B) that the beginning and end-of-year values of stock are determined without regard to any adjustments under section 961(a) or 1293(d), and before making the adjustment for earnings and profits provided in § 1.861–12(c)(1)(i)(A). The adjustment for total earnings and profits provided in § 1.861–12(c)(1)(i)(A) is only made after the average of the beginning and end of year values has been determined.

3. Determination of Stock Basis in Connection With Section 965(b)

In Part VII.D of the Explanation of Provisions of the notice of proposed rulemaking for the regulations under section 965, *see* 83 FR 39,531, the Treasury Department and the IRS acknowledged that the application of section 965(b)(4)(A) and (B) may warrant the issuance of special rules for the determination of adjusted basis. For example, if the increase in earnings and profits under section 965(b)(4)(B) and § 1.965–2(d)(2) is taken into account for purposes of determining the increase to adjusted basis under § 1.861–12(c)(2)(i)(A), and there is no corresponding reduction to the adjusted basis in the stock of the foreign corporation, the tax book value of the stock would be overstated by the amount of the increase.

If a shareholder elects to make the basis adjustments under proposed § 1.965–2(f)(2)(i), the tax book value of the stock of its foreign corporations that were specified foreign corporations (as defined in § 1.965–1(f)(45)) will generally reflect the proper adjusted basis amounts as long as any amounts included in basis under proposed § 1.965–2(f)(2)(ii)(A) are treated similarly to adjustments under section 961 and not included in the taxpayer's basis in stock under § 1.861–12T(c)(2)(i)(B). Accordingly, proposed § 1.861–12(c)(2)(i)(B)(*1*)(*ii*) provides that, for purposes of § 1.861–12(c)(2), a taxpayer determines the basis in the stock of a specified foreign corporation as if it had made the election under § 1.965–2(f)(2)(i), even if the taxpayer did not in fact make the election, but does not include the amount included in basis under § 1.965–2(f)(2)(ii)(A) (because the amount of that increase would not be included if the increase was by operation of section 961). For this purpose, the amount included in basis under proposed § 1.965–2(f)(2)(ii)(A) is determined without regard to whether any portion of the amount is netted against other basis adjustments under proposed § 1.965–2(h)(2). Proposed § 1.861–12(c)(2)(i)(B)(*1*)(*ii*) applies to the taxable year of the inclusion under section 965 as well as to future taxable years.

The Treasury Department and the IRS request comments on alternative ways to account for section 965(b) that minimize taxpayer burdens without distorting the measurement of a CFC's tax book value.

F. Characterization of Stock of Certain Foreign Corporations Under § 1.861–12

1. Characterization of CFC Stock To Account for Section 951A Category, Treaty Categories, and Section 904(b)(4)

Section 1.861–12 provides special rules for applying the asset method in order to apportion expenses to the separate categories in computing the foreign tax credit limitation. The proposed regulations clarify in § 1.861–12(a) that § 1.861–12 also applies in apportioning expenses among statutory and residual groupings for operative sections other than section 904.

Special rules are provided in § 1.861–12T(c) regarding the treatment of stock, including stock in 10 percent owned corporations (as defined in § 1.861–12T(c)(2)(ii)) and stock in CFCs. The purpose of the stock characterization rules of § 1.861–12T(c) is to characterize the stock by reference to the income which the stock generates to its owner. With respect to CFCs, the rules generally look through to the income generated by the assets of the CFC for purposes of characterizing the stock of the CFC. Before the Act, the income earned by the CFC was generally assigned to the same separate category to which that income would be assigned if earned directly by the United States shareholder because the categories of income of a CFC and U.S. person were the same, and the look-through rules

under section 904(d)(3) generally applied to ensure that once income was assigned to a separate category, the category of the income was maintained when the income was paid or distributed by the CFC to its owner or taken into account as an inclusion by the owner.

As described in Part II.B.3 of this Explanation of Provisions, the new separate category for section 951A category income applies only to an inclusion by a United States person of gross income under section 951A(a). Accordingly, gross tested income of a CFC is generally assigned to the general category, even though the stock of the CFC may give rise to a GILTI inclusion that is section 951A category income in the hands of a United States shareholder. Therefore, § 1.861–12T(c) would not result in characterizing any of the stock of the CFC as a section 951A category asset because the tested income of the CFC is assigned to the general category, even though the related income included by the United States shareholder is assigned to the section 951A category. Accordingly, the proposed regulations in § 1.861–13 provide special rules to account for the fact that, with respect to the section 951A category, the application of § 1.861–12T(c) to determine the income of the CFC or the income generated by the assets of the CFC does not, on its own, reflect the separate category of the income generated by the stock of the CFC to the United States shareholder. The proposed regulations also address a similar issue that arises when a CFC earns U.S. source income that is included under section 951(a) or 951A(a) in gross income of a United States shareholder who elects under an income tax treaty to treat the inclusion as foreign source income, resulting in separate category treatment for income resourced under a tax treaty (a ''treaty category''). *See* section 904(h). Proposed § 1.861–13 applies solely for purposes of characterizing stock when section 904 is the operative section.

Under proposed § 1.861–13, a taxpayer first determines the amount of the stock of a CFC that is characterized in each of the statutory groupings described in § 1.861–13(a)(1) under the asset method or the modified gross income method. Under the modified gross income method, stock of a CFC may be characterized as producing general category gross tested income even though the CFC has a tested loss. *See* proposed § 1.861–13(a)(1)(ii).

Next, a portion of the stock characterized as producing general category gross tested income is assigned to the section 951A category. Only a portion of the stock so characterized is assigned to the section 951A category because the amount of the GILTI inclusion by the United States shareholder may be less than the aggregate tested income of its CFCs because of offsets from another CFC's tested loss or because of a reduction for net deemed tangible income return described in section 951A(b)(2). The inclusion percentage, as defined in section 960(d)(2), takes into account the percentage of net CFC tested income that is not included under section 951A(a) due to tested losses or the net deemed tangible income return. Accordingly, proposed § 1.861–13(a)(2) assigns a United States shareholder's stock in a CFC generating gross tested income to the section 951A category based on the United States shareholder's inclusion percentage as determined under § 1.960–2(c)(2). In general, earnings and profits related to the gross tested income that is not included under section 951A(a), when distributed, result in dividend income that is assigned to the general category.

The use of the inclusion percentage to assign stock to the section 951A category applies regardless of whether the stock of the CFC produces tested income or a tested loss for the year, in order to reflect the aggregate nature of the calculation of a United States shareholder's GILTI inclusion. Stock of a CFC is generally assigned to the statutory grouping for gross tested income, under either the asset or modified gross income methods described in proposed § 1.861–12(c)(3), if the CFC's assets generate gross tested income or if the CFC earns gross tested income, even if the CFC ultimately produces a tested loss for the taxable year. However, a United States shareholder with no GILTI inclusion for a taxable year has an inclusion percentage of zero, and therefore none of the stock of its CFCs is assigned to the section 951A category in that year.

Under proposed § 1.861–13(a)(3), a similar rule applies for characterizing stock as a treaty category asset if stock of a CFC is assigned to the statutory grouping for gross tested income that was resourced under a treaty. The portion of the stock of the CFC that is assigned to a treaty category is based on the United States shareholder's inclusion percentage. In the case of stock of a CFC initially assigned to the statutory groupings for gross subpart F income that is resourced under a treaty, all of that stock is assigned to a treaty category.

Finally, in the case of stock of a CFC assigned to the general and passive categories or the residual grouping for U.S. source income, proposed § 1.861–13(a)(5) provides rules for subdividing the categories or groupings into a section 245A subgroup and non-section 245A subgroup for purposes of applying section 904(b)(4). See Part I.H of this Explanation of Provisions for a description of the regulations under section 904(b)(4). In general, these rules provide that the portion of stock that does not generate income that is included under section 951A(a) or 951(a)(1) and does not represent income described in section 245(a)(5) (which gives rise to a dividends received deduction under section 245 instead of section 245A) is assigned to the section 245A subgroup.

2. Treatment of Gross Tested Income for Tiers of CFCs

Both the asset method and modified gross income method described in § 1.861–12T(c)(3) provide rules to characterize stock in a CFC when there are tiers of CFCs. Under the modified gross income method in § 1.861–12T(c)(3)(iii), a taxpayer characterizes the value of the first-tier CFC based on the gross income net of interest expense of the CFC within each relevant separate category. In the case of vertically-owned CFCs, gross income of any higher-tier CFC includes the gross income net of interest expense of any lower-tier CFC, but does not include subpart F income of any lower-tier CFC. *See* § 1.861–9T(j)(2). However, § 1.861–12T(c)(3)(iii) provides that for purposes of applying the modified gross income method to characterize CFC stock, the gross income of the first-tier CFC includes the total amount of subpart F income (net of interest expense apportioned at the level of the CFC that earned the income) of any lower-tier CFC.

The proposed regulations add similar rules for GILTI inclusions. In particular, the proposed regulations provide in §§ 1.861–9(j)(2)(ii)(C) and 1.861–12(c)(3)(iii) that for purposes of characterizing CFC stock under the modified gross income method, the gross tested income of lower-tier CFCs, net of interest expense apportioned to the tested income, is excluded from the gross income of intermediate-tier CFCs but is included in the gross income of the first-tier CFC. The Treasury Department and the IRS request comments on whether additional rules are required to account for gross tested income earned in lower-tier CFCs, including gross tested income of lower-tier CFCs that produce tested losses.

3. Characterization of Stock of a Noncontrolled 10-Percent Owned Foreign Corporation

To reflect the repeal of section 902, the Act modifies section 904(d)(2)(E) to provide a new definition for a noncontrolled 10-percent owned foreign corporation. The proposed regulations modify § 1.861–12(c)(4) to provide that stock in a noncontrolled 10-percent owned foreign corporation is generally characterized under the same rules previously used for noncontrolled section 902 corporations.

G. Allocation and Apportionment of Research and Experimental Expenditures

In general, R&E expenditures are apportioned between groupings within product categories according to either a sales or gross income method of apportionment at the taxpayer's election. § 1.861–17(c) and (d). Under § 1.861–17(e)(1), a taxpayer may choose to use either the sales method or gross income method for its original return for its first taxable year. The taxpayer's use of either method constitutes a binding election to use the method chosen for that year and for the subsequent four years. Within this five-year period, the election can only be revoked with the Commissioner's consent. A taxpayer may change the election at any time after five years, but the new election is binding for a new five-year period. § 1.861–17(e)(2).

In light of the numerous amendments to the foreign tax credit rules made by the Act, the proposed regulations provide a one-time exception to the five-year binding election period. Accordingly, under proposed § 1.861–17(e)(3), even if a taxpayer is subject to the binding election period, for the taxpayer's first taxable year beginning after December 31, 2017, the taxpayer may change its apportionment method without obtaining the Commissioner's consent. This one-time change of method constitutes a binding election to use the method chosen for that year and for the next four taxable years.

The Treasury Department and the IRS request comments on whether other aspects of § 1.861–17 should be revised in light of the changes to section 904(d), in particular the addition of the section 951A category. For example, because the look-through rules in section 904(d)(3)(C) do not assign interest, rents, or royalties that reduce tested income to the section 951A category, royalties paid by a CFC to a United States shareholder are generally general category income even though the sales by the CFC to which the royalties relate may generate income in the section 951A category to the United States shareholder. This could result in R&E expenditures being apportioned under the sales method solely to the section 951A category, even though the royalty income is assigned to the general category. However, under the gross income method, R&E expenditures would be apportioned to both the general and section 951A category. Comments are requested on whether and how the regulations governing either or both methods should be revised to account for the addition of the section 951A category.

H. Section 904(b)(4)

1. Effect of Section 904(b)(4) on the Foreign Tax Credit Limitation

Under new section 904(b)(4), for purposes of the foreign tax credit limitation in section 904(a), a domestic corporation that is a United States shareholder with respect to a specified 10-percent owned foreign corporation disregards the ''foreign-source portion'' of any dividend received from the foreign corporation and any deductions properly allocable or apportioned to income (other than amounts includible under section 951(a)(1) or 951A(a)) with respect to the stock of the foreign corporation or to the stock itself (to the extent income with respect to the stock is other than amounts includible under section 951(a)(1) or 951A(a)). Dividends and deductions that are disregarded under section 904(b)(4) result in an adjustment to both the taxpayer's foreign source taxable income in the relevant separate category (the numerator of the fraction under section 904(a)) and its worldwide taxable income (the denominator of the fraction under section 904(a)) in all separate categories.

In general, under section 904(b)(4), disregarding both the dividend income eligible for a deduction under section 245A as well as the associated deduction under section 245A has no effect on the foreign tax credit limitation in any separate category because they generally net to zero. However, additional deductions that are disregarded under section 904(b)(4)(B) generally have the effect of increasing the foreign tax credit limitation with respect to the separate category to which the deductions are allocated and apportioned, because both the numerator (foreign source taxable income in the category) and the denominator (worldwide taxable income) of the fraction under section 904(a) are increased by the same amount. In contrast, the limitation in other categories will generally decrease because the numerator (foreign source taxable income in the category) is unchanged but the denominator (worldwide taxable income) of the fraction is increased.

2. Income Other Than Amounts Includible Under Section 951(a)(1) or 951A(a)

Section 904(b)(4)(B) requires determining what income with respect to stock of a specified 10-percent owned foreign corporation is income ''other than amounts includible under section 951(a)(1) or 951A(a).'' The terms used in section 904(b)(4) are defined by reference to definitions provided in section 245A.

As discussed in Part I.A of this Explanation of Provisions, with respect to other dividends received deductions, section 864(e)(3) provides that rules similar to the exempt income and exempt asset rules apply to the dividends and stock on which the dividends are paid. The Act did not extend this treatment to the section 245A deduction but instead added section 904(b)(4). In contrast to section 864(e)(3), which removes the exempt income and assets from the determination before deductions are allocated and apportioned under the rules of §§ 1.861–8 through 1.861–17, section 904(b)(4) provides that the deductions are disregarded after they have been allocated and apportioned. Disregarding the deductions after they have been allocated and apportioned is consistent with a policy that the deductions are properly allocable and apportioned to income eligible for a section 245A deduction and, therefore, should not be apportioned to income in other separate categories or U.S. source income. By disregarding these deductions, section 904(b)(4) has the effect of computing the foreign tax credit limitation fraction in section 904(a) (but not the pre-credit U.S. tax) as if the deductions had not been allowed.

The proposed regulations provide that income ''other than amounts includible under section 951(a)(1) or 951A(a)'' refers to income for which a section 245A deduction is allowed. Thus, in the case of section 904(b)(4)(B)(i), proposed § 1.904(b)–3(c)(1) provides that income for which a section 245A deduction is allowed means dividends for which a section 245A deduction is allowed. In the case of section 904(b)(4)(B)(ii), proposed § 1.904(b)–3(c)(1) and (2) provide rules for determining what amount of stock of the foreign corporation corresponds to income that, if distributed, is generally eligible for a

section 245A deduction, by subdividing a portion of the stock into a section 245A subgroup and a non-section 245A subgroup within each separate category.

3. Expenses Properly Allocable to Dividend Income

Proposed § 1.904(b)–3(a)(1)(ii) provides that deductions ''properly allocable'' to dividends for which a section 245A deduction is allowed are disregarded. The amount of properly allocable deductions is determined by treating each section 245A subgroup for each separate category as a statutory grouping under § 1.861–8(a)(4) for purposes of allocating and apportioning deductions. Only dividend income for which a section 245A deduction is allowed is included in a section 245A subgroup. *See* § 1.904(b)–3(b) and (c)(1). Because hybrid dividends described in section 245A(e)(4), and dividends on stock with respect to which the holding period requirements of section 246(c) are not met, are ineligible for a deduction under section 245A, the dividends and the deductions allocable or apportioned to them are not disregarded under section 904(b)(4).

The deductions allocated and apportioned to the section 245A subgroup within each separate category are disregarded for purposes of determining the foreign source taxable income in the separate category and the entire taxable income included in the fraction under section 904(a) for all separate categories. Deductions allocated and apportioned to the section 245A subgroup within the residual grouping for U.S. source income are disregarded solely for purposes of determining the denominator of the limitation fraction (worldwide taxable income) in the separate categories that have foreign source taxable income. Proposed § 1.904(b)–3(a)(2). Dividends in the residual grouping for which a section 245A deduction is allowed could include, for example, dividends from a United States-owned foreign corporation (as defined in section 904(h)(6)) paid out of U.S. source income that is neither effectively connected income nor dividend income received from a domestic corporation. *See* sections 245A(c)(3) and 245(a)(5).

Proposed § 1.904(b)–3(b) also provides that the section 245A deduction is always allocated solely to a section 245A subgroup and therefore is always disregarded under section 904(b)(4).

4. Expenses Properly Allocable to Stock

In order to determine the deductions ''properly allocable'' to stock of a specified 10-percent owned foreign corporation that is in the section 245A subgroup, the stock is first characterized for purposes of allocating and apportioning expenses under § 1.861–12 and, if applicable, § 1.861–13. In the case of a specified 10-percent owned foreign corporation that is not a CFC, all of the value of its stock is generally in a section 245A subgroup because the stock cannot generate an inclusion under section 951(a)(1) or 951A(a). Proposed § 1.904(b)–3(c)(2). If the specified 10-percent owned foreign corporation is a CFC, a portion of the value of stock in each separate category and in the residual grouping for U.S. source income is subdivided between a section 245A and non-section 245A subgroup under the rules described in § 1.861–13(a)(5). *See* Part I.F.1 of this Explanation of Provisions. The amount of properly allocable deductions is determined by treating the section 245A subgroup for each separate category as a statutory grouping under § 1.861–8(a)(4) for purposes of allocating and apportioning deductions on the basis of assets, which include the stock.

Previously taxed earnings and profits do not affect the amount of expenses that are disregarded under section 904(b)(4). The characterization of stock in a specified 10-percent owned foreign corporation for purposes of section 904(b)(4)(B)(ii) is determined on an annual basis by applying the rules in § 1.861–12(c), which generally requires applying either the asset method or the modified gross income method. Whether or not the CFC has previously taxed earnings and profits, including from prior years or due to section 965, has no bearing on how either method is applied to characterize stock. *See also* proposed § 1.861–12(c)(2)(i)(B)(*2*).

5. Coordination With OFL/ODL Rules

Because the section 904(b)(4) adjustments apply in computing the foreign tax credit limitation under section 904(a), proposed § 1.904(b)–3(d) provides that the adjustments under section 904(b)(4), like the adjustments under section 904(b)(2) to account for foreign source capital gain net income and rate differentials, apply before the operation of both the separate limitation loss and overall foreign loss rules in section 904(f) and the overall domestic loss rules in section 904(g). This rule permits loss accounts to be recaptured out of income that is added to the foreign tax credit limitation calculation by reason of the section 904(b)(4) adjustments.

II. Foreign Tax Credit Limitation Under Section 904

The proposed regulations update §§ 1.904–1 through 1.904–6 (the ''section 904 regulations'') to eliminate deadwood and reflect statutory amendments made to section 904 before the Act. For example, proposed §§ 1.904–1 through 1.904–3 reflect the repeal of the overall limitation and per-country limitation. Proposed § 1.904–4 reflects statutory amendments made before the Act eliminating various separate categories described in section 904(d)(1).

The proposed regulations also propose revisions and additions to the section 904 regulations to reflect the changes made under the Act. Part II.A of this Explanation of Provisions describes proposed transition rules to account for the addition of separate categories for section 951A category income and foreign branch category income. Part II.B of this Explanation of Provisions describes (1) proposed amendments to the rules relating to the passive category with respect to high-taxed income, export financing interest, and financial services income; (2) rules relating to the foreign branch category, section 951A category, and separate category described in section 904(d)(6) for items resourced under a treaty; and (3) rules for assigning the section 78 gross up and section 986(c) gain or loss to a separate category. Part II.C of this Explanation of Provisions describes updates relating to amendments made by the Act replacing references to ''noncontrolled section 902 corporations'' with ''non-controlled 10 percent owned foreign corporations.'' Part II.D of this Explanation of Provisions describes proposed amendments to the look-through rules under sections 904(d)(3) and (d)(4) to account for the addition of the foreign branch category and section 951A category under the Act. Part II.E of this Explanation of Provisions describes the proposed changes to the rules for allocating and apportioning foreign taxes to separate categories.

A. Transition Rules in Proposed §§ 1.904–2(j) and 1.904(f)–12(j) Accounting for the Increase in Section 904(d)(1) Separate Categories

1. Carryovers and Carrybacks of Unused Foreign Taxes Under Section 904(c)

The Act does not provide any transition rules for assigning carryforwards of unused foreign taxes earned in pre-2018 taxable years to a different separate category, including the new post-2017 separate categories for section 951A category income and

foreign branch category income. Therefore, proposed § 1.904–2(j)(1)(ii) provides that if unused foreign taxes paid or accrued or deemed paid with respect to a separate category of income are carried forward to a taxable year beginning after December 31, 2017, those taxes are allocated to the same post-2017 separate category as the pre-2018 separate category from which the unused foreign taxes are carried.

However, double taxation may result if unused foreign taxes paid, accrued, or deemed paid in a pre-2018 taxable year are not assigned to the separate category to which the taxes would have been assigned if the new post-2017 separate categories had existed in the pre-2018 taxable year. This could arise, for example, if unused foreign taxes imposed on income derived through foreign branches in a pre-2018 taxable year are not associated with foreign branch category income. Matching the unused foreign taxes to the separate category that includes income of the same type as the income on which the taxes were imposed furthers the purpose of the section 904(c) foreign tax credit carryover rules to mitigate the effect of timing differences in the recognition of income for U.S. and foreign tax purposes that could otherwise result in double taxation. *See* H.R. Rep. No. 85–775, at 27 (1957).

Therefore, proposed § 1.904–2(j)(1)(iii) provides an exception that permits taxpayers to assign unused foreign taxes in the pre-2018 separate category for general category income to the post-2017 separate category for foreign branch category income to the extent they would have been assigned to that separate category if the taxes had been paid or accrued in a post-2017 taxable year. Any remaining unused taxes are assigned to the post-2017 separate category for general category income. The exception applies only to unused taxes that were paid or accrued, and not taxes that were deemed paid with respect to dividends or inclusions from foreign corporations, because income derived through foreign corporations cannot be foreign branch category income. *See* Part II.B.2 of this Explanation of Provisions.

Because the new post-2017 separate category for foreign branch category income does not include income that would have been passive category income or income in a separate category described in proposed § 1.904–4(m) that is not listed in section 904(d)(1) (a ''specified separate category'') if earned in a pre-2018 taxable year, the exception in proposed § 1.904–2(j)(1)(iii) applies only to unused foreign taxes that were paid or accrued with respect to income in the pre-2018 separate category for general category income. Furthermore, because the determination of taxable income in the section 951A category is intertwined with numerous other new provisions in the Code outside of section 904 that contain novel elements (such as the section 250 deduction and the new inclusion rules in section 951A that permit the sharing of tested losses among CFCs) that did not exist under prior law, it is not possible to reconstruct the amount of unused foreign taxes in a pre-2018 taxable year that would have been assigned to section 951A category income. Therefore, the reallocation exception in the proposed regulations does not require or allow taxpayers to assign any unused foreign taxes to the post-2017 separate category for section 951A category income, which is not eligible to be sheltered from U.S. tax by foreign tax credit carryovers. *See* section 904(c).

The proposed regulations require taxpayers applying the exception in § 1.904–2(j)(1)(iii) to analyze general category income earned in prior years in order to determine the extent to which the income would have been foreign branch category income under the rules described in proposed § 1.904–4(f). Unused foreign taxes in the general category arising in those prior years are then allocated and apportioned under § 1.904–6 between the general category and the foreign branch category. This analysis does not require applying any other post-Act provisions to prior years (for example, the new expense allocation rules described in the proposed regulations would not be relevant to the analysis).

The Treasury Department and the IRS recognize that taxpayers may face difficulties in reconstructing the allocation of unused foreign taxes. Therefore, the Treasury Department and the IRS request comments on whether the final regulations should include a simplified rule for taxpayers that choose to reconstruct the allocation of general category unused foreign taxes (for example, by looking to the relative amounts of foreign branch category and general category income or assets in the first post-2017 taxable year to which the unused foreign taxes are carried), what form such a rule should take, and whether there are any special concerns regarding members that have left a consolidated group. See, for example, § 1.904–7(f)(4)(ii).

All income included in the post-2017 separate category for foreign branch category income would have been general category income if earned in a pre-2018 taxable year. All income included in the post-2017 separate categories for general category income, passive category income, or income in a specified separate category would have been treated as general category income, passive category income, or income in a specified separate category, respectively, if earned in a pre-2018 taxable year. Accordingly, proposed § 1.904–2(j)(2)(ii) and (iii) provides that any unused foreign taxes with respect to general category income or foreign branch category income in a post-2017 taxable year that are carried back to a pre-2018 taxable year are allocated to the pre-2018 separate category for general category income, and any excess foreign taxes with respect to passive category income or income in a specified separate category in a post-2017 taxable year that are carried back to a pre-2018 taxable year are allocated to the same pre-2018 separate category. No rule is included with respect to the post-2017 separate category for section 951A category income (including a separate category for a GILTI inclusion that is resourced under a tax treaty), because carrybacks are not allowed for unused foreign taxes in that separate category.

2. Separate Limitation Losses, Overall Foreign Losses, and Overall Domestic Losses

Similar to the transition rules for carryovers and carrybacks of unused foreign taxes, the proposed regulations provide transition rules for recapture in a post-2017 taxable year of an overall foreign loss (OFL) or separate limitation loss (SLL) in a pre-2018 separate category that offset U.S. source income or income in another pre-2018 separate category, respectively, in a pre-2018 taxable year, as well as for recapture of an overall domestic loss (ODL) that offset income in a pre-2018 separate category in a pre-2018 taxable year.

Proposed § 1.904(f)–12(j) provides that any SLL or OFL accounts in the pre-2018 separate category for passive category income or income in a specified separate category remain in the same post-2017 separate category. Any SLL or OFL account in the pre-2018 separate category for general category income is allocated between the post-2017 separate categories for general category income and foreign branch category income in the same proportion that any unused foreign taxes with respect to the pre-2018 separate category for general category income are allocated to those post-2017 separate categories. Therefore, in the case of a taxpayer that does not apply the exception described in proposed § 1.904–2(j)(1)(iii), all of its SLL or OFL accounts in the pre-2018 separate

category for general category income remain in the general category. In addition, if there were no unused foreign taxes in the pre-2018 general category to be allocated, proposed § 1.904(f)–12(j)(3)(i) provides that all SLL or OFL accounts in the pre-2018 separate category for general category income remain in the general category. Similar rules are provided with respect to the recapture of SLLs or ODLs that reduced income in a separate category in a pre-2018 taxable year, as well as for foreign losses that are part of a net operating loss that is incurred in a pre-2018 taxable year and carried forward to post-2017 taxable years.

B. Separate Categories of Income

1. Treatment of Export Financing Interest, High-Taxed Income, and Financial Services Income

Under section 904(d)(2)(B)(iii), passive income does not include export financing interest and high-taxed income. Before the Act, the only separate category described in section 904(d)(1) aside from passive category income was general category income, and therefore §§ 1.904–4(c) and (h)(2) treated export financing interest and high-taxed income as general category income.

Given the expansion of categories under section 904(d)(1) to include foreign branch category and section 951A category income, and the fact that section 904(d)(2)(B)(iii) only provides that export financing interest and high-taxed income are not passive income, the proposed regulations provide that export financing interest and high-taxed income should be categorized based on whether the income otherwise meets the definition of foreign branch category income, section 951A category income, or general category income. Therefore, the proposed regulations revise § 1.904–4(c) and (h)(2) to provide that export financing interest and high-taxed income are assigned to separate categories other than passive category income based on the general rules in § 1.904–4.

To coordinate the high-taxed income rules of section 904(d)(2)(F) with the new rules for computing foreign income taxes deemed paid under section 960 described in Part IV of this Explanation of Provisions, the proposed regulations revise the grouping rules of § 1.904–4(c)(4) to group passive category income from dividends, subpart F and GILTI inclusions from each foreign corporation, and passive category income derived from each foreign qualified business unit (QBU), under the grouping rules in § 1.904–4(c)(3) rather than by reference to the source of the corporation's or QBU's income. The Treasury Department and the IRS request comments on whether additional changes should be made to the high-taxed income rules in § 1.904–4(c) in light of changes to section 904(d) made by the Act.

Both before and after the Act, section 904(d)(2)(C)(i) provides that certain financial services income is treated as general category income. However, the Act's addition of foreign branch category and section 951A category income, which are new and more specific categories, take precedence over the treatment of financial services income as general category income. Therefore, the proposed regulations provide that any financial services income not treated as foreign branch category income or section 951A category income is generally treated as general category income. *See* proposed § 1.904–4(e).

The proposed regulations do not include any substantive changes to the definition of financial services entity in § 1.904–4(e)(3). It is intended that the current classification of an entity as a financial services entity is generally unaffected by the changes made by the proposed regulations to the look-through rules in § 1.904–5. However, the Treasury Department and the IRS are considering modifications to the gross income-based test for determining financial services entity status and request comments in this regard, particularly with respect to the appropriate treatment of related party payments.

2. Foreign Branch Category Income

i. Gross Income in the Category

Section 904(d)(1)(B) provides a new separate category for foreign branch category income, which is defined in section 904(d)(2)(J) as the business profits of a United States person attributable to a qualified business unit (QBU) in a foreign country (excluding passive category income). Section 904(d)(1)(B) further provides that the amount of business profits attributable to a QBU is determined under rules established by the Secretary.

Section 904(d)(2)(J) limits foreign branch income to income of a United States person. Therefore, foreign persons (including CFCs) cannot have foreign branch category income. While a domestic partnership (or other pass-through entity) that is a United States person may earn income that is attributable to a foreign branch of such partnership, a distributive share of income earned by a domestic partnership cannot be foreign branch category income to foreign partners of the partnership. To avoid any conflict, the proposed regulations define foreign branch category income as the gross income of a United States person (other than a pass-through entity).

Specifically, proposed § 1.904–4(f)(1)(i) provides that foreign branch category income means the gross income of a United States person (other than a pass-through entity) that is attributable to foreign branches held directly or indirectly through disregarded entities by the United States person. Foreign branch category income also includes a United States person's (other than a pass-through entity) distributive share of partnership income that is attributable to a foreign branch held by the partnership directly or indirectly through another partnership or other pass-through entity. Similar principles apply for income of any other type of pass-through entity that is attributable to a foreign branch. All the income described is aggregated in a single foreign branch category; there are not separate categories for each foreign branch. Conforming changes are made to the rules for allocating and apportioning partnership deductions and creditable foreign tax expenditures. *See* proposed §§ 1.861–9(e)(9) and 1.904–6(b)(4)(ii).

In general, gross income is attributable to a foreign branch to the extent it is reflected on a foreign branch's separate set of books and records. For this purpose, items of gross income must be adjusted to conform to Federal income tax principles. In addition, the proposed regulations provide several rules adjusting the gross income attributable to a foreign branch from what is reflected on the foreign branch's separate set of books and records.

First, the proposed regulations provide that gross income attributable to a foreign branch does not include items arising from activities carried out in the United States. Proposed § 1.904–4(f)(2)(ii).

Second, the regulations provide that gross income attributable to a foreign branch does not include items of gross income arising from stock, including dividend income, income included under section 951(a)(1), 951A(a), or 1293(a) or gain from the disposition of stock. Proposed § 1.904–4(f)(2)(iii)(A); *cf.* § 1.987–2(b)(2) (providing a similar rule in connection with attribution of items of income, gain, deduction, or loss to a section 987 QBU). An exception is provided for gain from the disposition of stock, where the stock would be

dealer property. Proposed § 1.904–4(f)(2)(iii)(B).

Third, the proposed regulations provide that foreign branch category income does not include gain realized by a foreign branch owner on the disposition of an interest in a disregarded entity or an interest in a partnership or other pass-through entity. Proposed § 1.904–4(f)(2)(iv)(A). However, an exception is provided for the sale of a partnership interest if the gain is reflected on the books and records of a foreign branch and the interest is held in the ordinary course of the foreign branch owner's trade or business. Proposed § 1.904–4(f)(2)(iv)(B).

Fourth, the proposed regulations provide anti-abuse rules relating to the reflection of income on the books and records of a branch. The Treasury Department and the IRS are concerned that in certain cases gross income items could be inappropriately recorded on the books and records of a foreign branch or a foreign branch owner. Therefore, the proposed regulations include an anti-abuse rule providing for the reattribution of gross income if a principal purpose of recording, or failing to record, an item on the books and records of a foreign branch is the avoidance of Federal income tax or avoiding the purposes of section 904 or section 250. Proposed § 1.904–4(f)(2)(v). The rule further provides a presumption that interest income received by a foreign branch from a related party is not gross income attributable to the foreign branch unless the interest income meets the definition of financial services income.

Finally, in order to accurately reflect the gross income attributable to a foreign branch, a determination that affects not only the application of section 904(a) but also the determination of deduction eligible income under section 250(b)(3)(A), the proposed regulations provide that gross income attributable to a foreign branch that is not passive category income must be adjusted to reflect certain transactions that are disregarded for Federal income tax purposes. Proposed § 1.904–4(f)(2)(vi). This rule applies to transactions between a foreign branch and its foreign branch owner, as well as transactions between or among foreign branches, involving payments that would be deductible or capitalized if the payment were regarded for Federal income tax purposes. For example, a payment made by a foreign branch to its foreign branch owner may, to the extent allocable to non-passive category income, result in a downward adjustment to the gross income attributable to the foreign branch and an increase in the general category gross income of the United States person. Each payment in a series of disregarded back-to-back payments, for example, a payment from one foreign branch to another foreign branch followed by a payment to the foreign branch owner, must be accounted for separately under these rules. Comments are requested on whether special rules are required in the case of a true branch (generally, a branch that is taxable solely on profits from a business conducted in the country and not taxable as a resident of that country) with respect to amounts that are deemed to be made to or from the home office of the branch under the foreign jurisdiction's rules for attributing profits to the branch.

In general, the proposed regulations do not treat disregarded transactions as ''regarded'' for Federal income tax purposes; rather, they provide that certain disregarded transactions result in a redetermination of whether gross income of the United States person is attributable to its foreign branch or to the foreign branch owner. Thus, while disregarded transactions may allocate income between the foreign branch category and the general category, those transactions have no effect on the amount, character, or source of a United States person's gross income. U.S. source gross income that is reallocated from the general category to the foreign branch category and that is properly subject to foreign tax may be eligible to be treated as foreign source income under the terms of an income tax treaty, in which case the resourced income would be subject to a separate foreign tax credit limitation for income resourced under a tax treaty. *See* section 904(d)(6).

The proposed regulations provide an exception from the special rules regarding disregarded transactions that applies to contributions, remittances, and payments of interest (including certain interest equivalents). Proposed § 1.904–4(f)(2)(vi)(C). Generally, contributions, remittances, and interest payments to or from a foreign branch reflect a shift of, or return on, capital rather than a payment for goods and services. However, the different treatment of contributions and remittances, on the one hand, and other disregarded transactions, on the other, could allow for non-economic reallocations of the amount of gross income attributable to the foreign branch category. To prevent this in connection with certain transactions, the proposed regulations require the amount of gross income attributable to a foreign branch (and the amount attributable to the foreign branch owner) to be adjusted to account for consideration that would be due in any disregarded transactions in which property described in section 367(d)(4) is transferred to or from a foreign branch if the transactions were regarded, whether or not a disregarded payment is made in connection with the transfer. Proposed § 1.904–4(f)(2)(vi)(D). The proposed regulations further require that the amount of any adjustment under the disregarded payment provisions must be determined under the arm's length principle of section 482 and the regulations under that section. Proposed § 1.904–4(f)(2)(vi)(E).

The Treasury Department and the IRS request comments on how adjustments relating to these transactions could be limited or simplified to reduce administrative and compliance burdens while still providing for an accurate categorization of gross income, consistent with the purpose of both sections 904 and 250(b)(3)(A). For example, comments are requested on whether these rules should be narrowed to cover a more limited set of transactions or whether disregarded payments should be netted before determining the amount of reallocation.

The proposed regulations do not propose any special rules for determining the amount of deductions allocated and apportioned to foreign branch category income, including deductions reflected on the books and records of foreign branches. Therefore, the proposed regulations provide that the rules for allocating and apportioning deductions in §§ 1.861–8 through 1.861–17 that apply with respect to the other separate categories also apply to the foreign branch category. The Treasury Department and the IRS request comments on whether any special rules should be issued for determining the allocation and apportionment of deductions between the foreign branch category and the general category. In addition, the Treasury Department and the IRS request comments on whether special rules should be provided for financial institutions with branches subject to regulatory capital requirements, including for example, rules similar to those in § 1.882–5.

ii. Definition of a Foreign Branch

The proposed regulations define a foreign branch by reference to the regulations under section 989 (''section 989 regulations'') by providing that a foreign branch is a QBU described in § 1.989(a)–1(b)(2)(ii) and (b)(3) that carries on a trade or business outside the United States. Proposed § 1.904–

4(f)(3)(iii). In general, § 1.989(a)–1(b)(2)(ii) provides rules for treating activities of a branch of a taxpayer as a QBU. Specifically, it provides that the activities of a corporation, partnership, trust, estate, or individual qualify as a separate QBU if the activities constitute a trade or business, and a separate set of books and records is maintained with respect to the activities. Section 1.989(a)–1(b)(3) includes a special rule treating activities generating income effectively connected with the conduct of a trade or business as a separate QBU.

The section 989 regulations treat partnerships and trusts as *per se* QBUs. *See* § 1.989(a)–1(b)(2)(i). As a result, they do not include a rule treating the activities of a partnership or trust that constitute a trade or business, but for which a separate set of books and records is not maintained, as a QBU. For example, § 1.989(a)–1(b)(2)(ii) would not treat the activities of a partnership QBU as a QBU if no separate set of books is maintained with respect to the activities.

In order to ensure that foreign branch category income does not include income reflected on the books and records of a QBU unless the QBU conducts a trade or business, the proposed regulations' definition of foreign branch does not incorporate the section 989 regulations' *per se* QBU rules, and instead requires that a foreign branch carry on a trade or business. In addition, the proposed regulations include a special rule, as illustrated by an example, providing that a foreign branch may consist of activities conducted through a partnership or trust that constitute a trade or business conducted outside the United States, but for which no separate set of books and records is maintained. *See* § 1.904–4(f)(4)(i), *Example 1.*

The proposed regulations also modify the trade or business requirements in the section 989 regulations for purposes of the foreign branch definition. Specifically, to constitute a foreign branch, a QBU must carry on a trade or business outside the United States. For this purpose, activities that constitute a permanent establishment in a foreign country under a bilateral U.S. tax treaty, whether or not the activities also rise to the level of a separate trade or business, are presumed to constitute a trade or business. *See* proposed § 1.904–4(f)(3)(iii)(B).

Under § 1.989(a)–1(c), for activities to constitute a trade or business, they must ordinarily include the collection of income and the payment of expenses. The proposed regulations provide that, for purposes of determining whether a set of activities satisfy the trade or business requirement of § 1.989(a)–1(c) in the context of the definition of a foreign branch, activities that relate to disregarded transactions are taken into account and may give rise to a trade or business for this purpose. *See* proposed § 1.904–4(f)(3)(iii)(B).

3. Section 951A Category Income

Section 904(d)(1)(A) defines a new separate category as ''any amount includible in gross income under section 951A (other than passive category income).'' Consistent with that language, proposed § 1.904–4(g) provides that the gross income included in the section 951A category is generally the gross income of a United States shareholder from a GILTI inclusion. However, a GILTI inclusion that is allocable to passive category income under the look-through rules in § 1.904–5(c)(6) is excluded from section 951A category income. A passive category GILTI inclusion could arise, for example, from a CFC's distributive share of partnership income in which the CFC owns less than 10 percent of the value in the partnership. *See* proposed § 1.904–4(n)(1)(ii). Comments are requested on whether the rules treating a less than 10 percent partner's distributive share of partnership income as passive category income should be modified.

In addition, the proposed regulations amend § 1.904–2(a) to reflect the exclusion of foreign tax credit carryovers under section 904(c) for foreign taxes paid or accrued with respect to section 951A category income or with respect to section 951A category income that is treated as income in a separate category for income resourced under a tax treaty.

4. Items Resourced Under a Treaty

Legislation commonly referred to as the Education Jobs and Medicaid Assistance Act (EJMAA), enacted on August 10, 2010, added section 904(d)(6), which, as amended by the Tax Cuts and Jobs Act, provides that if, without regard to any treaty obligation of the United States, any item of income would be treated as derived from sources within the United States, under a treaty obligation of the United States the item of income would be treated as arising from sources outside the United States, and the taxpayer chooses the benefits of the treaty obligation to treat the income as arising from sources outside the United States, then subsections 904(a), (b), and (c) and sections 907 and 960 shall be applied separately with respect to each item. Thus, section 904(d)(6)(A) applies a separate foreign tax credit limitation to each item of resourced income, without regard to the separate category to which the item would otherwise be assigned.

i. Grouping Methodology

Proposed § 1.904–4(k)(2) adopts a grouping methodology similar to that employed in § 1.904–5(m)(7) with respect to income treated as in a separate category under the separate treaty resourcing rules of section 904(h)(10). Under the proposed regulations, the taxpayer must segregate income treated as foreign source under each treaty and then compute a separate foreign tax credit limitation for income in each separate category that is resourced under that treaty.

For purposes of allocating foreign taxes to each grouping of section 904(d)(6) income, the principles of § 1.904–6 apply to allocate to the section 904(d)(6) separate category all foreign income taxes related to the income included in that group, including taxes imposed by a third country. The Treasury Department and the IRS are considering whether the regulations should provide a special rule limiting the tax assigned to a section 904(d)(6) separate category to tax paid to the foreign country that is a party to the income tax treaty pursuant to which the income is resourced, and request comments on this issue.

ii. Coordination With Certain Treaty and Code Provisions

Some U.S. income tax treaties contain provisions for the tax treatment in both Contracting States of certain types of income derived from sources within the United States by U.S. citizens who are residents of the other Contracting State. See, for example, paragraph 3 of Article 24 (Relief from Double Taxation) of the income tax convention between the United States and Ireland, signed on July 28, 1997. These rules generally use a three-step approach to determine the U.S. citizen's ultimate U.S. income tax liability with respect to an applicable item of income. First, the other Contracting State provides a credit against its tax for the notional U.S. tax that would apply under the treaty to a resident of the other Contracting State who is not a U.S. citizen. Second, the United States provides a credit against U.S. tax for the income tax paid or accrued to the other Contracting State after the application of the credit for notional U.S. tax by the other Contracting State. Finally, the income is deemed to arise in the other Contracting State to the extent necessary to avoid double taxation under these rules.

These treaty rules are generally designed to preserve the United States'

primary right to tax U.S. source income and to resource only enough income to allow a taxpayer to claim a credit for the related foreign taxes, as reduced by the notional credit for U.S. source-based tax. Although excess foreign tax credits may arise from the operation of these rules, excess limitation permitting the use of unrelated foreign tax credits to offset the U.S. tax on the resourced income generally cannot. Since U.S. citizens subject to these provisions generally cannot generate excess limitation, and it would be burdensome to subject individuals to the operation of section 904(d)(6) when they are already subject to the three-step treaty rule, the proposed regulations exclude the income of these individuals from the operation of section 904(d)(6). Accordingly, proposed § 1.904–4(k)(4)(i) provides that income resourced under the relief from double taxation provisions in U.S. income tax treaties that are solely applicable to U.S. citizens who are residents of the other Contracting State is not subject to section 904(d)(6)(A) and § 1.904–4(k)(1).

In addition, under the mutual agreement procedures of U.S. income tax treaties, U.S. taxpayers may request assistance from the U.S. competent authority, such as for the relief of double taxation in cases not provided for in the treaty. Where the U.S. competent authority agrees to grant relief to a taxpayer that involves resourcing, the taxpayer has effectively chosen the benefit of a treaty obligation of the United States to treat the item of income as foreign source. Accordingly, proposed § 1.904–4(k)(4)(ii) clarifies that section 904(d)(6) separate category treatment applies to items of income resourced pursuant to a competent authority agreement.

5. Section 78 Gross Up and Section 986(c) Gain or Loss

Numerous comments were received requesting guidance on the appropriate separate category to which the gross up described in section 78 attributable to foreign taxes deemed paid under section 960(d) should be assigned. Proposed § 1.904–4(o) provides a rule consistent with existing § 1.904–6(b)(3) that assigns the gross up to the same separate category as the deemed paid taxes. See Part II.E.3 of this Explanation of Provisions for a description of rules for allocating and apportioning deemed paid taxes to separate categories.

Proposed § 1.904–4(p) also provides a rule assigning gain or loss under section 986(c) with respect to a distribution of previously taxed earnings and profits to the separate category from which the distribution was made.

C. Noncontrolled 10-Percent Foreign Corporation

Under section 904(d)(2)(E) as amended by the Act, the term ''noncontrolled section 902 corporation'' has been revised to ''noncontrolled 10-percent owned foreign corporation.'' The definition has also been amended to reflect the repeal of section 902, but maintains pre-Act rules for when a taxpayer meets the requisite stock ownership with respect to a passive foreign investment company (''PFIC''). The proposed regulations update the references in the section 904 regulations to noncontrolled section 902 corporations to reflect the revised statutory term and definition.

The ownership requirement for PFICs differs from the United States shareholder requirement that generally applies to a noncontrolled 10-percent owned foreign corporation described in section 904(d)(2)(E)(i)(I). The proposed regulations in § 1.904–5(a)(4)(vi) provide that for purposes of the regulations under section 904, any reference to a United States shareholder in the context of a noncontrolled 10-percent owned foreign corporation also includes a taxpayer that meets the stock ownership requirements described in section 904(d)(2)(E)(i)(II), even if the taxpayer is not a United States shareholder within the meaning of section 951(b).

D. Look-Through Rules

Before amendments made by the American Jobs Creation Act of 2004 (AJCA), section 904(d)(3) generally provided that dividends, interest, rents, and royalties (''look-through payments'') received or accrued by a taxpayer from a CFC in which the taxpayer is a United States shareholder were treated as income in the separate category to which the payment was allocable. Section 904(d)(4) provided similar look-through rules for dividends from noncontrolled section 902 corporations. The AJCA reduced the number of separate categories from nine to two, and revised section 904(d)(3). Under section 904(d)(3)(A) as amended by the AJCA, except as otherwise provided by section 904(d)(3), dividends, interest, rents, and royalties received or accrued by a taxpayer from a CFC in which the taxpayer is a United States shareholder are not treated as passive category income. Exceptions are provided, generally, when the payment is allocable to passive category income. However, the existing regulations under § 1.904–5 were largely unchanged after the AJCA amendments and retained the pre-AJCA approach to assigning dividends, interest, rents, and royalties based on the separate category of the income to which the payment was allocable, rather than excluding the income from the passive category to the extent not allocable to the passive category. In practice, because there were generally only two separate categories after the AJCA and because the general category was a residual category, the approach under the existing regulations of assigning payments to a separate category based on the separate category to which they were allocable resulted in payments that were not allocable to passive category income being assigned to the general category.

The Act added two new separate categories to section 904(d)(1) but made no changes to the look-through rules in section 904(d)(3) and (4). In addition, the legislative history does not provide any indication of how the look-through rules were intended to operate with the addition of the new separate categories.

The proposed regulations provide that the look-through rules under section 904(d)(3) provide look-through treatment solely for payments allocable to the passive category. Any other payments described in section 904(d)(3) are assigned to a separate category other than the passive category based on the general rules in § 1.904–4. Therefore, proposed § 1.904–5 revises the various look-through rules to reflect the application of look-through rules solely with respect to payments allocable to passive category income. Dividends, interest, rents, or royalties paid from a CFC to a United States shareholder thus are not assigned to a separate category (other than the passive category) under the look-through rules, but are assigned to the foreign branch category, a specified separate category described in proposed § 1.904–4(m), or the general category under the rules of proposed § 1.904–4(d).

Consistent with the general rule for look-through payments, section 904(d)(3)(B) assigns amounts included under section 951(a)(1)(A) (''subpart F inclusions'') to the passive category to the extent the inclusion is attributable to passive category income. Under the authority of section 951A(f)(1)(B), the proposed regulations treat GILTI inclusions in the same manner as subpart F inclusions for purposes of section 904(d)(3)(B). Therefore, proposed § 1.904–5(c)(6) provides that GILTI inclusions are treated as passive category income to the extent the amount so included is attributable to income received or accrued by the CFC that is passive category income.

Under the proposed regulations, the look-through rules also do not apply to

treat deductible payments made by a foreign branch that are allocable to foreign branch category income (for example, payments made by a foreign disregarded entity that constitutes a foreign branch to a related look-through entity) as foreign branch category income. Instead, the rules of § 1.904–4 apply to characterize the income in the hands of the recipient.

Finally, as a result of the proposed revisions to § 1.904–5 that limit the look-through rules generally to passive category income, the proposed regulations include a rule addressing income subject to the separate category required under section 901(j)(1)(B). These rules ensure that income from sources within countries described in section 901(j)(2) that is paid or accrued through one or more entities retains its source and therefore continues to be subject to the separate category described in section 901(j)(1)(B). *See* proposed § 1.901(j)–1(a).

E. Allocation and Apportionment of Foreign Taxes

1. Special Rule for Base and Timing Differences

Section 904(d)(2)(H)(i) and § 1.904–6(a)(1)(iv) provide a special rule for allocating foreign tax that is imposed on an amount that does not constitute income under Federal income tax principles (a ''base difference''). Section 1.904–6(a)(1)(iv) also provides special rules for timing differences.

The proposed regulations clarify that base differences arise only in limited circumstances, such as in the case of categories of items such as life insurance proceeds or gifts, which are excluded from income for Federal income tax purposes but may be taxed as income under foreign law. In contrast, a computational difference attributable to differences in the amounts, as opposed to the types, of items included in U.S. taxable income and the foreign tax base does not give rise to a base difference. *See* proposed § 1.904–6(a)(1)(iv). For example, a difference between U.S. and foreign tax law in the amount of deductions that are allowed to reduce gross income, like a difference in depreciation conventions or in the timing of recognition of gross income, is not considered to give rise to a base difference.

In addition, the proposed regulations clarify that the fact that a distribution of previously taxed earnings and profits is exempt from Federal income tax does not mean that a tax imposed on the distribution is attributable to a base difference. Instead, because the previously taxed earnings and profits were included in U.S. taxable income in a prior year, the tax imposed on the distribution is treated as attributable to a timing difference and is allocated to the separate category to which the earnings and profits from which the distribution was paid are attributable.

2. Taxes Imposed in Connection With Foreign Branches

The regulations in § 1.904–6(a) generally provide that foreign taxes are allocated and apportioned to separate categories by reference to the separate category of the income to which the foreign tax relates. Disregarded transactions between a foreign branch and the United States owner of the foreign branch (or between two foreign branches of the same United States person) may involve disregarded payments that are subject to foreign tax, including disregarded payments that result in the reallocation of gross income between the foreign branch category and the general category under the proposed regulations in § 1.904–4(f)(2)(vi). *See* proposed § 1.904–4(f) and Part II.B.2 of this Explanation of Provisions. While existing regulations under § 1.904–6(a) provide general rules for allocating and apportioning foreign taxes imposed with respect to income of a foreign branch, proposed § 1.904–6(a)(2) provides special rules to coordinate the existing regulations under § 1.904–6(a)(1) with the computation of foreign branch category income in proposed § 1.904–4(f).

The proposed regulations are consistent with the general principles and purpose of § 1.904–6(a)(1) and are intended to provide clarity where the application of these principles would be difficult or uncertain. The Treasury Department and the IRS recognize that there may be additional circumstances where the application of these rules may be ambiguous and request comments on whether further guidance is needed to clarify how foreign taxes should be allocated and apportioned between the foreign branch category and other separate categories.

3. Taxes Deemed Paid Under Section 960

The proposed regulations propose modifications to § 1.904–6(b) to reflect the Act's repeal of section 902 and revisions to section 960. In general, the proposed regulations provide that foreign income taxes deemed paid under section 960(a) or (d) are allocated to the same separate category to which the related section 951(a)(1) or 951A(a) inclusion is assigned. Similarly, in the case of a distribution of previously taxed earnings and profits described in section 960(b)(1) or (2), any foreign tax deemed paid with respect to the distribution under section 960(b) is allocated to the separate category to which the distribution is attributable.

4. Creditable Foreign Tax Expenditures

As discussed in Part II.B.2 of this Explanation of Provisions, a U.S. or foreign partnership does not characterize any of its income as foreign branch category income. Instead, a distributive share of a partnership's income may be characterized as foreign branch category income in the hands of certain U.S. partners. In order to ensure that creditable foreign tax expenditures (CFTEs) that are allocated to a partner that has a distributive share of income that is assigned to the foreign branch category are appropriately assigned, proposed § 1.904–6(b)(4) provides rules for allocating and apportioning CFTEs to the foreign branch category.

III. Treatment of Subsequent Reductions in Tax in Applying Section 954(b)(4)

The Treasury Department and the IRS are aware that certain taxpayers have formed CFCs in certain jurisdictions that purport to have a type of integration regime whereby all or substantially all of the corporate income tax paid by the CFC on its earnings is refunded to its shareholder when the earnings are distributed, even though the shareholder is not subject to any foreign tax on the distribution. These taxpayers rely on the rules in § 1.954–1(d)(3), which provide that a subsequent reduction in corporate foreign income taxes when earnings are later distributed to a shareholder does not affect the amount of foreign income taxes used to compute the effective tax rate on an item of income unless the reduction requires a redetermination of the United States shareholder's U.S. tax under section 905(c). These taxpayers claim that the high-tax exception from foreign base company income under section 954(b)(4) allows them to exclude the CFC's income from current taxation under subpart F, despite the fact that all or substantially all of the foreign corporate income tax is later refunded to the shareholder.

The proposed regulations modify § 1.954–1(d)(3) to provide that to the extent the foreign income taxes paid or accrued by a CFC are reasonably certain to be returned to a shareholder upon a subsequent distribution to the shareholder, the foreign income taxes are not treated as paid or accrued for purposes of the high-tax exception under section 954(b)(4). The IRS may also challenge these arrangements under

existing law, for example, on the ground that the payment to the shareholder constitutes a refund under § 1.901–2(e)(2) or a subsidy under section 901(i) and § 1.901–2(e)(3) that reduces the amount of tax the CFC is considered to have paid.

Comments are requested on what special rules under § 1.954–1(d)(3), § 1.901–2, and section 905(c) should be considered to account for genuine integration regimes that do not have the effect of exempting resident corporations and their shareholders from all or substantially all tax.

IV. Deemed Paid Taxes Under New Section 960 and New Section 78

Section 960(a) and (d), as revised by the Act, deems a domestic corporation that is a United States shareholder of a CFC to pay the portion of the foreign income taxes paid or accrued by the CFC that is properly attributable to income of the CFC that the United States shareholder takes into account in computing its subpart F or GILTI inclusion, subject to certain limitations. Section 960(b), as revised by the Act, provides rules for taxes that are deemed paid in connection with distributions by a CFC of previously taxed earnings and profits to either a United States shareholder that is a domestic corporation or to a shareholder that is a CFC. *Cf.* section 960(a)(3) (as in effect on December 21, 2017). Proposed §§ 1.960–1 through 1.960–3 provide rules for determining a domestic corporation's deemed paid taxes under section 960(a), (b), and (d).

Additionally, the Act redesignated former section 960(b), relating to excess limitation accounts, without change, as section 960(c). The proposed regulations treat a GILTI inclusion amount as a subpart F inclusion for purposes of section 960(c). *See* section 951A(f)(1)(B). Therefore, the proposed regulations modify §§ 1.960–4 and 1.960–5 to reflect the additional application of section 960(c) to GILTI inclusion amounts. Comments are requested on whether additional amendments to the proposed regulations are appropriate, including additional rules in § 1.960–4 to account for unique aspects of the section 951A category.

Finally, § 1.960–7 includes updated applicability dates for §§ 1.960–1 through 1.960–6, which are consistent with the effective dates of the Act.

The Act also amended section 78 to, among other things, reflect the addition of deemed paid credits under section 960(d) and to provide that any amount of taxes deemed paid under section 960 that is treated as a dividend under section 78 (a ''section 78 dividend'') is not eligible for a section 245A deduction. The proposed regulations revise § 1.78–1 to reflect changes made to section 78.

Part IV.A of this Explanation of Provisions describes computational and grouping rules relating to the calculation of deemed paid taxes under section 960(a), (b), and (d). Part IV.B of this Explanation of Provisions describes specific rules for the calculation of deemed paid taxes under section 960(a) and (d). Part IV.C of this Explanation of Provisions describes specific rules for the calculation of deemed paid taxes under section 960(b). Part IV.D of this Explanation of Provisions describes the application of the rules under section 960(a), (b), and (d) when the domestic corporation owns the CFC through a domestic partnership. Part IV.E of this Explanation of Provisions describes revisions to § 1.78–1.

A. Computational and Grouping Rules for Purposes of Calculating Taxes Deemed Paid Under Section 960

1. Current Year Taxes

For a particular taxable year, a CFC may have subpart F income or tested income that is taken into account by a domestic corporation that is a United States shareholder of the CFC under sections 951(a)(1)(A) or 951A(a), and may incur foreign income taxes related to that income that may be treated as deemed paid by the United States shareholder under sections 960(a) or (d). Additionally, a CFC may receive distributions of previously taxed earnings and profits and incur foreign income taxes with respect to those distributions that may subsequently be treated as deemed paid by the United States shareholder or an upper-tier CFC under section 960(b).

Proposed § 1.960–1 provides definitions as well as computational and grouping rules that associate the current year foreign income taxes (''current year taxes'') of the CFC with current year income of the CFC or a distribution of previously taxed earnings and profits received by the CFC. These taxes, in turn, may be deemed paid by the United States shareholder or upper-tier CFC under section 960. Foreign income taxes generally include income, war profits, and excess profits taxes that are imposed by a foreign country or a possession of the United States. *See* proposed § 1.960–1(b)(5). The term ''possession of the United States'' means American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, Puerto Rico, or the U.S. Virgin Islands. Current year taxes of a CFC are foreign income taxes paid or accrued by the CFC in its current taxable year, and the rules of section 461 and the ''relation-back'' doctrine apply to determine the timing of the accrual of foreign income taxes and the year for which they are taken into account. *See* proposed § 1.960–1(b)(4). Thus, for example, foreign income taxes calculated on the basis of net income accrue in the U.S. taxable year of the CFC with or within which its foreign taxable year ends, and are eligible to be deemed paid in the taxable year of the United States shareholder with or within which the U.S. taxable year of the CFC ends, even if a portion of the foreign taxable year of the CFC falls within an earlier or later U.S. taxable year of the CFC or its United States shareholder. Current year taxes of a CFC that are imposed on an amount under foreign law that would be income under U.S. law in a different taxable year are eligible to be deemed paid in the year in which the foreign tax accrues, and not in the earlier or later year when the related income is recognized for U.S. tax purposes. The current taxable year of the CFC is its U.S. taxable year for which a domestic corporation that is a United States shareholder of the CFC has a subpart F or GILTI inclusion with respect to the CFC, or during which the CFC receives a section 959(b) distribution or makes a section 959(a) distribution or a section 959(b) distribution.

2. Computational Rules

Proposed § 1.960–1(c)(1) describes and orders the computations involved in calculating the foreign income taxes deemed paid by either a domestic corporation that is a United States shareholder of a CFC or by a CFC that is a shareholder of another CFC. These steps are applied by each CFC in a chain of ownership beginning with the lowest-tier CFC with respect to which the domestic corporation is a United States shareholder.

Under these computational rules, a United States shareholder first applies the grouping rules described in Part IV.A.3 of this Explanation of Provisions to assign the income of the CFC to separate categories of income described in proposed § 1.904–5(a)(4)(v) (each a ''section 904 category'') and then to groups that correspond to certain types of income (each, an ''income group'') in a section 904 category. If the CFC receives a distribution of previously taxed earnings and profits (''PTEP''), it increases the group or groups (each, a ''PTEP group'') within an annual PTEP account that corresponds both to the taxable year for which a CFC took into account the income from which the

previously taxed earnings and profits arose, and to the separate category of the United States shareholder to which the amount of the resulting inclusion under sections 951(a)(1)(A) or 951A was assigned. The rules for grouping previously taxed earnings and profits within an annual PTEP account are described in Part IV.C.1 of this Explanation of Provisions. The income and PTEP groups, which are discussed in more detail below, are the mechanism for computing taxes deemed paid under section 960.

Second, deductions of the CFC, including for expenses attributable to current year taxes, are allocated and apportioned to the income groups. Current year taxes are also allocated and apportioned to a PTEP group that was increased in the first step. Third, taxes deemed paid by the United States shareholder under section 960(a) and (d), and taxes deemed paid by the CFC under section 960(b)(2) in connection with its receipt of a section 959(b) distribution, are calculated. Fourth, the previously taxed earnings and profits resulting from the subpart F inclusion or GILTI inclusion of the United States shareholder are added to an annual PTEP account and further assigned to the relevant PTEP groups within the account. Fifth, the first four steps are repeated for each higher-tier CFC. Sixth, with respect to the highest-tier CFC, the United States shareholder computes its taxes deemed paid under section 960(b)(1).

Proposed § 1.960–1(c)(2) provides that only items that the CFC takes into account during its current taxable year are used in the computational rules of § 1.960–1(c)(1). The items of gross income and expense that are in a section 904 category and income group within a section 904 category are therefore items that the CFC accrues and takes into account in its current taxable year, and the foreign income taxes that are eligible to be deemed paid are foreign income taxes that the CFC pays or accrues in its current taxable year. Proposed § 1.960–1(c)(3) provides rules relating to foreign currency and translation.

3. Associating Current Year Taxes With Income Groups

In order to determine the foreign income taxes paid or accrued by the CFC that are properly attributable to amounts that a domestic corporation that is a United States shareholder of the CFC takes into account in determining its subpart F or GILTI inclusions, proposed § 1.960–1(d) provides rules associating current year taxes of the CFC with the types of income earned by the CFC from which the inclusions arise. Proposed § 1.960–1(d) requires a CFC to assign its income to one or more income groups within each section 904 category. Deductions of the CFC, including for current year taxes, are allocated and apportioned to the income groups in order to determine net income (or loss) in each income group and to identify the current year foreign income taxes that relate to the income in each income group for section 960 purposes.

i. Income Group Definitions

Proposed § 1.960–1(d)(2)(ii) defines several separate income groups with respect to the subpart F income of the CFC (''subpart F income groups'') within each applicable section 904 category. Each single item of foreign base company income as defined in § 1.954–1(c)(1)(iii) is a separate subpart F income group. For example, with respect to a CFC, § 1.954–1(c)(1)(iii)(A)(*2*) identifies as a single item of income all foreign base company income (other than foreign personal holding company income) that falls within both a single separate category (typically, general category income) and a single category of foreign base company income described in each of § 1.954–1(c)(1)(iii)(A)(*2*)(*i*) through (*v*). Therefore, there is a single subpart F income group within the general category that consists of all of a CFC's foreign base company sales income. Section 1.954–1(c)(1)(iii)(B) provides grouping rules for items of passive category foreign personal holding company income, each of which is also treated as a separate subpart F income group under § 1.960–1. Proposed § 1.960–1(d)(2)(ii)(B)(*2*) also defines a separate subpart F income group for the CFC's insurance income described in section 952(a)(1), for its international boycott income described in section 952(a)(3), for the sum of its illegal bribes and kickbacks described in section 952(a)(4), and for income included in a section 901(j) separate category described in section 952(a)(5).

Proposed § 1.960–1(d)(2)(ii)(C) also defines separate income groups for tested income (each, a ''tested income group'') in each section 904 category. In general, tested income will be in a single tested income group within the general category. Because a CFC cannot earn section 951A category income or foreign branch category income at the CFC level, there is no tested income group within either section 904 category. With respect to the CFC's general category tested income group, GILTI inclusion amounts and taxes with respect to the tested income group will generally be treated as income and deemed paid taxes in the section 951A category. *See* §§ 1.904–4(g), 1.904–6(b)(1).

Income in a section 904 category that is not of a type that is included in one of the subpart F income groups or tested income groups is assigned to the residual income group. *See* proposed § 1.960–1(d)(2)(ii)(D).

ii. Computing Net Income in an Income Group and Assigning Current Year Taxes to an Income Group

In order to determine its net income in each income group, a CFC first assigns its items of gross income to a section 904 category and to the appropriate income group within the category, and then allocates and apportions its deductions and expenses, including current year taxes, to the categories and to the income groups within the categories under the rules of sections 861 through 865 and 904(d) and the regulations under those sections.

Current year taxes are allocated and apportioned to income groups for two purposes. The first purpose is to deduct current year taxes (in functional currency) from gross income in the income group in computing the net income in the income group. The second purpose is to associate an amount of current year taxes (in U.S. dollars) with an income group. These current year taxes associated with an income group are eligible to be deemed paid by a United States shareholder that has a subpart F or GILTI inclusion that is attributable to that income group. The rules for allocating and apportioning current year taxes are the same for both purposes. *See also* proposed § 1.861–8(e)(6) (clarifying that the rules for allocating and apportioning deductions for foreign income tax expense are the same as the rules for allocating and apportioning foreign income taxes to separate categories under § 1.904–6).

Proposed § 1.960–1(d)(3)(ii) applies the rules of § 1.904–6 to allocate and apportion current year taxes to and among the section 904 categories based upon the amount of taxable income, as calculated under foreign law, of the CFC that is in each section 904 category. Proposed § 1.960–1(d)(3)(ii) then applies the principles of § 1.904–6 to allocate and apportion current year taxes to and among the income groups. If a PTEP group of the CFC is increased as a result of a section 959(b) distribution that it receives in the current taxable year, then for purposes of allocating and apportioning current year taxes that are imposed solely by reason of the section 959(b) distribution, the PTEP group is treated as an income group within the

section 904 category. Part IV.C of this Explanation of Provisions discusses the rules for tracking amounts in PTEP groups and for computing deemed paid credits with respect to distributions of previously taxed earnings and profits from a PTEP group. Current year taxes that are not allocated and apportioned to a subpart F or tested income group, or to a PTEP group that is treated as an income group, are allocated and apportioned to a residual income group. Current year taxes allocated and apportioned to a residual income group cannot be deemed paid under section 960 for any taxable year. Proposed § 1.960–1(e).

Under § 1.904–6, Federal income tax principles apply to determine the separate category, income group, or PTEP group of the CFC's gross items of income and expense, the amounts of which are computed under foreign law, that are included in the foreign tax base. For example, if the United States treats a distribution as resulting in capital gain that is passive category income, but foreign law treats the item as a dividend that would be general category income, the item is assigned to the passive category for purposes of allocating and apportioning current year taxes of the CFC to the item. *See also* proposed § 1.904–6(a)(1)(i). The amount of the item, however, is determined under foreign law, and expenses (also determined under foreign law) are allocated and apportioned to the income under foreign law principles or as otherwise provided in § 1.904–6(a)(1)(ii).

Proposed § 1.960–1(d)(3)(ii)(B) also provides a rule for addressing base and timing differences (within the meaning of proposed § 1.904–6(a)(1)(iv)) for purposes of allocating and apportioning current year taxes of a CFC to income groups and PTEP groups. Current year taxes that are attributable to a base difference are allocated to the residual income group, and therefore are ineligible to be deemed paid. Current year taxes that are attributable to a timing difference—namely, current year tax imposed on an amount that is income of the CFC in a different taxable year under Federal income tax law—are allocated and apportioned to a section 904 category and income group as though the income that foreign law recognizes in the CFC's current taxable year were also recognized for Federal income tax purposes in that year. Proposed § 1.960–1(d)(3)(ii)(B) includes a special rule, which is discussed in Part IV.C.2 of this Explanation of Provisions, for current year taxes that are attributable to a timing difference resulting from a section 959(b) distribution.

B. Taxes Deemed Paid Under Section 960(a) and (d) for Subpart F Inclusions and GILTI Inclusion Amounts

Section 960(a) provides that a domestic corporation that is a United States shareholder of a CFC is deemed to have paid the CFC's foreign income taxes that are properly attributable to the item of income of the CFC that the United States shareholder includes in gross income under section 951(a)(1) as a subpart F inclusion.

Section 960(d) provides that a domestic corporation that is a United States shareholder is deemed to have paid 80 percent of an amount that is equal to the product of the United States shareholder's inclusion percentage and the aggregate of the tested foreign income taxes paid or accrued by the CFCs of the United States shareholder. The inclusion percentage of the United States shareholder is the ratio of the United States shareholder's GILTI inclusion amount with respect to its CFCs to the aggregate amount of the United States shareholder's pro rata share of tested income of those CFCs. Section 960(d)(3) defines tested foreign income taxes as the foreign income taxes paid or accrued by a CFC of a United States shareholder that are properly attributable to the tested income of the CFC that the United States shareholder takes into account in computing its GILTI inclusion amount.

1. Subpart F Inclusions

Under proposed § 1.960–2(b), the amount of the foreign income taxes of a CFC that its United States shareholder that is a domestic corporation is deemed to pay under section 960(a) is computed with respect to the income of the CFC, determined under Federal income tax principles in each subpart F income group within a section 904 category. A domestic corporate shareholder that has a subpart F inclusion with respect to its CFC is deemed to pay the CFC's foreign income taxes that are properly attributable to the items of income of the CFC that give rise to the subpart F inclusion of that shareholder. The amount of taxes that are properly attributable to an item of income for this purpose is equal to the domestic corporate shareholder's proportionate share of the current year taxes of the CFC that are allocated and apportioned to the subpart F income group within a section 904 category of the CFC to which the item of income is attributable. The proportionate share for each subpart F income group is equal to the current year taxes that are allocated and apportioned to a subpart F income group within a section 904 category multiplied by a fraction equal to the portion of the subpart F inclusion that is attributable to that subpart F income group to the total income in that subpart F income group. Therefore, no tax is deemed paid by a corporate United States shareholder of a CFC with respect to a subpart F income group to which current year taxes of the CFC are allocated and apportioned (including by reason of the rule for timing differences) but with respect to which no portion of a subpart F inclusion is attributable.

The denominator of the fraction, the net income in the subpart F income group, is not reduced to reflect any prior year deficits because those deficits do not reduce the subpart F income of the CFC in the current year. A pro rata share of a prior year qualified deficit reduces the amount of a United States shareholder's subpart F inclusion, and therefore by its own account reduces the numerator of the fraction. Proposed § 1.960–2(b)(3)(ii). The denominator of the fraction is, however, reduced to reflect the limitation in section 952(c)(1)(A) of the subpart F income of the CFC to its current year earnings and profits. The denominator is also reduced to reflect any reduction in the subpart F income of a CFC under section 952(c)(1)(C), which allows a CFC to reduce certain of its subpart F income by an amount of certain current year deficits of certain CFCs in the same chain of ownership. Proposed § 1.960–2(b)(3)(iii).

Section 960(a) treats foreign income taxes of a CFC as deemed paid by a United States shareholder only with respect to an item of income of a CFC that is included in the gross income of the United States shareholder under section 951(a)(1). Proposed § 1.960–2(b)(1) treats taxes as deemed paid under section 960(a) specifically with respect to subpart F inclusions because the inclusions are with respect to items of income of the CFC. In contrast, an inclusion under section 951(a)(1)(B) is not an inclusion of an ''item of income'' of the CFC but instead is an inclusion equal to an amount that is determined under the formula in section 956(a). Therefore, proposed § 1.960–2(b)(1) provides that no foreign income taxes are deemed paid under section 960(a) with respect to an inclusion under section 951(a)(1)(B).

2. GILTI Inclusion Amounts

Proposed § 1.960–2(c) provides that the amount of the tested foreign income taxes that a United States shareholder is deemed to pay under section 960(d) is computed with respect to the income of

the CFC in each tested income group within a section 904 category. For purposes of determining a United States shareholder's tested foreign income taxes, the CFC's current year taxes are first allocated and apportioned to the tested income group within a section 904 category in order to determine the foreign income taxes ''properly attributable'' to the tested income group. The United States shareholder's tested foreign income taxes for a tested income group within a section 904 category is equal to its proportionate share of the CFC's current year taxes, determined by multiplying the CFC's current year taxes that are allocated and apportioned to a tested income group within a section 904 category by a fraction that is equal to the tested income of the CFC in the tested income group that is included in computing the domestic corporation's aggregate amount described in section 951A(c)(1)(A) and proposed § 1.951A–1(c)(2)(i), divided by the total income in the tested income group.

The United States shareholder's inclusion percentage is required to determine the amount of taxes deemed paid by the United States shareholder. In general, current year taxes allocated and apportioned to a tested income group will be in the general category at the level of the CFC, although in limited cases involving passive category tested income, current year taxes may be allocated and apportioned to the passive category. However, the domestic corporation computes only a single inclusion percentage with respect to all of its tested income, regardless of the section 904 category to which the tested income is assigned.

In the case of a United States shareholder that is a member of a consolidated group, the numerator of the inclusion percentage is computed using the GILTI inclusion amount of a United States shareholder as determined under § 1.1502–51. *See* § 1.951A–1(c)(4).

C. Taxes Deemed Paid Under Section 960(b) With Respect to Section 959 Distributions

Section 960(b)(1) provides that a United States shareholder of a CFC is deemed to have paid the CFC's foreign income taxes that the United States shareholder has not been previously deemed to pay and that are properly attributable to a distribution from the CFC that the United States shareholder excludes from its income under section 959(a) (a ''section 959(a) distribution''). Section 960(b)(2) provides that a CFC is deemed to have paid the foreign income taxes of another CFC that have not previously been deemed paid by a United States shareholder and that are properly attributable to a distribution from the other CFC to which section 959(b) applies (a ''section 959(b) distribution,'' and together with a section 959(a) distribution, a ''section 959 distribution'').

1. PTEP Groups in Annual PTEP Accounts and Associated Taxes

Proposed § 1.960–3(c)(1) requires a CFC to establish a separate, annual account (''annual PTEP account'') for its earnings and profits for its current taxable year to which subpart F or GILTI inclusions of United States shareholders of the CFC are attributable. Each account must correspond to the inclusion year of the previously taxed earnings and profits and to the section 904 category of the inclusions at the United States shareholder level. Accordingly, a CFC may have an annual PTEP account in the section 951A category or a treaty category (as defined in § 1.861–13(b)(6)), even though income of the controlled foreign corporation cannot initially be assigned to the section 951A category or a treaty category. The previously taxed earnings and profits in each annual account are then assigned to one of ten possible groups of previously taxed earnings and profits described in proposed § 1.960–3(c)(2) (each, a ''PTEP group''). The PTEP groups serve a similar function to the subpart F income groups and tested income groups—they are the mechanism for associating foreign taxes paid or accrued, or deemed paid, by a CFC with section 959 distributions of previously taxed earnings and profits. If, following the issuance of new guidance under section 959 (which will be addressed in a separate guidance project), it is determined that maintaining all ten of the PTEP groups is unnecessary, or that grouping of annual accounts into multi-year accounts is permissible, the Treasury Department and the IRS will consider consolidating PTEP groups as part of finalizing the proposed regulations.

A CFC accounts for a section 959(b) distribution that it receives by adding the distribution amount to an annual PTEP account and PTEP group that corresponds to the annual PTEP account and PTEP group from which the distributing CFC made the distribution. Proposed § 1.960–3(c)(3). A CFC that makes a section 959 distribution must similarly reduce the annual PTEP account and PTEP group within the account from which the distribution is made by the distribution amount. A CFC must also reduce PTEP groups that relate to previously taxed earnings and profits described in section 959(c)(2) (''section 959(c)(2) PTEP'') to account for reclassification of amounts into those groups as previously taxed earnings and profits described in section 959(c)(1) (''reclassified PTEP''), and increase the PTEP group that corresponds to the reclassified amount. Proposed § 1.960–3(c)(4).

2. Associating Foreign Income Taxes With PTEP Groups

A CFC must also account for the foreign income taxes that it pays, accrues or is deemed to pay with respect to the amount in each PTEP group (''PTEP group taxes''). PTEP group taxes are accounted for with respect to previously taxed earnings and profits assigned to a PTEP group within an annual PTEP account. PTEP group taxes consist of (1) the current year taxes paid or accrued by the CFC as the result of its receipt of a section 959(b) distribution that are allocated and apportioned to the PTEP group; (2) foreign income taxes that are deemed paid by the CFC with respect to an amount in a PTEP group; and (3) in the case of a reclassified PTEP group, foreign income taxes that were paid, accrued or deemed paid with respect to an amount that was initially included in a section 959(c)(2) PTEP group and subsequently added to a corresponding reclassified PTEP group. Proposed § 1.960–3(d)(1). PTEP group taxes are reduced by the amount of foreign income taxes in the group that are deemed paid by a United States shareholder under section 960(b)(1) or by another CFC under section 960(b)(2), and foreign income taxes relating to a PTEP group that is reclassified to a section 959(c)(1) PTEP group. Proposed § 1.960–3(d)(2).

As discussed in Part IV.A.3.ii of this Explanation of Provisions, proposed § 1.960–1(d)(3)(ii)(A) associates current year taxes of a CFC with a PTEP group for purposes of section 960(b) only in the case of an increase in a PTEP group as a result of the receipt of a section 959(b) distribution. The increased PTEP group is treated as an income group to which current year taxes that are imposed solely by reason of that section 959(b) distribution are allocated and apportioned. For example, a withholding tax imposed on a section 959(b) distribution received by an upper-tier CFC is allocated and apportioned to the PTEP group that is increased by the section 959(b) distribution. The withholding tax also reduces (as a deduction) the amount in that same PTEP group.

Proposed § 1.960–1(d)(3)(ii)(B) generally applies the timing difference rule of § 1.904–6(a)(1)(iv) to allocate and apportion current year taxes that are

attributable to a timing difference to a section 904 category and income group as if the CFC recognized the related income under Federal income tax principles in its current taxable year. Proposed § 1.960–1(d)(3)(ii)(B) also clarifies the rule for previously taxed earnings and profits by providing that if current year taxes are attributable to a timing difference, the taxes are only treated as related to a PTEP group if the taxes are imposed solely by reason of a section 959(b) distribution that increases the PTEP group. For example, a timing difference described in proposed § 1.904–6(a)(1)(iv) could include a situation in which Federal income tax principles require marking-to-market gain on an asset, resulting in an inclusion under section 951A(a), but the foreign jurisdiction only imposes tax when the asset is disposed of in a later year. Under proposed § 1.960–1(d)(3)(ii)(B), the later-imposed foreign income tax is treated as related to the tested income group (if any) for the year in which the tax is imposed, and not to a PTEP group in an annual PTEP account for the earlier year in which the gain was recognized for Federal income tax purposes. In addition, an income tax imposed on a distributing CFC (in contrast to a tax, such as a withholding tax, imposed on the recipient of the distribution) by reason of a section 959 distribution is treated as a timing difference and is treated as related to the subpart F income group or tested income group for the current taxable year (if any) in which the distribution is made, and not to a PTEP group in an annual PTEP account for the earlier year in which the distributed earnings and profits were recognized for Federal income tax purposes.

Therefore, under proposed § 1.960–1(d)(3)(ii)(B), the only taxes that are allocated and apportioned to a PTEP group are taxes that are imposed solely by reason of a CFC's receipt of a section 959(b) distribution and that are otherwise allocated and apportioned to the PTEP group under § 1.904–6 principles. For example, a net basis tax imposed on a CFC's receipt of a section 959(b) distribution by the CFC's country of residence is treated as related to a PTEP group. Similarly, a withholding tax imposed with respect to a CFC's receipt of a section 959(b) distribution is allocated and apportioned to a PTEP group. In contrast, a withholding tax imposed on a disregarded payment from a disregarded entity to a CFC owner is treated as a timing difference and is never treated as related to a PTEP group (even if all of the CFC's earnings and profits are previously taxed earnings and profits from income earned by the disregarded entity), because the tax is not imposed solely by reason of a section 959(b) distribution. The withholding tax, however, may be treated as related to a subpart F income group or tested income group under the rule for timing differences.

3. Computational Rules

Proposed § 1.960–3(b) provides rules for determining the amount of taxes deemed paid with respect to a section 959(a) distribution. A domestic corporation that receives a section 959(a) distribution is deemed to have paid the foreign income taxes that are properly attributable to the section 959(a) distribution from the PTEP group of the distributing CFC, to the extent the PTEP group taxes have not already been deemed to have been paid in the current taxable year or any prior taxable year. Proposed § 1.960–3(b)(1). The amount of foreign income taxes that are properly attributable to a domestic corporation's receipt of a section 959(a) distribution from a PTEP group within a section 904 category are its proportionate share of PTEP group taxes associated with the PTEP group. The domestic corporation's proportionate share of foreign income taxes associated with a section 959(a) distribution from a PTEP group is determined by a fraction equal to the amount of the section 959(a) distribution attributable to the PTEP group over the total amount of previously taxed earnings and profits in the PTEP group.

A single section 959(a) distribution could be attributable to multiple PTEP groups, with respect to multiple different inclusion years, of the distributing CFC. The proposed regulations, including the order of the list of PTEP groups in § 1.960–3(c)(2), do not provide rules for the allocation of distributions among different kinds of previously taxed earnings and profits under section 959(c). The Treasury Department and the IRS anticipate that future regulations under section 959 will provide ordering rules for determining the annual PTEP account and PTEP group to which a section 959 distribution is attributable.

Proposed § 1.960–3(b)(2) provides similar rules to those in proposed § 1.960–3(b)(1) for taxes deemed paid under section 960(b)(2) with respect to a CFC's receipt of a section 959(b) distribution.

Proposed § 1.960–3(d)(3) provides a rule relating to foreign income taxes paid or accrued in a taxable year of a CFC that began before January 1, 2018, with respect to an annual PTEP account, and a PTEP group within such account, that was established for an inclusion year of a CFC that began before January 1, 2018. Specifically, in certain cases, the foreign income taxes may be deemed paid under section 960(b) with respect to a section 959 distribution in a year of the CFC that begins after December 31, 2017.

However, the Treasury Department and the IRS recognize that with respect to CFC taxable years beginning before January 1, 2018, the application of section 960(a)(3) was uncertain and some taxpayers may have added taxes paid or accrued with respect to a section 959 distribution to post-1986 foreign income taxes described in section 902(c)(2) (as in effect on December 21, 2017). In that case, those foreign income taxes could have been included in computing foreign taxes deemed paid under section 902 with respect to a distribution or inclusion of post-1986 undistributed earnings (including by reason of sections 960 and 965) in taxable years of CFCs beginning before January 1, 2018, in which case the taxes are not available to be deemed paid under section 960(b).

The proposed regulations under section 965, see 83 FR 39,514, reserved on the application of section 965(g) to taxes deemed paid under new section 960(b). The preamble to the regulations under section 965 indicated that future regulations would provide rules for new section 960(b) similar to the rules that apply for section 960(a)(3) (as in effect on December 21, 2017).

The proposed regulations in this document provide a rule in proposed § 1.965–5(c)(1)(iii) similar to the rule that applies to taxes deemed paid under section 960(a)(3) that is in proposed § 1.965–5(c)(1)(i) and (ii). In particular, no credit is allowed for the applicable percentage of taxes deemed paid under section 960(b) that are attributable to the PTEP groups described in § 1.960–3(c)(2) that relate to section 965.

In order to ensure that the disallowance under section 965(g) only applies once, the rule in proposed § 1.965–5(c)(1)(iii) does not apply to taxes deemed paid under section 960(b)(2) with respect to a section 959(b) distribution, but only applies when previously taxed earnings and profits are distributed to a domestic corporate shareholder.

D. Domestic Partnerships

If a domestic corporation owns an interest in a CFC through a domestic partnership, to the extent the domestic corporation is a United States shareholder with respect to the CFC, the proposed regulations provide that the domestic corporation is deemed to have

paid foreign income taxes as if the domestic corporation had included the income from the CFC directly rather than as a distributive share of the partnership's income. Proposed § 1.960–2(b)(4) provides that a domestic corporation that has a distributive share of a domestic partnership's subpart F inclusion and is also a United States shareholder with respect to the CFC that gives rise to a subpart F inclusion is treated as a subpart F inclusion of the domestic corporation for purposes of section 960(a). Similarly, the domestic corporation's distributive share of a domestic partnership's receipt of a section 959(a) distribution is treated as a receipt by the domestic corporation directly for purposes of proposed § 1.960–3(b)(1). *See* proposed § 1.960–3(b)(5). In the case of section 960(d), the GILTI inclusion amount of a domestic corporation that is also a United States shareholder of a CFC through its interest in a domestic partnership is generally determined at the partner level and therefore the rules in proposed § 1.960–2(c) apply in the same manner as if the domestic corporation included the GILTI inclusion amount directly. *See* proposed § 1.951A–5(c).

E. Section 78 Dividend

The proposed regulations revise § 1.78–1 to reflect the amended section 78, as well as make conforming changes to reflect pre-Act statutory amendments. In addition, the proposed regulations provide that section 78 dividends that relate to taxable years of foreign corporations that begin before January 1, 2018, are not treated as dividends for purposes of section 245A. This rule is necessary by reason of the enactment of section 245A to ensure that similarly situated taxpayers do not have different tax consequences under section 245A with respect to section 78 dividends. Absent this rule, a United States shareholder of a CFC using a fiscal year beginning in 2017 as its U.S. taxable year (a ''fiscal year CFC'') could potentially claim a section 245A deduction with respect to its section 78 dividend attributable to the United States shareholder's inclusion under section 951 (including by reason of section 965) for the CFC's fiscal year ending in 2018, whereas a United States shareholder of a CFC using the calendar year as its U.S. taxable year could not claim a section 245A deduction with respect to any section 78 dividend for any taxable year. There is no indication that Congress intended to treat these similarly situated taxpayers differently with respect to the section 78 dividend given that the purpose of the section 78 dividend—to prevent a taxpayer from obtaining the benefit of both a credit under section 901 and a deduction with respect to the same foreign tax—is unrelated to the CFC's U.S. taxable year. Accordingly, proposed § 1.78–1(c) includes a special applicability date to prevent this potential disparate treatment and double benefit to taxpayers with fiscal year CFCs.

V. Effect of Section 965(n) Election

Section 965(n) allows a taxpayer to exclude section 965(a) inclusions (reduced by section 965(c) deductions) and associated section 78 gross ups in determining the amount of the net operating loss carryover or carryback that is absorbed in the taxable year of the inclusions. Proposed § 1.965–7(e)(1), as proposed to be added at 83 FR 39,514 (August 9, 2018), provides that the election also applies to the determination of the amount of the net operating loss for the taxable year.

These proposed regulations at § 1.965–7(e)(1)(i) clarify that if the section 965(n) election creates or increases a net operating loss under section 172 for the taxable year, then the taxable income of the person for the taxable year cannot be less than the amount described in proposed § 1.965–7(e)(1)(ii). This rule is necessary to prevent the same deduction from being taken into account in the taxable year and also used again to create a net operating loss that is deducted in a different taxable year. The amount of the deductions that create or increase a net operating loss for the taxable year in each separate category and the U.S. source residual category by reason of the section 965(n) election is determined under proposed § 1.965–7(e)(1)(iv), and those amounts are not also taken into account in computing taxable income or the foreign tax credit limitations under section 904 for that year.

Proposed § 1.965–7(e)(1)(iv)(A) clarifies that the election under section 965(n) applies solely for purposes of determining the amount of the net operating loss for the election year and the amount of net operating loss carryover or carryback to that year. The proposed regulations provide ordering rules to coordinate the election's effect on section 172 with the computation of the foreign tax credit limitations under section 904.

First, deductions that would have been allowed for the taxable year but for the section 965(n) election, other than the amount of any net operating loss carryover or carryback to the election year that is not allowed by reason of the election, are allocated and apportioned under §§ 1.861–8 through 1.861–17 in the taxable year for which the section 965(n) election is made. The section 965(a) inclusions and associated section 78 gross ups are taken into account for this purpose, and also in applying the rules under § 1.904(g)–3(b)(3) to determine the source components of a partial net operating loss carryover to the taxable year for which the section 965(n) election is made, if any, including when the amount deducted under section 172 in that year is reduced by reason of the section 965(n) election. Proposed § 1.965–7(e)(1)(iv)(B)(*1*).

Second, the proposed regulations provide that the amount by which a net operating loss is created or increased by reason of the section 965(n) election, if any, is considered to comprise a ratable portion of all of the taxpayer's deductions (other than the section 965(c) deduction) that are allocated and apportioned to each statutory and residual grouping for the taxable year under the rules in proposed § 1.965–7(e)(1)(iv)(B)(*1*). Proposed § 1.965–7(e)(1)(iv)(B)(*2*).

Third, deductions allocated and apportioned to the statutory and residual groupings, to the extent deducted in the election year rather than deferred to create or increase a net operating loss, are combined with income in those groupings to determine the foreign tax credit limitations for the year. Deductions allocated and apportioned to the section 965(a) inclusions and associated section 78 gross ups therefore reduce income in the separate category or categories (or U.S. source residual category) to which those section 965 amounts are assigned, and are not re-allocated to reduce other income, other than by operation of the separate limitation loss and overall domestic loss allocation rules of section 904(f) and (g). *See* proposed § 1.965–7(e)(1)(iv)(B)(*3*). Accordingly, the section 965(a) inclusions and associated section 78 gross ups may both attract and absorb deductions in the election year in calculating the separate foreign tax credit limitations under section 904.

VI. Applicability Dates

In general, the portions of the proposed regulations that relate to statutory amendments made by the Act apply to taxable years beginning after December 22, 2017. *See* section 7805(b)(2). Other portions of the proposed regulations that do not relate to the Act apply for taxable years ending on or after December 4, 2018. Certain portions of the proposed regulations contain rules that relate to the Act as well as rules that do not relate to the Act. These regulations generally apply to taxable years that satisfy both of the

following two conditions: (1) The taxable year begins after December 22, 2017, and (2) ends on or after December 4, 2018. *See* section 7805(b)(1)(B).

A special applicability date is provided is provided in § 1.861–12(k) in order to apply § 1.861–12(c)(2)(i)(*B*)(*1*)(*ii*) to the last taxable year of a foreign corporation beginning before January 1, 2018, since there may be an inclusion under section 965 for that taxable year. A special applicability date is also provided in § 1.904(b)–3(f) with respect to that section because section 904(b)(4) applies to deductions with respect to taxable years ending after December 31, 2017. Finally, a special applicability date is provided in § 1.78–1(c) in order to apply the second sentence of § 1.78–1(a) to section 78 dividends received after December 31, 2017, with respect to a taxable year of a foreign corporation beginning before January 1, 2018. *See* Part IV.E of this Explanation of Provisions.

Proposed §§ 1.965–5(c)(1)(iii) and 1.965–7(e)(1)(i) and (iv) have the applicability dates provided in proposed § 1.965–9 (contained in 83 FR 39,514).

VII. Conforming Amendments

Sections 1.902–0 through 1.902–4 will be withdrawn as part of finalizing the proposed regulations. With respect to portions of the temporary regulations under sections 861 through 865 that are being reproposed under the proposed regulations, the Treasury Department and the IRS will remove the corresponding temporary regulations upon finalization of the proposed regulations. In addition, the Treasury Department and the IRS intend to make conforming amendments to the examples throughout the foreign tax credit regulations upon finalization of the proposed regulations. In light of the numerous changes made under the Act to various defined terms and statutory cross references, the Treasury Department and the IRS also request comments on other regulations that require updating to conform to changes made by the Act.

Special Analyses

I. Regulatory Planning and Review

Executive Orders 13563 and 12866 direct agencies to assess 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. The Executive Order 13771 designation for any final rule resulting from these proposed regulations will be informed by comments received. The preliminary E.O. 13771 designation for this proposed rule is regulatory.

The proposed regulations have been designated by the Office of Information and Regulatory Affairs (OIRA) as subject to review under Executive Order 12866 pursuant to the Memorandum of Agreement (MOA, April 11, 2018) between the Treasury Department and the Office of Management and Budget regarding review of tax regulations. OIRA has designated this rule as a significant regulatory action, under Executive Order 12866, and as economically significant under E.O. 12866 and section 1(c) of the MOA. Accordingly, the proposed regulations have been reviewed by the Office of Information and Regulatory Affairs. For more detail on the economic analysis, please refer to the following analysis.

A. Background

Before the Act, the United States taxed its citizens, residents, and domestic corporations on their worldwide income. However, to the extent that both the foreign jurisdiction and the U.S. taxed the same income, this would have resulted in double taxation. The U.S. foreign tax credit (FTC) regime alleviated the double taxation issue by allowing a non-refundable credit for foreign income taxes paid or accrued to reduce U.S. tax on foreign source income.

Under the Code, the FTC calculation is applied separately to different categories of income (a ''separate category''). For example, suppose a domestic corporate taxpayer has $100 of active foreign source income in the ''general category,'' $100 of passive foreign source income in the ''passive category,'' $50 of foreign taxes associated with the ''general category'' income, and $0 of foreign taxes associated with the ''passive category'' income. The allowable FTC is determined separately for the different categories of income (general and passive). Therefore, none of the $50 of ''general category'' FTCs can be used to offset U.S. tax on the ''passive category'' income. This taxpayer has a pre-FTC U.S. tax liability of $42 (21 percent of $200) but can claim a FTC for only $21 (21 percent of $100) of this liability, which is with respect to active foreign source income in the general category. The taxpayer carries over the remaining $29 of foreign taxes ($50 minus $21) and can generally apply the taxes as a credit in the prior taxable year or over the next 10 years against U.S. tax on general category foreign source income, subject to certain restrictions.

Further, certain expenses borne by U.S. parents and domestic affiliates that support foreign operations are allocated to separate categories based, for example, on gross income or assets. These allocations reduce foreign source taxable income and therefore reduce the allowable FTCs for the separate category, since FTCs are limited to the U.S. income tax on the foreign source taxable income (*i.e.,* foreign source income less allocated expenses) in that separate category. The foreign income and related taxes from one separate category generally cannot be combined with another category. Prior to 2007, there were generally nine separate categories. In general, the American Jobs Creation Act of 2004 reduced the number of separate categories to two—the passive and general categories of income. These two separate categories generally prevailed until passage of the Act.[1]

The 2017 Act made several significant changes to the FTC rules and related rules for allocating expenses to foreign income for the purpose of calculating the allowable FTCs. In particular, the Act repealed the fair market value method of asset valuation used to apportion interest expense to separate categories based on the fair market value of assets, added new separate categories for global intangible low-taxed income (the section 951A category) and foreign branch income, and amended Code sections which address deemed paid credits for subpart F income, global intangible low-taxed income (GILTI), and distributions of previously taxed earnings and profits. Further, because repatriated dividends are no longer taxable, the Act also repealed section 902 (which allowed a domestic corporation to claim FTCs with respect to dividends paid from a foreign corporation) and made other conforming changes.

These regulations provide the detail, structure and language required to implement the changes made by the statute. The following analysis describes the need for the proposed regulations, as well as provides an overview of the regulations, discussion of the costs and benefits of these regulations as compared with the baseline, and a

[1] Although there are several other separate categories that may apply, such as under sections 901(j) and 904(h)(10), these separate categories generally arise only in rare circumstances.

discussion of alternative policy choices that were considered.

B. The Need for Proposed Regulations

The numerous changes to the FTC rules in the Act require practical guidance for implementation. The proposed regulations provide the details, methodology, and approaches necessary to conform the existing FTC regulations to the many changes specified in the Act; for example, they provide structure and detail concerning how to incorporate the new separate categories of income into the foreign tax credit calculation, including how expenses will be allocated to separate categories. The regulations also update outdated portions of the existing regulations to help conform the existing regulations to the post-Act world. Thus, the guidance provides certainty, clarity, and consistency regarding FTC computations, which promotes efficiency and equity, contingent on the overall Code.

C. Baseline

The economic analysis that follows compares the proposed regulations to a no-action baseline reflecting anticipated federal income tax-related behavior in the absence of these proposed regulations. A no-action baseline reflects the current environment including the existing FTC regulations, prior to any amendment by the proposed regulations.

D. Overview of the Proposed Regulations

As noted above, the proposed regulations specify the methodologies and approaches necessary to conform the existing regulations to the many changes specified in the Act. Several aspects of the proposed regulations are particularly noteworthy, as they involve more discretion on the part of the Treasury Department and the IRS. These are the aspect of the regulations governing expense allocation, the aspect of the regulations governing FTC carryovers to the new foreign income categories, the special applicability date regarding the section 78 gross up, and the anti-abuse rules addressing certain loans made to partnerships. The ultimate rules proposed, as well as the alternatives that were considered are discussed below.

Most notably, in response to taxpayer requests for guidance, these regulations help interpret the statute by providing details regarding how expenses must be apportioned to the new separate categories created by the Act. In particular, the proposed regulations specify that, for purposes of applying the expense allocation and apportionment rules, the gross income offset by the section 250 deduction is treated as exempt income, and the stock giving rise to GILTI that is offset by the section 250 deduction is treated as an exempt asset (see Part I.A of the Explanation of Provisions). Such treatment implies that fewer expenses will be allocated to the section 951A category as a result of this rule, leading to higher computed foreign source taxable income, a larger foreign tax credit limitation, and a larger foreign tax credit offset with respect to GILTI income. Because these expenses are now allocated to another separate category (where they may be less likely to displace FTCs) or to U.S. source income, this rule will in general reduce the tax burden of U.S. multinational corporations with GILTI income and allocable expenses.

The regulations also address how FTC carryovers are to be allocated across the new separate categories. The formation of two new separate categories requires a determination regarding how pre-Act FTC carryovers must be allocated across new and existing separate categories. The Treasury Department and the IRS determined that, because continuity in the definition of income and assignment of tax attributes is appropriate, taxpayers should be able to analyze their general category income earned in prior years to determine the extent to which it would have been considered to belong in the new separate category for foreign branch income under the rules described here (see Part II.A of the Explanation of Provisions). However, because allocation of pre-Act income to hypothetical post-Act separate categories has the potential to be administratively burdensome, the regulation provides that the allocation of FTC carryovers to the new foreign branch category is optional, which allows for continuity of income treatment while minimizing administrative and compliance burdens during the transition. For taxpayers that do not choose to allocate FTC carryovers to the new foreign branch category, their FTC carryovers will remain in the general category. See Part I.E.2 of this Special Analyses for a discussion of alternatives considered and additional reasoning regarding the approach taken under the proposed regulations.

Further, as described in section IV.E of the Explanation of Provisions, the proposed regulations include an updated applicability date for the new section 78 provisions. In particular, the proposed regulations provide that section 78 dividends relating to taxable years of foreign corporations beginning before January 1, 2018, are not treated as dividends for purposes of the section 245A deduction. As further noted in section IV.E of the Explanation of Provisions, absent this rule, taxpayers that have calendar year CFCs instead of fiscal year CFCs would be treated differently with respect to their section 78 dividends solely on the basis of this difference in tax year status; and taxpayers with fiscal year CFCs could receive the double benefit of a section 245A deduction and a FTC under section 960 with respect to the same foreign taxes. Allowing a double benefit for a single expense erodes the U.S. tax base and treats otherwise similar taxpayers (those who have different CFC tax years) inequitably. Based on these equity considerations, the Treasury Department and the IRS expect that the proposed regulation will provide greater net benefits than the alternative of not issuing a regulation on this issue.

The regulations also address certain potentially abusive borrowing arrangements, such as when a U.S. person lends money to a foreign partnership in order to artificially increase foreign source income (and therefore the FTC limitation) without affecting U.S. taxable income (see Part I.C. of the Explanation of Provisions). This is accomplished, for example, by lending to a controlled partnership, which has no effect on U.S. taxable income, because the interest income received from the partnership is offset by the lender's share of the interest expense incurred by the partnership. However, the transaction can increase foreign source income and allowable foreign tax credits, because the existing interest expense allocation rules do not generally allocate interest income and interest expenses similarly. To prevent such artificial inflation of foreign tax credits, the regulations specify that interest income attributable to borrowing through a partnership will be allocated across foreign tax credit separate categories in the same manner as the associated interest expense. See Part I.E.2 of this Special Analyses for a discussion of alternatives considered and additional reasoning regarding the approach taken under the proposed regulations.

In addition, the regulations clarify and provide guidance on numerous other technical issues. For example, they clarify the regulatory environment by updating inoperative language in §§ 1.904–1 through 1.904–3; parts of the regulations have not previously been updated to reflect changes to section 904 made in 1978. They also ease transitional administrative burdens associated with the implementation of the Act; for example, allowing a one-

time exception to the 5 year waiting period for the election of the gross income or sales method for R&D expense allocation (See Part I.G of the Explanation of Provisions), or by allowing a simplified definition of average basis for the first year taxpayers are required to use the tax book method of valuation (See Part I.E.1 of the Explanation of Provisions).

The regulations further clarify the § 1.904–6 rules concerning how allocation of taxes across separate categories should be calculated in the presence of base and timing differences. A base difference occurs, for example, if the foreign jurisdiction taxes income, such as life insurance proceeds or gifts, which are excluded from income for U.S. tax purposes. A timing difference occurs, for example, if the U.S. tax rules define income as being earned by marking an asset to market, but a domestic corporation operates a CFC in a foreign jurisdiction that defines income as being earned by realization upon sale. Regulatory guidance instructs taxpayers how to appropriately navigate these cross jurisdictional base and timing differences in the assignment of taxes to FTC separate categories. They also fill technical gaps in how to implement the statute in practice, for example, by providing a clear rule for how to characterize the value of stock in each separate category in the context of the new separate categories.

The guidance, clarity, and specificity provided by the regulations help ensure that all taxpayers calculate foreign income and the foreign tax credit in a similar manner. The economic analysis that follows discusses the costs and benefits of these regulations, and the alternative choices that could have been made, in greater detail.

E. Economic Analysis

1. Anticipated Benefits and Costs of the Proposed Regulations

The Treasury Department and the IRS have assessed the benefits and costs of the proposed regulations against a no-action baseline—which, as explained above, is the *status quo* in the absence of the proposed regulations. The Treasury Department and IRS expect that the certainty and clarity provided by these proposed regulations, relative to the no-action baseline, will improve U.S. economic efficiency. For example, because separate categories for GILTI and foreign branch income did not previously exist, taxpayers can benefit from the enhanced specificity regarding how income, expenses, and carryover foreign tax credits should be allocated across these separate categories. In the absence of this enhanced clarity, similarly situated taxpayers might interpret the statute differently, potentially resulting in inequitable outcomes. For example, some taxpayers may forego specific investments that other taxpayers deem worthwhile based on different interpretations of the tax consequences alone. The guidance provided in these regulations helps to ensure that taxpayers face more uniform incentives when making economic decisions, which will generally improve economic efficiency. In order to give a rough sense of the population potentially affected by these regulations, a table reporting the number of affected filers is provided in Part II of this Special Analyses.

In the absence of the enhanced specificity provided by the regulations described above, similarly situated taxpayers might interpret the statutory rules differently, and different taxpayers might then pursue or forego economic activities based on different interpretations of the tax consequences alone. By providing clear rules to eliminate ambiguity and to fill in technical gaps, the guidance provided in these regulations helps to ensure that taxpayers face more uniform incentives. Such uniformity across economic decision-makers is a tenet of economic efficiency. Clear and consistent rules also increase transparency and decrease the incentives and opportunities for tax evasion. Rules to combat abusive transactions also help to ensure that taxpayers make decisions based on market conditions rather than on tax considerations.

Further, because the changes introduced in the Act are substantial, the start-up costs and learning curves involved in complying with the Act will also be substantial. In particular, the Act's elimination of tax imposed on repatriations going forward, the creation of the tax on global intangible low taxed income (and the corresponding section 951A category), and the creation of a deduction for foreign-derived intangible income each embody a completely new component of U.S. international tax law, and together restructure a U.S. international tax system that had remained relatively constant since 1987. By definition, transitioning to such a completely new system will involve substantial start-up costs in terms of learning the nuances of the new rules, and revamping record keeping, documentation, and software systems to aid in filling out the new tax forms and to ensure the availability of all the records required to benefit from new exclusions and deductions (such as the section 250 deduction). The proposed regulations assist taxpayers in this process by providing definitional clarity in order to minimize the disruption caused by the move to the new system. When possible and appropriate, they further provide significant transitional flexibility in order to help relieve compliance burdens and reduce transition administrative costs. Additional details, including the types of cost savings and benefits expected, are discussed below, as well as in Part I.E.2 of this Special Analyses.

Notably, as mentioned in Part I of the Explanation of Provisions, taxpayers have repeatedly requested regulatory guidance concerning appropriate expense allocation in light of the new separate categories for GILTI and foreign branch income; in the absence of new regulations, the correct approach for allocating expenses is subject to interpretation. Therefore, the proposed regulations seek to clarify the allowable expense allocation rules that are consistent with legislative history's description of the section 250 deduction as effectively exempting income, by specifying that the income associated with the section 250 deduction is, for foreign tax credit purposes, treated as partially exempt. The regulations therefore potentially increase the competitiveness of U.S. corporations relative to the no-action baseline, which includes proposed though not yet final regulations under section 951A, by generally reducing the amount of U.S. parent expenses that are allocated to the section 951A category. They also provide certainty and clarity for taxpayers, which, as noted above, increases efficiency and transparency, and reduces the incentive for evasion, relative to the no-action baseline.

However, the reduced expense allocation to the section 951A category resulting from these proposed regulations has the potential to reduce Federal tax revenue relative to the statute and in consideration of proposed though not yet final regulations related to section 951A. In addition, it could also provide some taxpayers with the incentive to locate more of their worldwide expenses in the United States, because U.S. expenses will have the potential to reduce U.S. taxable income, and also increase allowable foreign tax credits relative to the no-action baseline. However, the post-Act U.S. interest expense limitation rules under section 163(j) make it more difficult to use excessive interest expense to reduce U.S. taxable income, and the significantly lower U.S. statutory corporate rate reduces the (previously strong) incentive to locate ''fungible'' deductions such as interest

expense in the United States. Therefore, any increase in the incentive to report interest expense in the United States resulting from the reduced expense allocation to the section 951A category is likely to be relatively minor. The Treasury Department and the IRS welcome comments on this estimated impact of the reduced expense allocation.

In addition to the provisions described in the overview section above, the look-through rules provide an example of a proposed rule that fills a technical gap left by the implementation of the Act that if left unaddressed would impose significant tax uncertainty on taxpayers and negatively impact taxpayers' economic decision making. Before the Act, dividends, interest, rents and royalties (''look-through payments'') paid to a United States shareholder by its CFC were generally allocated to the general category to the extent that they were not treated as passive category income. The Act split the general category income into three categories: General category, section 951A category, and foreign branch category, creating a question of how to assign non-passive category look-through payments to the two new separate categories. The Treasury Department and the IRS studied this issue and propose to revise the look-through rules to clarify that non-passive look-through payments cannot be assigned to the section 951A category but instead are generally assigned to the general category or foreign branch category. This treatment is consistent with the fact that the new section 951A category by definition cannot include payments of dividends, interest, rents, and royalties made directly to a United States shareholder. On the other hand, certain interest, rents, and royalties earned by a foreign branch can meet the definition of foreign branch category income, and the general category is a residual category that encompasses all income that is not specifically assigned to any other category.

Whether a deduction is disallowed under section 267A with respect to a payment of interest or royalties does not affect the treatment of such payment in the hands of the recipient for purposes of section 904(d)(3). Furthermore, future regulations issued under section 267A will address whether such payments that are subject to U.S. tax are subject to the disallowance under section 267A.

2. Alternatives Considered

The Treasury Department and the IRS next considered the benefits and costs of providing these specific methodologies and definitions regarding FTC calculations relative to possible alternatives. In choosing among alternatives, the Treasury Department and the IRS strive to adhere to Congressional intent and consistency with existing law, while minimizing economic distortions and compliance burdens imposed on taxpayers, and promoting market-driven decision making and administrative feasibility.

The Act created two new separate categories with respect to FTCs, splitting the existing general category into general, section 951A, and foreign branch categories. The Act did not, however, specify how FTC carryovers were to be treated. The Treasury Department and the IRS considered alternative methods of allocating FTC carryovers originally associated with the general category to the new section 951A and foreign branch categories. One option that was considered would have required taxpayers to reassign existing general category FTC carryovers to the section 951A category as if that category existed prior to the adoption of the statute. Allocating carryovers to the section 951A category was deemed infeasible because it would be extraordinarily burdensome on taxpayers to attempt to recreate historical GILTI and would present numerous technical challenges. Such an approach would also result in eliminating the ability of taxpayers to credit those FTC carryovers since no carryovers are allowed for FTCs attributable to the section 951A category. This outcome would negatively impact taxpayers that had potentially structured their prior decisions on their presumed ability to use these FTC carryovers against U.S. tax on general category income and could result in costly and undesirable financial statement adjustments for some companies without providing any corresponding economic efficiency gains.

By contrast, allocating carryovers to the foreign branch category would be technically feasible and therefore does not present the same technical challenges as allocating FTC carryovers to the section 951A category would. However, with respect to FTC carryovers and the foreign branch category, the Treasury Department and the IRS first considered providing no additional guidance beyond the existing statutory language, which would mean that FTC carryovers would remain in the general category and none would be reassigned to the foreign branch category. However, requiring FTC carryovers to remain in the general category would potentially prevent taxpayers with substantial historic and continuing branch operations and who previously incurred taxes on their branch income from being able to utilize FTC carryovers in future years because general category carryovers would not be available to offset U.S. tax on future foreign branch category income. This outcome would negatively impact taxpayers that had potentially structured their prior decisions on their presumed ability to use these FTC carryovers to reduce U.S. tax on what became their future foreign branch category income.

As an alternative, the Treasury Department and the IRS considered requiring that all taxpayers do a computation to assign general category FTC carryovers to the foreign branch category. The concept of branch income existed prior to TCJA, and thus there would have been continuity in the assignment of pre- and post-TCJA FTCs associated with foreign branch category income. However, these FTC carryovers had previously been allocated to the general category and hence some taxpayers had potentially structured their prior decisions on their presumed ability to use these taxes against U.S. tax on general category income. Therefore, reassigning such FTC carryovers after the fact could create perverse incentives for some taxpayers to restructure their ongoing operations into branch form in order to generate foreign branch category income that can absorb FTC carryovers that were reassigned to the foreign branch category. Furthermore, requiring taxpayers to reconstruct prior year events in order to determine what income and FTCs would have been associated with the foreign branch category would be burdensome for taxpayers, again with no corresponding efficiency gains. The benefit of matching income and FTCs which applies more generally as a principle of economically efficient taxation is less relevant in this context because the foreign taxes have already been incurred.

On the basis of these considerations of compliance burden and efficiency gains (or lack thereof), the proposed regulations settled on an approach whereby FTC carryovers would by default remain in the general category but the regulations also provide an option to allow taxpayers to allocate transitional FTC carryovers to the foreign branch category. The Treasury Department and the IRS chose this approach in response to some taxpayers' concerns that their business and investment plans were based on the presumption that FTC carryovers could be used against U.S. tax on general category income and precluding them from using FTCs in this way would have

negative economic implications. On the other hand, taxpayers whose foreign branch category income could absorb greater levels of FTCs can self-select into reconstructing what income and FTCs would have been associated with the foreign branch category income. Thus, taxpayers for whom the costs exceed the benefits would choose to retain the FTCs in the general category, while taxpayers for whom the benefits exceed the costs would choose to incur the costs of doing the computation. This rule provides the most flexibility, continuity, and compliance cost savings to taxpayers with respect to these transitional FTC carryovers.

The Treasury Department and the IRS also faced the question of how to align interest income and interest expenses related to loans to a partnership from a U.S. partner. The Treasury Department and the IRS chose to match interest income allocation to interest expense allocation, rather than the reverse, because this minimizes distortions that could arise in the apportionment of other types of expenses. Under the matching rule in the proposed regulations, the gross interest income is apportioned between U.S. and foreign sources in each separate category based on a taxpayer's interest expense apportionment ratios. The Treasury Department and the IRS considered an alternative approach of tracing expenses to gross income under which the gross interest income would, under the general rules for sourcing interest income, be 100 percent foreign source income if paid by a foreign partnership not engaged in a U.S. trade or business. Some deductions, such as general and administrative expenses, can be apportioned on the basis of gross income to foreign sources. A rule that did not alter the source of the gross interest income would affect the allocation and apportionment of these other expenses, such as general and administrative expenses, that can be allocated on the basis of gross income to foreign sources. The matching rule limits these distortions because it minimizes the artificial increase in gross foreign source income based solely on a related party loan to a partnership. Accordingly, the proposed matching rule achieves a more neutral foreign tax credit limitation result and better minimizes the impact of related party loans on a taxpayer's foreign tax credit limitation.

The Treasury Department and the IRS considered two options with respect to the application of the section 245A deduction to section 78 dividends. The first option considered was to do nothing and allow taxpayers with fiscal year CFCs to get a double benefit, leaving taxpayers with calendar year CFCs at a relative disadvantage. An additional drawback of this approach is that taxpayers with fiscal year CFCs would likely face uncertainty with respect to their tax positions, as the availability of a section 245A deduction to a section 78 dividend may be anticipated to be deemed inappropriate and ultimately be reversed. Such delayed changes would force taxpayers that are publicly traded companies to issue costly restatements of their financial accounts, which could result in stock market volatility. The second option considered was to eliminate this inequity of tax treatment between taxpayers with calendar year CFCs versus fiscal year CFCs by providing that section 78 dividends relating to taxable years beginning before January 1, 2018, are not treated as dividends for purposes of the section 245A deduction. The advantage of this approach is that it eliminates the disparate tax treatment of otherwise similarly situated taxpayers because it removes the unintended benefit for taxpayers with fiscal year CFCs. This approach also promotes economic efficiency by resolving the uncertainty related to the availability of a section 245A deduction to a section 78 dividend. The latter option is the approach adopted in the proposed regulations.

II. Paperwork Reduction Act

The rules relating to foreign tax credits that were modified by the Act are reflected in several revised and new schedules added to existing forms. For purposes of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) (''PRA''), the reporting burden associated with the revised and new schedules will be reflected in the IRS Forms 14029, Paperwork Reduction Act Submission, associated with the forms described in this Part II.

Form 1118, Foreign Tax Credit—Corporations, has been revised to add new Schedule C (Tax Deemed Paid With Respect to Section 951(a)(1) Inclusions by Domestic Corporation Filing Return (Section 960(a)), Schedule D (Tax Deemed Paid With Respect to Section 951A Income by Domestic Corporation Filing the Return (Section 960(d)), and Schedule E (Tax Deemed Paid With Respect to Previously Taxed Income by Domestic Corporation Filing the Return (Section 960(b)). In addition, the existing schedules of Form 1118 have been modified to account for the two new separate categories of income under section 904(d); the repeal of section 902 indirect credits for foreign taxes deemed paid with respect to dividends from foreign corporations; modified indirect credits under section 960 for inclusions under sections 951(a)(1) and 951A; modified section 78 gross up with respect to inclusions under sections 951(a)(1) and 951A; the revised sourcing rule for certain income from the sale of inventory under section 863(b); the repeal of the fair market value method for apportioning interest expense under 864(e); new adjustments for purposes of section 904 with respect to expenses allocable to certain stock or dividends for which a dividends received deduction is allowed under section 245A; the election to increase pre-2018 section 904(g) Overall Domestic Loss (ODL) recapture; and limited foreign tax credits with respect to inclusions under section 965. For purposes of the PRA, the reporting burden associated with these changes is reflected in the IRS Form 14029, Paperwork Reduction Act Submission, associated with Form 1118 (OMB control number 1545–0123, which represents a total estimated burden time, including all other related forms and schedules, of 3.157 billion hours and total estimated monetized costs of $58.148 billion).

Form 5471, Information Return of U.S. Persons With Respect to Certain Foreign Corporations, has also been revised to add Schedule E–1 (Taxes Paid, Accrued, or Deemed Paid on Accumulated Earnings and Profits (E&P) of Foreign Corporation) and Schedule P (Previously Taxed Earnings and Profits of U.S. Shareholder of Certain Foreign Corporations) and to amend Schedule E (Income, War Profits, and Excess Profits Taxes Paid or Accrued) and Schedule J (Accumulated Earnings & Profits (E&P) of Controlled Foreign Corporations). These changes to the Form 5471 reflect the two new separate categories of income under section 904(d); the repeal of section 902 indirect credits for foreign taxes deemed paid with respect to dividends from foreign corporations; modified indirect credits under section 960 for inclusions under sections 951(a)(1) and 951A; and limited foreign tax credits with respect to inclusions under section 965. For purposes of the PRA, the reporting burden associated with these changes is reflected in the IRS Form 14029, Paperwork Reduction Act Submission, associated with Schedules E, E–1, J, and P of Form 5471 (OMB control number 1545–0123).

Schedule B (Specifically Attributable Taxes and Income (Section 999(c)(2)) of the Form 5713, International Boycott Report, has also been revised to reflect the repeal of section 902. Schedule C (Tax Effect of the International Boycott Provisions) of the Form 5713 has been revised to account for the new section

904(d) categories of income. For purposes of the PRA, the reporting burden associated with these changes is reflected in the IRS Form 14029, Paperwork Reduction Act Submission, associated with Schedules B and C of Form 5713 (OMB control number 1545–0216, which represents a total estimated burden time, including all other related forms and schedules, of 143,498 hours).

Schedules K and K–1 of the following forms have been revised to account for the new section 904(d) categories of income: Form 1065, U.S. Return of Partnership Income, Form 1120–S, U.S. Income Tax Return for an S Corporation, and Form 8865, Return of U.S. Persons With Respect to Certain Foreign Partnerships. Form 1116, Foreign Tax Credit (Individual, Estate, or Trust), has also been revised to account for the new section 904(d) categories of income. For purposes of the PRA, the reporting burden associated with these changes is reflected in the IRS Form 14029, Paperwork Reduction Act Submission, associated with Forms 1065 and 1120S (OMB control number 1545–0123), associated with Form 8865 (OMB control number 1545–1668, which represents a total estimated burden time, including all other related forms and schedules, of 289,354 hours), and associated with Form 1116 (OMB control numbers 1545–0121, which represents a total estimated burden time, including all other related forms and schedules, of 25,066,693 hours; and 1545–0074, which represents a total estimated burden time, including all other related forms and schedules, of 1.784 billion hours and total estimated monetized costs of $31.764 billion).

The IRS estimates the number of affected filers for the aforementioned forms to be the following:

Form	Number of respondents * (estimated)
Form 1116	8,000,000
Form 1118	15,000
Form 1065	4,000,000
Form 1065 Schedule K–1	24,750,000
Form 1120–S	4,750,000
Form 1120–S Schedule K–1	7,500,000
Form 5471	28,000
Form 5471 Schedule E	10,000
Form 5471 Schedule J	25,500
Form 5713 Schedule B	<1,000
Form 5713 Schedule C	<1,000
Form 8865	14,500

Data tabulated from 2015 and 2016 Business Return Transaction File and E-file data.

* Except for K–1 filings, which count the total number of K–1s received; same issuer K–1s are aggregated at the recipient level.

The current status of the Paperwork Reduction Act submissions related to foreign tax credits is provided in the following table. The burden estimates provided in the above narrative are aggregate amounts that relate to the entire package of forms associated with the OMB control number, and include but do not isolate the estimated burden of only the foreign tax credit-related forms that are included in the tables in this Part II. The Treasury Department and the IRS have assumed that any burden estimates and forms, including new information collections, related to foreign tax credits capture changes made by the Act and that no additional information collection burdens arise out of discretionary authority exercised in these regulations. The Treasury Department and the IRS welcome comments on all aspects of information collection burdens related to the foreign tax credit. In addition, the IRS forms will be posted and available for comment at *https://apps.irs.gov/app/picklist/list/draftTaxForms.html.*

Form	Type of filer	OMB No.(s)	Status
Form 1116	All other Filers (mainly trusts and estates) (Legacy system).	1545–0121	Approved by OMB through 10/30/2020.
	Link: *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201704-1545-023*		
	Business (NEW Model)	1545–0123	Published in the **Federal Register** Notice (FRN) on 10/8/18. Public Comment period closes on 12/10/18.
	Link: *https://www.federalregister.gov/documents/2018/10/09/2018-21846/proposed-collection-comment-request-for-forms-1065-1065-b-1066-1120-1120-c-1120-f-1120-h-1120-nd.*		
	Individual (NEW Model)	1545–0074	Limited Scope submission (1040 only) on 10/11/18 at OIRA for review. Full ICR submission (all forms) scheduled in 3–2019. 60 Day FRN not published yet for full collection.
	Link: *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201808-1545-031.*		
Form 1118	Business (NEW Model)	1545–0123	Published in the FRN on 10/8/18. Public Comment period closes on 12/10/18.
	Link *https://www.federalregister.gov/documents/2018/10/09/2018-21846/proposed-collection-comment-request-for-forms-1065-1065-b-1066-1120-1120-c-1120-f-1120-h-1120-nd.*		
Form 1065 (including Schedule K–1)	Same as above	Same as above	Same as above.
	Link: Same as above.		
Form 1120–S (including Schedule K–1)	Same as above	Same as above	Same as above.
	Link: Same as above.		
Form 5471 (including Schedules E, J)	Business (NEW Model)	1545–0123	Published in the FRN on 10/8/18. Public Comment period closes on 12/10/18.

Form	Type of filer	OMB No.(s)	Status
	Link: *https://www.federalregister.gov/documents/2018/10/09/2018-21846/proposed-collection-comment-request-for-forms-1065-1065-b-1066-1120-1120-c-1120-f-1120-h-1120-nd*.		
	Individual (NEW Model)	1545–0074	Limited Scope submission (1040 only) on 10/11/18 at OIRA for review. Full ICR submission for all forms in 3–2019. 60 Day FRN not published yet for full collection.
	Link: *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201808-1545-031*.		
Form 5713 Schedules B, C	All other Filers (mainly trusts and estates) (Legacy system).	1545–0216	Published in the FRN on 3/28/18. Public Comment period closed 5/29/18. Renewal submitted on 10/11/18 for review to OIRA. New 2018 Forms not included in renewal to OIRA due to timing of submission.
	Link: *https://www.federalregister.gov/documents/2018/10/29/2018-23515/agency-information-collection-activities-submission-for-omb-review-comment-request-multiple-internal, https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201807-1545-001*.		
	Business (NEW Model)	1545–0123	Published in the FRN on 10/11/18. Public Comment period closes on 12/10/18.
	Link: *https://www.federalregister.gov/documents/2018/10/09/2018-21846/proposed-collection-comment-request-for-forms-1065-1065-b-1066-1120-1120-c-1120-f-1120-h-1120-nd*.		
	Individual (NEW Model)	1545–0074	Limited Scope submission (1040 only) on 10/11/18 at OIRA for review. Full ICR submission for all forms in 3–2019. 60 Day FRN not published yet for full collection.
	Link: *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201808-1545-031*.		
Form 8865	All other Filers (mainly trusts and estates) (Legacy system).	1545–1668	Published in the FRN on 10/1/18. Public Comment period closes on 11/30/18. ICR in process by Treasury as of 10/17/18.
	Link: *https://www.federalregister.gov/documents/2018/10/01/2018-21288/proposed-collection-comment-request-for-regulation-project*.		
	Business (NEW Model)	1545–0123	Published in the FRN on 10/8/18. Public Comment period closes on 12/10/18.
	Link: *https://www.federalregister.gov/documents/2018/10/09/2018-21846/proposed-collection-comment-request-for-forms-1065-1065-b-1066-1120-1120-c-1120-f-1120-h-1120-nd*.		
	Individual (NEW Model)	1545–0074	Limited Scope submission (1040 only) on 10/11/18 at OIRA for review. Full ICR submission for all forms in 3–2019. 60 Day FRN not published yet for full collection.
	Link: *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201808-1545-031*.		

III. Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act (5 U.S.C. chapter 6), it is hereby certified that this regulation, if adopted, will not have a significant economic impact on a substantial number of small entities within the meaning of section 601(6) of the Regulatory Flexibility Act.

The proposed regulations provide guidance needed to comply with statutory changes and affect individuals and corporations claiming foreign tax credits. The domestic small business entities that are subject to the foreign tax credit rules in the Code and this notice of proposed rulemaking are generally those domestic small business entities that are at least 10 percent corporate shareholders of foreign corporations, and so are eligible to claim dividends-received deductions or compute foreign taxes deemed paid under section 960 with respect to inclusions under subpart F and section 951A from controlled foreign corporations. Other provisions of the Act, such as the new separate foreign tax credit limitation category for foreign branch income and the repeal of the option to allocate and apportion interest expense on the basis of the fair market value (rather than tax basis) of a taxpayer's assets, might also affect domestic small business entities that operate in foreign jurisdictions. Data about the number of domestic small business entities potentially affected by these aspects of the Act, and therefore potentially by these proposed regulations, is not readily available.

However, the Treasury Department and IRS do not believe a substantial number of domestic small business entities will be affected by this notice of proposed rulemaking. Many of the more significant aspects of the proposed regulations, including all of the rules in proposed §§ 1.861–8(d)(2)(C), 1.861–10, 1.861–12, 1.861–13, 1.901(j)–1, 1.904–5, 1.904(b)–3, 1.954–1, 1.960–1 through 1.960–3, and 1.965–7 apply only to United States persons that operate a foreign business in corporate form, and, in most cases, only if the foreign

corporation is a CFC. Because it takes significant resources and investment for a foreign business to operate outside of the United States in corporate form, and in particular to own a CFC, the owners of such businesses will infrequently be domestic small business entities. Consequently, the Treasury Department and the IRS do not believe that the proposed regulations will affect a substantial number of domestic small business entities. The Treasury Department and the IRS welcome comments regarding the amount and types of domestic small business entities that may be affected by this rule.

The Treasury Department and the IRS also do not believe that the proposed regulations will have a substantial economic effect on domestic small business entities. See Table below. Based on published information from 2013, foreign tax credits as a percentage of three different tax-related measures of annual receipts (see Table for variables) by corporations are substantially less than the 3 to 5 percent threshold for significant economic impact. The amount of foreign tax credits in 2013 is an upper bound on the change in foreign tax credits resulting from the proposed regulations.

Size (by business receipts)	Under $500,000 (%)	$500,000 under $1,000,000 (%)	$1,000,000 under $5,000,000 (%)	$5,000,000 under $10,000,000 (%)	$10,000,000 under $50,000,000 (%)	$50,000,000 under $100,000,000 (%)	$100,000,000 under $250,000,000 (%)	$250,000,000 or more (%)
FTC/Total Receipts	0.03	0.00	0.00	0.01	0.01	0.03	0.09	0.56
FTC/(Total Receipts-Total Deductions)	0.48	0.03	0.04	0.26	0.22	0.51	1.20	9.00
FTC/Business Receipts	0.05	0.00	0.00	0.01	0.01	0.04	0.10	0.64

Source: Statistics of Income (2013) Form 1120 available at https://www.irs.gov/statistics.

To the extent a domestic small business entity is affected by the Act, the proposed regulations help reduce their compliance costs by providing clarity, certainty, and flexibility to the taxpayer regarding how to take into account the changes made by the Act in claiming foreign tax credits. Therefore, a Regulatory Flexibility Analysis under the Regulatory Flexibility Act is not required with respect to the proposed regulations.

Notwithstanding this certification, the Treasury Department and the IRS invite comments on the impact of this rule on small entities.

Pursuant to section 7805(f), this notice of proposed rulemaking has been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small businesses. The Treasury Department and the IRS invites the public to comment on this certification.

IV. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditures in any one year by a state, local, or tribal government, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. In 2018, that threshold is approximately $150 million. This rule does not include any Federal mandate that may result in expenditures by state, local, or tribal governments, or by the private sector in excess of that threshold.

V. Executive Order 13132: Federalism

Executive Order 13132 (entitled ''Federalism'') prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial, direct compliance costs on state and local governments, and is not required by statute, or preempts state law, unless the agency meets the consultation and funding requirements of section 6 of the Executive Order. This proposed rule does not have federalism implications and does not impose substantial direct compliance costs on state and local governments or preempt state law within the meaning of the Executive Order.

Comments and Requests for Public Hearing

Before the proposed regulations are adopted as final regulations, consideration will be given to any comments that are submitted timely to the IRS as prescribed in this preamble under **ADDRESSES**. The Treasury Department and the IRS request comments on all aspects of the proposed rules. All comments will be available at *www.regulations.gov* or upon request. A public hearing will be scheduled if requested in writing by any person that timely submits comments. If a public hearing is scheduled, notice of the date, time, and place for the public hearing will be published in the **Federal Register**.

Drafting Information

The principal authors of the proposed regulations are Karen J. Cate, Jeffrey P. Cowan, Jeffrey L. Parry, Larry R. Pounders, and Suzanne M. Walsh of the Office of Associate Chief Counsel (International). However, other personnel from the Treasury Department and the IRS participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by revising the entries for §§ 1.861–8, 1.861–9, 1.861–9T, 1.861–10(e), 1.861–11, 1.904–4, 1.904–5, 1.904–6, and 1.960–1 and adding entries for §§ 1.861–12, 1.861–13, 1.901(j)–1, 1.904–1, 1.904–2, 1.904–3, 1.960–2, 1.960–3, 1.960–4, 1.960–5, 1.965–5, and 1.965–7, to read in part as follows:

Authority: 26 U.S.C. 7805.

* * * * *

Section 1.861–8 also issued under 26 U.S.C. 250(c), 864(e)(7), and 882(c).

Sections 1.861–9 and 1.861–9T also issued under 26 U.S.C. 863(a), 26 U.S.C. 864(e)(7), 26 U.S.C. 865(i), and 26 U.S.C. 7701(f).

Section 1.861–10(e) also issued under 26 U.S.C. 863(a), 26 U.S.C. 864(e)(7), 26 U.S.C. 865(i), and 26 U.S.C. 7701(f).

Section 1.861–11 also issued under 26 U.S.C. 863(a), 26 U.S.C. 864(e)(7), 26 U.S.C. 865(i), and 26 U.S.C. 7701(f).

Section 1.861–12 also issued under 26 U.S.C. 864(e)(7).

Section 1.861–13 also issued under 26 U.S.C. 864(e)(7).

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Section 1.901(j)–1 also issued under 26 U.S.C. 901(j)(4).

* * * * *

Section 1.904–1 also issued under 26 U.S.C. 904(d)(7).

Section 1.904–2 also issued under 26 U.S.C. 904(d)(7).

Section 1.904–3 also issued under 26 U.S.C. 904(d)(7).

Section 1.904–4 also issued under 26 U.S.C. 250(c), 904(d)(2)(J)(i), 904(d)(6)(C), 26 U.S.C. 904(d)(7), and 26 U.S.C. 951A(f)(1)(B).

Section 1.904–5 also issued under 26 U.S.C. 904(d)(7), and 26 U.S.C. 951A(f)(1)(B).

Section 1.904–6 also issued under 26 U.S.C. 904(d)(7).

* * * * *

Section 1.960–1 also issued under 26 U.S.C. 960(f).

Section 1.960–2 also issued under 26 U.S.C. 960(f).

Section 1.960–3 also issued under 26 U.S.C. 960(f).

Section 1.960–4 also issued under 26 U.S.C. 951A(f)(1)(B) and 26 U.S.C. 960(f).

Section 1.965–5 also issued under 26 U.S.C. 965(o).

Section 1.965–7 also issued under 26 U.S.C. 965(o).

* * * * *

■ **Par. 2** Section 1.78–1 is revised to read as follows:

§ 1.78–1 Gross up for deemed paid foreign tax credit.

(a) *Taxes deemed paid by certain domestic corporations treated as a dividend.* If a domestic corporation chooses to have the benefits of the foreign tax credit under section 901 for any taxable year, an amount that is equal to the foreign income taxes deemed to be paid by the corporation for the year under section 960 (in the case of section 960(d), determined without regard to the phrase ''80 percent of'' in section 960(d)(1)) is, to the extent provided by this section, treated as a dividend (a *section 78 dividend*) received by the domestic corporation from the foreign corporation. A section 78 dividend is treated as a dividend for all purposes of the Code, except that it is not treated as a dividend for purposes of section 245 or 245A, and does not increase the earnings and profits of the domestic corporation or decrease the earnings and profits of the foreign corporation. Any reduction under section 907(a) of the foreign income taxes deemed paid with respect to combined foreign oil and gas income does not affect the amount treated as a section 78 dividend. *See* § 1.907(a)–1(e)(3). Similarly, any reduction under section 901(e) of the foreign income taxes deemed paid with respect to foreign mineral income does not affect the amount treated as a section 78 dividend. *See* § 1.901–3(a)(2)(i), (b)(2)(i)(b), and (d), *Example 8.* Any reduction under section 6038(c)(1)(B) in the foreign taxes paid or accrued by a foreign corporation is taken into account in determining foreign taxes deemed paid and the amount treated as a section 78 dividend. See, for example, § 1.6038–2(k)(5), *Example 1.* To the extent provided in the Code, section 78 does not apply to any tax not allowed as a credit. See, for example, sections 901(j)(3), 901(k)(7), 901(l)(4), 901(m)(6), and 908(b). For rules on determining the source of a section 78 dividend in computing the limitation on the foreign tax credit under section 904, see §§ 1.861–3(a)(3), 1.862–1(a)(1)(ii), and 1.904–5(m)(6). For rules on assigning a section 78 dividend to a separate category, see § 1.904–4(o).

(b) *Date on which section 78 dividend is received.* A section 78 dividend is considered received by a domestic corporation on the date on which—

(1) The corporation includes in gross income under section 951(a)(1)(A) the amounts by reason of which there are deemed paid under section 960(a) the foreign income taxes that give rise to that section 78 dividend, notwithstanding that the foreign income taxes may be carried back or carried over to another taxable year and deemed to be paid or accrued in such other taxable year under section 904(c); or

(2) The corporation includes in gross income under section 951A(a) the amounts by reason of which there are deemed paid under section 960(d) the foreign income taxes that give rise to that section 78 dividend.

(c) *Applicability date.* This section applies to taxable years of foreign corporations that begin after December 31, 2017, and to taxable years of United States shareholders in which or with which such taxable years of foreign corporations end. The second sentence of paragraph (a) of this section also applies to section 78 dividends that are received after December 31, 2017, by reason of taxes deemed paid under section 960(a) with respect to a taxable year of a foreign corporation beginning before January 1, 2018.

■ **Par. 3.** Section 1.861–8 is amended by:

■ 1. Removing the last sentence of paragraph (a)(1).

■ 2. Removing the third sentence through fifth sentences of paragraph (a)(4).

■ 3. Removing paragraph (a)(5).

■ 4. Revising paragraphs (c)(2) and (d)(2).

■ 5. Adding two sentences after the sixth sentence in paragraph (e)(1).

■ 6. Removing the first sentence of paragraph (e)(6)(i).

■ 7. Adding a new first sentence and a new second sentence to paragraph (e)(6)(i).

■ 8. Removing paragraphs (e)(6)(iii) and (e)(12)(iv).

■ 9. Adding paragraphs (e)(13) through (e)(15).

■ 10. Revising paragraph (f)(1)(i).

■ 11. Adding paragraph (h).

The revisions and additions read as follows:

§ 1.861–8 Computation of taxable income from sources within the United States and from other sources and activities.

* * * * *

(c) * * *

(2) *Apportionment based on assets.* Certain taxpayers are required by paragraph (e)(2) of this section and § 1.861–9T to apportion interest expense on the basis of assets. A taxpayer may apportion other deductions based on the comparative value of assets that generate income within each grouping, provided that this method reflects the factual relationship between the deduction and the groupings of income and is applied in accordance with the rules of § 1.861–9T(g). In general, such apportionments must be made either on the basis of the tax book value of those assets or, except in the case of interest expense, on the basis of their fair market value. *See* § 1.861–9(h). Taxpayers using the fair market value method for their last taxable year beginning before January 1, 2018, must change to the tax book value method (or the alternative tax book value method) for purposes of apportioning interest expense for their first taxable year beginning after December 31, 2017. The Commissioner's approval is not required for this change. In the case of any corporate taxpayer that—

(i) Uses tax book value or alternative tax book value, and

(ii) Owns directly or indirectly (within the meaning of § 1.861–12T(c)(2)(ii)(B)) 10 percent or more of the total combined voting power of all classes of stock entitled to vote in any other corporation (domestic or foreign) that is not a member of the affiliated group (as defined in section 864(e)(5)), the taxpayer must adjust its basis in that stock in the manner described in § 1.861–12(c)(2).

* * * * *

(d) * * *

(2) *Allocation and apportionment to exempt, excluded, or eliminated income*—(i) *In general.* [Reserved]. For further guidance, see § 1.861–8T(d)(2)(i).

(ii) *Exempt income and exempt asset defined*—(A) *In general.* For purposes of this section, the term *exempt income* means any gross income to the extent that it is exempt, excluded, or eliminated for Federal income tax purposes. The term *exempt asset* means any asset to the extent income from the asset is (or is treated as under paragraph (d)(2)(ii)(B) or (C) of this section) exempt, excluded, or eliminated for Federal income tax purposes.

(B) [Reserved]. For further guidance, see § 1.861–8T(d)(2)(ii)(B).

(C) *Foreign-derived intangible income and inclusions under section 951A(a)*—(*1*) *Exempt income.* The term ''exempt income'' includes an amount of a domestic corporation's gross income included in foreign-derived intangible income (as defined in section 250(b)(1)), and also includes an amount of a domestic corporation's gross income from an inclusion under section 951A(a) and the gross up under section 78 attributable to such an inclusion, in each case equal to the amount of the deduction allowed under section 250(a) for such gross income (taking into account the reduction under section 250(a)(2)(B), if any). Therefore, for purposes of apportioning deductions using a gross income method, gross income does not include gross income included in foreign-derived intangible income, an inclusion under section 951A(a), or the gross up under section 78 attributable to an inclusion under section 951A(a), in an amount equal to the amount of the deduction allowed under section 250(a)(1)(A), (B)(i), or (B)(ii), respectively (taking into account the reduction under section 250(a)(2)(B), if any).

(*2*) *Exempt assets*—(*i*) *Assets that produce foreign-derived intangible income.* The term ''exempt asset'' includes the portion of a domestic corporation's assets that produce gross income included in foreign-derived intangible income equal to the amount of such assets multiplied by the fraction that equals the amount of the domestic corporation's deduction allowed under section 250(a)(1)(A) (taking into account the reduction under section 250(a)(2)(B)(i), if any) divided by its foreign-derived intangible income. No portion of the value of stock in a foreign corporation is treated as an exempt asset by reason of this paragraph (d)(2)(ii)(C)(*2*)(*i*), including by reason of a transfer of intangible property to a foreign corporation subject to section 367(d) that gives rise to income eligible for a deduction under section 250(a)(1)(A).

(*ii*) *Controlled foreign corporation stock that gives rise to inclusions under section 951A(a).* The term ''exempt asset'' includes a portion of the value of a United States shareholder's stock in a controlled foreign corporation if the United States shareholder is a domestic corporation that is eligible for a deduction under section 250(a) with respect to income described in section 250(a)(1)(B)(i) and all or a portion of the domestic corporation's stock in the controlled foreign corporation is characterized as GILTI inclusion stock. The portion of foreign corporation stock that is treated as an exempt asset for a taxable year equals the portion of the value of such foreign corporation stock (determined in accordance with §§ 1.861–9(g), 1.861–12, and 1.861–13) that is characterized as GILTI inclusion stock multiplied by a fraction that equals the amount of the domestic corporation's deduction allowed under section 250(a)(1)(B)(i) (taking into account the reduction under section 250(a)(2)(B)(ii), if any) divided by its GILTI inclusion amount (as defined in § 1.951A–1(c)(1) or, in the case of a member of a consolidated group, § 1.1502–51(b)) for such taxable year. The portion of controlled foreign corporation stock treated as an exempt asset under this paragraph (d)(2)(ii)(C)(*2*)(*ii*) is treated as attributable to the relevant categories of GILTI inclusion stock described in each of paragraphs (d)(2)(ii)(C)(*3*)(*i*) through (*v*) of this section based on the relative value of the portion of the stock in each such category.

(*3*) *GILTI inclusion stock.* For purposes of paragraph (d)(2)(ii)(C)(*2*)(*ii*) of this section, the term *GILTI inclusion stock* means the aggregate of the portions of the value of controlled foreign corporation stock that are—

(*i*) Assigned to the section 951A category under § 1.861–13(a)(2);

(*ii*) Assigned to a particular treaty category under § 1.861–13(a)(3)(i) (relating to resourced gross tested income stock);

(*iii*) Assigned under § 1.861–13(a)(1) to the gross tested income statutory grouping within the foreign source passive category less the amount described in § 1.861–13(a)(5)(iii)(A);

(*iv*) Assigned under § 1.861–13(a)(1) to the gross tested income statutory grouping within the U.S. source general category less the amount described in § 1.861–13(a)(5)(iv)(A); and

(*v*) Assigned under § 1.861–13(a)(1) to the gross tested income statutory grouping within the U.S. source passive category less the amount described in § 1.861–13(a)(5)(iv)(B).

(*4*) *Non-applicability to section 250(b)(3).* This paragraph (d)(2)(ii)(C) does not apply when apportioning deductions for purposes of determining deduction eligible income under the operative section of section 250(b)(3).

(*5*) *Example.* The following example illustrates the application of this paragraph (d)(2)(ii)(C).

(*i*) *Facts.* USP, a domestic corporation, directly owns all of the stock of CFC1 and CFC2, both of which are controlled foreign corporations. The tax book value of CFC1 and CFC2's stock is $10,000 and $9,000, respectively. Pursuant to § 1.861–13(a), $6,100 of the stock of CFC1 is assigned to the section 951A category under § 1.861–13(a)(2) (''section 951A category stock'') and the remaining $3,900 of the stock of CFC1 is assigned to the general category (''general category stock''). Additionally, $4,880 of the stock of CFC2 is section 951A category stock and the remaining $4,120 of the stock of CFC2 is general category stock. Under section 951A and the section 951A regulations (as defined in § 1.951A–1(a)(1)), USP's GILTI inclusion amount is $610. The portion of USP's deduction under section 250 described in section 250(a)(1)(B)(i) is $305. No portion of USP's deduction is reduced by reason of section 250(a)(2)(B)(ii).

(*ii*) *Analysis.* Under paragraph (d)(2)(ii)(C)(*1*) of this section, $305 of USP's gross income attributable to its GILTI inclusion amount is exempt income for purposes of apportioning deductions for purposes of section 904. Under paragraph (d)(2)(ii)(C)(*3*) of this section, the GILTI inclusion stock of CFC1 is the $6,100 of stock that is section 951A category stock and the GILTI inclusion stock of CFC2 is the $4,880 of stock that is section 951A category stock. Under paragraph (d)(2)(ii)(C)(*2*) of this section, the portion of the value of the stock of CFC1 and CFC2 that is treated as an exempt asset equals the portion of the value of the stock of CFC1 and CFC2 that is GILTI inclusion stock multiplied by 50% ($305/$610). Accordingly, the exempt portion of the stock of CFC1 is $3,050 (50% × $6,100) and the exempt portion of CFC2's stock is $2,440 (50% × $4,880). Therefore, the stock of CFC1 taken into account for purposes of apportioning deductions is $3,050 of non-exempt section 951A category stock and $3,900 of general category stock. The stock of CFC2 taken into account for purposes of apportioning deductions is $2,440 of non-exempt section 951A category stock and $4,120 of general category stock.

(d)(2)(iii) through (d)(2)(iii)(B) [Reserved]. For further guidance, see § 1.861–8T(d)(2)(iii) through § 1.861–8T(d)(2)(iii)(B).

(C) Dividends for which a deduction is allowed under section 245A;

(D) Foreign earned income as defined in section 911 and the regulations thereunder (however, the rules of § 1.911–6 do not require the allocation and apportionment of certain deductions, including home mortgage interest, to foreign earned income for purposes of determining the deductions disallowed under section 911(d)(6)); and

(E) Inclusions for which a deduction is allowed under section 965(c). *See* § 1.965–6(d).

(iv) *Value of stock attributable to previously taxed earnings and profits.* No portion of the value of stock in a controlled foreign corporation is treated as an exempt asset by reason of the adjustment under § 1.861–12(c)(2) in respect of previously taxed earnings and profits described in section 959(c)(1) or (c)(2) (including earnings and profits described in section 959(c)(2) by reason

of section 951A(f)(1) and § 1.951A–6(b)(1)). *See also* § 1.965–6(d).

(e) * * * (1) * * * Paragraphs (e)(13) and (14) of this section contain rules with respect to the allocation and apportionment of the deduction allowed under section 250(a). Paragraph (e)(15) of this section contains rules with respect to the allocation and apportionment of a taxpayer's distributive share of a partnership's deductions. * * *

* * * * *

(6) * * * (i) *In general.* The deduction for foreign income, war profits and excess profits taxes (*foreign income taxes*) allowed by section 164 is allocated and apportioned among the applicable statutory and residual groupings under the principles of § 1.904–6(a)(1)(i), (ii), and (iv). The deduction for state and local taxes (*state income taxes*) allowed by section 164 is considered definitely related and allocable to the gross income with respect to which such state income taxes are imposed. * * *

* * * * *

(13) *Foreign-derived intangible income.* The portion of the deduction that is allowed for foreign-derived intangible income under section 250(a)(1)(A) (taking into account the reduction under section 250(a)(2)(B)(i), if any) is considered definitely related and allocable to the class of gross income included in the taxpayer's foreign-derived deduction eligible income (as defined in section 250(b)(4)). If necessary, the portion of the deduction is apportioned within the class ratably between the statutory grouping (or among the statutory groupings) of gross income and the residual grouping of gross income based on the relative amounts of foreign-derived deduction eligible income in each grouping.

(14) *Global intangible low-taxed income and related section 78 gross up.* The portion of the deduction that is allowed for the global intangible low-taxed income amount described in section 250(a)(1)(B)(i) (taking into account the reduction under section 250(a)(2)(B)(ii), if any) is considered definitely related and allocable to the class of gross income included under section 951A(a). If necessary (for example, because a portion of the inclusion under section 951A(a) is passive category income or U.S. source income), the portion of the deduction is apportioned within the class ratably between the statutory grouping (or among the statutory groupings) of gross income and the residual grouping of gross income based on the relative amounts of gross income in each grouping. Similar rules apply to allocate and apportion the portion of the deduction that is allowed for the section 78 gross up under section 250(a)(1)(B)(ii).

(15) *Distributive share of partnership deductions.* In general, if deductions are incurred by a partnership in which the taxpayer is a partner, the taxpayer's deductions that are allocated and apportioned include the taxpayer's distributive share of the partnership's deductions. See §§ 1.861–9(e), 1.861–17(f), and 1.904–4(n)(1)(ii) for special rules for apportioning a partner's distributive share of deductions of a partnership.

(f) * * *

(1) * * *

(i) *Separate foreign tax credit limitations.* Section 904(d)(1) and other sections described in § 1.904–4(m) require that a separate foreign tax credit limitation be determined with respect to each separate category of income specified in those sections. Accordingly, the foreign source income within each separate category described in § 1.904–5(a)(4)(v) constitutes a separate statutory grouping of income. U.S. source income is treated as income in the residual category for purposes of determining the limitation on the foreign tax credit.

* * * * *

(h) *Applicability date.* This section applies to taxable years that both begin after December 31, 2017, and end on or after December 4, 2018.

■ **Par. 4.** Section 1.861–9 is amended by:

■ 1. Revising the section heading.

■ 2. Revising paragraphs (a) through (e)(1).

■ 3. Removing the last sentences in paragraph (e)(2) and (e)(3).

■ 4. Revising paragraphs (e)(4) through (f)(3)(i).

■ 5. Revising the heading of paragraph (f)(4).

■ 6. Removing the language ''noncontrolled section 902 corporations'' wherever it appears in paragraphs (f)(4)(i) and (f)(4)(ii) and adding the language ''noncontrolled 10-percent foreign owned corporations'' in its place.

■ 7. Removing the last sentence of paragraph (f)(4)(ii).

■ 8. Revising paragraph (f)(4)(iii).

■ 9. Revising paragraphs (f)(5) through (h)(3), and (h)(5).

■ 10. Revising the first and second sentences of paragraph (i)(2)(i).

■ 11. Removing the language ''paragraph (i)(2)'' from the third and fourth sentences of paragraph (i)(2) and adding the language ''paragraph (i)(2)(i)'' in its place.

■ 12. Revising paragraphs (j) and (k).

The revisions and additions read as follows:

§ 1.861–9 Allocation and apportionment of interest expense and rules for asset-based apportionment.

(a) through (c)(4) [Reserved]. For further guidance, see § 1.861–9T(a) through (c)(4).

(5) *Section 163(j).* If a taxpayer is subject to section 163(j), the taxpayer's deduction for business interest expense is limited to the sum of the taxpayer's business interest income, 30 percent of the taxpayer's adjusted taxable income for the taxable year, and the taxpayer's floor plan financing interest expense. In the taxable year that any deduction is permitted for business interest expense with respect to a disallowed business interest carryforward, that business interest expense is apportioned for purposes of this section under rules set forth in paragraphs (d), (e), or (f) of this section (as applicable) as though it were incurred in the taxable year in which the expense is deducted.

(d) through (e)(1) [Reserved]. For further guidance, see § 1.861–9T(d) through (e)(1).

* * * * *

(4) *Entity rule for less than 10 percent limited partners and less than 10 percent corporate general partners*—(i) *Partnership interest expense.* A limited partner (whether individual or corporate) or corporate general partner whose ownership, together with ownership by persons that bear a relationship to the partner described in section 267(b) or section 707, of the capital and profits interests of the partnership is less than 10 percent directly allocates its distributive share of partnership interest expense to its distributive share of partnership gross income. Under § 1.904–4(n)(1)(ii), such a partner's distributive share of foreign source income of the partnership is treated as passive income (subject to the high-taxed income exception of section 904(d)(2)(B)(iii)(II)), except in the case of income from a partnership interest held in the ordinary course of the partner's active trade or business, as defined in § 1.904–4(n)(1)(ii)(B). A partner's distributive share of partnership interest expense (other than partnership interest expense that is directly allocated to identified property under § 1.861–10T) is apportioned in accordance with the partner's relative distributive share of gross foreign source income in each separate category and of gross domestic source income from the partnership. To the extent that partnership interest expense is directly allocated under § 1.861–10T, a

comparable portion of the income to which such interest expense is allocated is disregarded in determining the partner's relative distributive share of gross foreign source income in each separate category and domestic source income. The partner's distributive share of the interest expense of the partnership that is directly allocable under § 1.861–10T is allocated according to the treatment, after application of § 1.904–4(n)(1), of the partner's distributive share of the income to which the expense is allocated.

(e)(4)(ii) through (e)(7) [Reserved]. For further guidance, see § 1.861–9T(e)(4)(ii) through (e)(7).

(8) *Special rule for specified partnership loans*—(i) *In general.* For purposes of apportioning interest expense that is not directly allocable under paragraph (e)(4) of this section or § 1.861–10T, the disregarded portion of a specified partnership loan is not considered an asset of a SPL lender. The disregarded portion of a specified partnership loan is the portion of the value of the loan (as determined under paragraph (h)(4)(i) of this section) that bears the same proportion to the total value of the loan as the matching income amount that is included by the SPL lender for a taxable year with respect to the loan bears to the total amount of SPL interest income that is included directly or indirectly in gross income by the SPL lender with respect to the loan during that taxable year.

(ii) *Treatment of interest expense and interest income attributable to a specified partnership loan.* If a SPL lender (or any other person in the same affiliated group as the SPL lender) takes into account a distributive share of SPL interest expense, the SPL lender includes the matching income amount for the taxable year that is attributable to the same loan in gross income in the same statutory and residual groupings as the statutory and residual groupings of gross income from which the SPL interest expense is deducted by the SPL lender (or any other person in the same affiliated group as the SPL lender).

(iii) *Anti-avoidance rule for third party back-to-back loans.* If, with a principal purpose of avoiding the rules in this paragraph (e)(8), a person makes a loan to a person that is not related (within the meaning of section 267(b) or 707) to the lender, the unrelated person makes a loan to a partnership, and the first loan would constitute a specified partnership loan if made directly to the partnership, then the rules of this paragraph (e)(8) apply as if the first loan was made directly to the partnership. Such a series of loans will be subject to this recharacterization rule without regard to whether there was a principal purpose of avoiding the rules in this paragraph (e)(8) if the loan to the unrelated person would not have been made or maintained on substantially the same terms irrespective of the loan of funds by the unrelated person to the partnership. The principles of this paragraph (e)(8)(iii) also apply to similar transactions that involve more than two loans and regardless of the order in which the loans are made.

(iv) *Anti-avoidance rule for loans held by CFCs.* A loan receivable held by a controlled foreign corporation with respect to a loan to a partnership in which a United States shareholder (as defined in § 1.904–5(a)(4)(vi)) of the controlled foreign corporation owns an interest, directly or indirectly through one or more other partnerships or other pass-through entities (as defined in § 1.904–5(a)(4)(iv)), is recharacterized as a loan receivable held directly by the United States shareholder with respect to the loan to such partnership for purposes of this paragraph (e)(8) if the loan was made or transferred with a principal purpose of avoiding the rules in this paragraph (e)(8).

(v) *Interest equivalents.* The principles of this paragraph (e)(8) apply in the case of a partner, or any person in the same affiliated group as the partner, that takes into account a distributive share of an expense or loss (to the extent deductible) that is allocated and apportioned in the same manner as interest expense under § 1.861–9T(b) and has a matching income amount with respect to the transaction that gives rise to that expense or loss.

(vi) *Definitions.* For purposes of this paragraph (e)(8), the following definitions apply.

(A) *Affiliated group.* The term *affiliated group* has the meaning provided in § 1.861–11(d)(1).

(B) *Matching income amount.* The term *matching income amount* means the lesser of the total amount of the SPL interest income included directly or indirectly in gross income by the SPL lender for the taxable year with respect to a specified partnership loan or the total amount of the distributive shares of the SPL interest expense of the SPL lender (or any other person in the same affiliated group as the SPL lender) with respect to the loan.

(C) *Specified partnership loan.* The term *specified partnership loan* means a loan to a partnership for which the loan receivable is held, directly or indirectly through one or more other partnerships, either by a person that owns an interest, directly or indirectly through one or more other partnerships, in the partnership, or by any person in the same affiliated group as that person.

(D) *SPL interest expense.* The term *SPL interest expense* means an item of interest expense paid or accrued with respect to a specified partnership loan, without regard to whether the expense was currently deductible (for example, by reason of section 163(j)).

(E) *SPL interest income.* The term *SPL interest income* means an item of gross interest income received or accrued with respect to a specified partnership loan.

(F) *SPL lender.* The term *SPL lender* means the person that holds the receivable with respect to a specified partnership loan. If a partnership holds the receivable, then any partner in the partnership (other than a partner described in paragraph (e)(4)(i) of this section) is also considered a SPL lender.

(9) *Characterizing certain partnership assets as foreign branch category assets.* For purposes of applying this paragraph (e) to section 904 as the operative section, a partner that is a United States person that has a distributive share of partnership income that is treated as foreign branch category income under § 1.904–4(f)(1)(i)(B) characterizes its pro rata share of the partnership assets that give rise to such income as assets in the foreign branch category.

(f) through (f)(1) [Reserved]. For further guidance, see § 1.861–9T(f) through (f)(1).

(2) *Section 987 QBUs of domestic corporations*—(i) *In general.* In the application of the asset method described in paragraph (g) of this section, a domestic corporation—

(A) Takes into account the assets of any section 987 QBU (as defined in § 1.987–1(b)(2)), translated according to the rules set forth in paragraph (g) of this section, and

(B) Combines with its own interest expense any deductible interest expense incurred by a section 987 QBU, translated according to the rules of section 987 and the regulations under that section.

(ii) *Coordination with section 987(3).* For purposes of computing foreign currency gain or loss under section 987(3) (including section 987 gain or loss recognized under § 1.987–5), the rules of this paragraph (f)(2) do not apply. *See* § 1.987–4.

(iii) *Example.* The following example illustrates the application of this paragraph (f)(2).

(A) *Facts.* X is a domestic corporation that operates B, a branch doing business in a foreign country. B is a section 987 QBU (as defined in § 1.987–1(b)(2)) as well as a foreign branch (as defined in § 1.904–

4(f)(3)(iii)). In 2020, without regard to B, X has gross domestic source income of $1,000 and gross foreign source general category income of $500 and incurs $200 of interest expense. Using the tax book value method of apportionment, X, without regard to B, determines the value of its assets that generate domestic source income to be $6,000 and the value of its assets that generate foreign source general category income to be $1,000. Applying the translation rules of section 987, X (through B) earned $500 of gross foreign source foreign branch category income and incurred $100 of interest expense. B incurred no other expenses. For 2020, the average functional currency book value of B's assets that generate foreign source foreign branch category income translated at the year-end rate for 2020 is $3,000.

(B) *Analysis.* The combined assets of X and B for 2020 (averaged under § 1.861–9T(g)(3)) consist 60% ($6,000/$10,000) of assets generating domestic source income, 30% ($3,000/$10,000) of assets generating foreign source foreign branch category income, and 10% ($1,000/$10,000) of assets generating foreign source general category income. The combined interest expense of X and B is $300. Thus, $180 ($300 × 60%) of the combined interest expense is apportioned to domestic source income, $90 ($300 × 30%) is apportioned to foreign source foreign branch category income, and $30 ($300 × 10%) is apportioned to foreign source general category income, yielding net U.S. source income of $820 ($1,000 − $180), net foreign source foreign branch category income of $410 ($500 − $90), and net foreign source general category income of $470 ($500 − $30).

(3) *Controlled foreign corporations*—(i) *In general.* For purposes of computing subpart F income and tested income and computing earnings and profits for all Federal income tax purposes, the interest expense of a controlled foreign corporation may be apportioned using either the asset method described in paragraph (g) of this section or the modified gross income method described in paragraph (j) of this section, subject to the rules of paragraph (f)(3)(ii) and (iii) of this section.

* * * * *

(4) *Noncontrolled 10-percent owned foreign corporations.* * * *

(iii) *Stock characterization.* The stock of a noncontrolled 10-percent owned foreign corporation is characterized under the rules in § 1.861–12(c)(4).

(f)(5) [Reserved]. For further guidance, see § 1.861–9T(f)(5).

(g) through (g)(1)(i) [Reserved]. For further guidance, see § 1.861–9T(g) through (g)(1)(i).

(ii) A taxpayer may elect to determine the value of its assets on the basis of either the tax book value or the fair market value of its assets. However, for taxable years beginning after December 31, 2017, the fair market value method is not allowed with respect to allocations and apportionments of interest expense. *See* section 864(e)(2). For rules concerning the application of an alternative method of valuing assets for purposes of the tax book value method, see paragraph (i) of this section. For rules concerning the application of the fair market value method, see paragraph (h) of this section.

(iii) [Reserved]

(iv) For rules relating to earnings and profits adjustments by taxpayers using the tax book value method for the stock in certain 10 percent owned corporations, see § 1.861–12(c)(2).

(v) [Reserved]

(2) *Asset values*—(i) *General rule*—(A) *Average of values.* For purposes of determining the value of assets under this section, an average of values (book or market) within each statutory grouping and the residual grouping is computed for the year on the basis of values of assets at the beginning and end of the year. For the first taxable year beginning after December 31, 2017 (*post-2017 year*), a taxpayer that determined the value of its assets on the basis of the fair market value method for purposes of apportioning interest expense in its prior taxable year may choose to determine asset values under the tax book value method (or the alternative tax book value method) by treating the value of its assets as of the beginning of the post-2017 year as equal to the value of its assets at the end of the first quarter of the post-2017 year, provided that each member of the affiliated group (as defined in § 1.861–11T(d)) determines its asset values on the same basis. Where a substantial distortion of asset values would result from averaging beginning-of-year and end-of-year values, as might be the case in the event of a major corporate acquisition or disposition, the taxpayer must use a different method of asset valuation that more clearly reflects the average value of assets weighted to reflect the time such assets are held by the taxpayer during the taxable year.

(B) *Tax book value method.* Under the tax book value method, the value of an asset is determined based on the adjusted basis of the asset. For purposes of determining the value of stock in a 10 percent owned corporation at the beginning and end of the year under the tax book value method, the tax book value is determined without regard to any adjustments under section 961(a) or 1293(d), see § 1.861–12(c)(2)(i)(B)(*1*), and before the adjustment required by § 1.861–12(c)(2)(i)(A) to the basis of stock in the 10 percent owned corporation. The average of the tax book value of the stock at the beginning and end of the year is then adjusted with respect to earnings and profits as described in § 1.861–12(c)(2)(i).

(g)(2)(ii) through (g)(2)(ii)(A)(*1*) [Reserved]. For further guidance, see § 1.861–9T(g)(2)(ii) through (g)(2)(ii)(A)(*1*).

(*2*) *United States dollar approximate separate transactions method.* In the case of a branch to which the United States dollar approximate separate transactions method of accounting described in § 1.985–3 applies, the beginning-of-year dollar amount of the assets is determined by reference to the end-of-year balance sheet of the branch for the immediately preceding taxable year, adjusted for United States generally accepted accounting principles and United States tax accounting principles, and translated into U.S. dollars as provided in § 1.985–3(c). The end-of-year dollar amount of the assets of the branch is determined in the same manner by reference to the end-of-year balance sheet for the current taxable year. The beginning-of-year and end-of-year dollar tax book value of assets, as so determined, within each grouping is then averaged as provided in paragraph (g)(2)(i) of this section.

(g)(2)(ii)(B) through (g)(3) [Reserved]. For further guidance, see § 1.861–9T(g)(2)(ii)(B) through (g)(3).

(h) *Fair market value method.* An affiliated group (as defined in section 1.861–11T(d)) or other taxpayer (the *taxpayer*) that elects to use the fair market value method of apportionment values its assets according to the methodology described in this paragraph (h). Effective for taxable years beginning after December 31, 2017, the fair market value method is not allowed for purposes of apportioning interest expense. *See* section 864(e)(2). However, a taxpayer may continue to apportion deductions other than interest expense that are properly apportioned based on fair market value according to the methodology described in this paragraph (h). *See* § 1.861–8(c)(2).

(h)(1) through (h)(3) [Reserved]. For further guidance, see § 1.861–9T(h)(1) through (h)(3).

* * * * *

(5) *Characterizing stock in related persons.* Stock in a related person held by the taxpayer or by another related person shall be characterized on the basis of the fair market value of the taxpayer's pro rata share of assets held by the related person attributed to each statutory grouping and the residual grouping under the stock characterization rules of § 1.861–12T(c)(3)(ii), except that the portion of

the value of intangible assets of the taxpayer and related persons that is apportioned to the related person under § 1.861–9T(h)(2) shall be characterized on the basis of the net income before interest expense of the related person within each statutory grouping or residual grouping (excluding income that is passive under § 1.904–4(b)).

* * * * *

(i) * * *

(2) * * * (i) Except as provided in this paragraph (i)(2)(i), a taxpayer may elect to use the alternative tax book value method. For the taxpayer's first taxable year beginning after December 31, 2017, the Commissioner's approval is not required to switch from the fair market value method to the alternative tax book value method for purposes of apportioning interest expense. * * *

* * * * *

(j) through (j)(2)(i) [Reserved]. For further guidance, see § 1.861–9T(j) through (j)(2)(i).

(ii) *Step 2.* Moving to the next higher-tier controlled foreign corporation, combine the gross income of such corporation within each grouping with its pro rata share (as determined under principles similar to section 951(a)(2)) of the gross income net of interest expense of all lower-tier controlled foreign corporations held by such higher-tier corporation within the same grouping adjusted as follows:

(A) Exclude from the gross income of the higher-tier corporation any dividends or other payments received from the lower-tier corporation other than interest income received from the lower-tier corporation;

(B) Exclude from the gross income net of interest expense of any lower-tier corporation any gross subpart F income, net of interest expense apportioned to such income;

(C) Exclude from the gross income net of interest expense of any lower-tier corporation any gross tested income as defined in § 1.951A–2(c)(1), net of interest expense apportioned to such income;

(D) Then apportion the interest expense of the higher-tier controlled foreign corporation based on the adjusted combined gross income amounts; and

(E) Repeat paragraphs (j)(2)(ii)(A) through (D) of this section for each next higher-tier controlled foreign corporation in the chain.

(k) *Applicability date.* This section applies to taxable years that both begin after December 31, 2017, and end on or after December 4, 2018.

■ **Par. 5.** Section 1.861–10 is amended by:

■ 1. Revising paragraph (e)(8)(vi).

■ 2. Removing and reserving paragraph (e)(10).

■ 3. Adding paragraph (f).

The revisions and additions read as follows:

§ 1.861–10 Special allocations of interest expense.

* * * * *

(e) * * *

(8) * * *

(vi) *Classification of hybrid stock.* In determining the amount of its related group indebtedness for any taxable year, a U.S. shareholder must not treat stock in a related controlled foreign corporation as related group indebtedness, regardless of whether the related controlled foreign corporation claims a deduction for interest under foreign law for distributions on such stock. For purposes of determining the foreign base period ratio under paragraph (e)(2)(iv) of this section for a taxable year that ends on or after December 4, 2018, the rules of this paragraph (e)(8)(vi) apply to determine the related group debt-to-asset ratio in each taxable year included in the foreign base period, including in taxable years that end before December 4, 2018.

* * * * *

(10) [Reserved]

* * * * *

(f) *Applicability date.* This section applies to taxable years that end on or after December 4, 2018.

■ **Par. 6.** Section 1.861–11 is amended by:

■ 1. Revising paragraphs (a) through (c).

■ 2. Removing the language ", except that section 936 corporations are also included within the affiliated group to the extent provided in paragraph (d)(2) of this section" from the first sentence of paragraph (d)(1).

■ 3. Removing and reserving paragraph (d)(2).

■ 4. Adding paragraph (h).

The revisions and addition read as follows:

§ 1.861–11 Special rules for allocating and apportioning interest expense of an affiliated group of corporations.

(a) [Reserved]. For further guidance, see § 1.861–11T(a).

(b) *Scope of application*—(1) *Application of section 864(e)(1) and (5) (concerning the definition and treatment of affiliated groups).* Section 864(e)(1) and (5) and the portions of this section implementing section 864(e)(1) and (5) apply to the computation of foreign source taxable income for purposes of section 904 (relating to various limitations on the foreign tax credit). Section 864(e)(1) and (5) and the portions of this section implementing section 864(e)(1) and (5) also apply in connection with section 907 to determine reductions in the amount allowed as a foreign tax credit under section 901. Section 864(e)(1) and (5) and the portions of this section implementing section 864(e)(1) and (5) also apply to the computation of the combined taxable income of the related supplier and a foreign sales corporation (FSC) (under sections 921 through 927) as well as the combined taxable income of the related supplier and a domestic international sales corporation (DISC) (under sections 991 through 997).

(b)(2) through (c) [Reserved]. For further guidance, see § 1.861–11T(b)(2) through (c).

(d) * * *

(2) [Reserved]

* * * * *

(h) *Applicability dates.* This section applies to taxable years that both begin after December 31, 2017, and end on or after December 4, 2018.

■ **Par. 7.** Section 1.861–12 is amended by:

■ 1. Revising paragraphs (a) through (c)(1).

■ 2. Revising the heading of paragraph (c)(2).

■ 3. Removing the language ", for taxable years beginning after April 25, 2006," from paragraph (c)(2)(i)(A).

■ 4. Revising paragraphs (c)(2)(i)(B) through (c)(3).

■ 5. Revising paragraph (c)(4).

■ 6. Removing paragraph (c)(5).

■ 7. Revising paragraphs (d) through (j).

■ 8. Adding paragraph (k).

The revisions and additions read as follows:

§ 1.861–12 Characterization rules and adjustments for certain assets.

(a) *In general.* The rules in this section are applicable to taxpayers in apportioning expenses under an asset method to income in the various separate categories described in § 1.904–5(a)(4)(v), and supplement other rules provided in §§ 1.861–9 through 1.861–11T. The principles of the rules in this section are also applicable in apportioning expenses among statutory and residual groupings for any other operative section. See also § 1.861–8(f)(2)(i) for a rule requiring conformity of allocation methods and apportionment principles for all operative sections. Paragraph (b) of this section describes the treatment of inventories. Paragraph (c)(1) of this section concerns the treatment of various stock assets. Paragraph (c)(2) of this section describes a basis adjustment for stock in 10 percent owned corporations. Paragraph (c)(3) of this

section sets forth rules for characterizing the stock in controlled foreign corporations. Paragraph (c)(4) of this section describes the treatment of stock of noncontrolled 10-percent owned foreign corporations. Paragraph (d)(1) of this section concerns the treatment of notes. Paragraph (d)(2) of this section concerns the treatment of notes of controlled foreign corporations. Paragraph (e) of this section describes the treatment of certain portfolio securities that constitute inventory or generate income primarily in the form of gains. Paragraph (f) of this section describes the treatment of assets that are subject to the capitalization rules of section 263A. Paragraph (g) of this section concerns the treatment of FSC stock and of assets of the related supplier generating foreign trade income. Paragraph (h) of this section concerns the treatment of DISC stock and of assets of the related supplier generating qualified export receipts. Paragraph (i) of this section is reserved. Paragraph (j) of this section sets forth an example illustrating the rules of this section, as well as the rules of § 1.861–9(g).

(b) through (c)(1) [Reserved]. For further guidance, see § 1.861–12T(b) through (c)(1).

(2) *Basis adjustment for stock in 10 percent owned corporations*—(i) * * *

(B) *Computational rules*—(*1*) *Adjustments to basis*—(*i*) *Application of section 961 or 1293(d).* For purposes of this section, a taxpayer's adjusted basis in the stock of a foreign corporation does not include any amount included in basis under section 961 or 1293(d) of the Code.

(*ii*) *Application of section 965(b).* If a taxpayer owned the stock of a specified foreign corporation (as defined in § 1.965–1(f)(45)) as of the close of the last taxable year of the specified foreign corporation that began before January 1, 2018, the taxpayer's adjusted basis in the stock of the specified foreign corporation for that taxable year and any subsequent taxable year is determined as if the taxpayer made the election described in § 1.965–2(f)(2)(i) (regardless of whether the election was actually made) but does not include the amount included (or that would be included if the election were made) in basis under § 1.965–2(f)(2)(ii)(A) (without regard to whether any portion of the amount is netted against the amounts of any other basis adjustments under § 1.965–2(h)(2)).

(*2*) *Amount of earnings and profits.* For purposes of this paragraph (c)(2), earnings and profits (or deficits) are computed under the rules of section 312 and, in the case of a foreign corporation, sections 964(a) and 986 for taxable years of the 10 percent owned corporation ending on or before the close of the taxable year of the taxpayer. Accordingly, the earnings and profits of a controlled foreign corporation includes all earnings and profits described in section 959(c). The amount of the earnings and profits with respect to stock of a foreign corporation held by the taxpayer is determined according to the attribution principles of section 1248 and the regulations under section 1248. The attribution principles of section 1248 apply without regard to the requirements of section 1248 that are not relevant to the determination of a shareholder's pro rata portion of earnings and profits, such as whether earnings and profits (or deficits) were derived (or incurred) during taxable years beginning before or after December 31, 1962.

(*3*) *Annual noncumulative adjustment.* The adjustment required by paragraph (c)(2)(i)(A) of this section is made annually and is noncumulative. Thus, the adjusted basis of the stock (determined without regard to prior years' adjustments under paragraph (c)(2)(i)(A) of this section) is adjusted annually by the amount of accumulated earnings and profits (or deficits) attributable to the stock as of the end of each year.

(*4*) *Translation of non-dollar functional currency earnings and profits.* Earnings and profits (or deficits) of a qualified business unit that has a functional currency other than the dollar must be computed under this paragraph (c)(2) in functional currency and translated into dollars using the exchange rate at the end of the taxpayer's current taxable year (and not the exchange rates for the years in which the earnings and profits or deficits were derived or incurred).

(C) *Examples.* The following examples illustrate the application of paragraph (c)(2)(i)(B) of this section.

(*1*) *Example 1: No election described in § 1.965–2(f)(2)(i)*—(*i*) *Facts.* USP, a domestic corporation, owns all of the stock of CFC1 and CFC2, both controlled foreign corporations. USP, CFC1, and CFC2 all use the calendar year as their U.S. taxable year. USP owned CFC1 and CFC2 as of December 31, 2017, and CFC1 and CFC2 were specified foreign corporations with respect to USP. USP did not make the election described in § 1.965–2(f)(2)(i), but if USP had made the election, USP's basis in the stock of CFC1 would have been increased by $75 under § 1.965–2(f)(2)(ii)(A) and USP's basis in the stock of CFC2 would have been decreased by $75 under § 1.965–2(f)(2)(ii)(B). For purposes of determining the value of the stock of CFC1 and CFC2 at the beginning of the 2019 taxable year, without regard to amounts included in basis under section 961 or 1293(d), USP's adjusted basis in the stock of CFC1 is $100 and its adjusted basis in the stock of CFC2 is $350 (before the application of this paragraph (c)(2)(i)(B)).

(*ii*) *Analysis.* Under paragraph (c)(2)(i)(B)(*1*) of this section, USP's adjusted basis in CFC1 and CFC2 is determined as if USP had made the election described in § 1.965–2(f)(2)(i), and therefore USP's adjusted basis in CFC2 includes the $75 reduction USP would have made to its basis in that stock under § 1.965–2(f)(2)(ii)(B). However, USP's adjusted basis in the stock of CFC1 does not include the $75 that USP would have included in its basis in that stock under § 1.965–2(f)(2)(ii)(A). Accordingly, for purposes of determining the value of stock of CFC1 and CFC2 at the beginning of the 2019 taxable year, USP's adjusted basis in the stock of CFC1 is $100 and USP's adjusted basis in the stock of CFC2 is $275 ($350 − $75).

(*2*) *Example 2: Election described in § 1.965–2(f)(2)(i)*—(*i*) *Facts.* USP, a domestic corporation, owns all of the stock of CFC1, which owns all of the stock of CFC2, both foreign corporations. USP, CFC1, and CFC2 all use the calendar year as their U.S. taxable year. USP owned CFC1, and CFC1 owned CFC2 as of December 31, 2017, and CFC1 and CFC2 were specified foreign corporations with respect to USP. USP made the election described in § 1.965–2(f)(2)(i). As a result of the election, USP was required to increase its basis in CFC1 by $90 under § 1.965–2(f)(2)(ii)(A), and to decrease its basis in CFC1 by $90 under § 1.965–2(f)(2)(ii)(B). Pursuant to § 1.965–2(h)(2), USP netted the increase of $90 against the decrease of $90 and made no net adjustment to the basis of the stock of CFC1. For purposes of determining the value of the stock of CFC1 at the beginning of the 2019 taxable year, without regard to amounts included in basis under section 961 or 1293(d), USP's adjusted basis in the stock of CFC1 is $600 (before the application of this paragraph (c)(2)(i)(B)).

(*ii*) *Analysis.* Under paragraph (c)(2)(i)(B)(*1*) of this section, USP's adjusted basis in CFC1 is determined as if USP had made the election described in § 1.965–2(f)(2)(i), and therefore USP's adjusted basis in CFC1 includes the $90 reduction USP would have made to its basis in that stock, without regard to the netting rule described in § 1.965–2(h)(2). However, USP's adjusted basis in the stock of CFC1 does not include the amount that would have been included in basis under § 1.965–2(f)(2)(ii)(A) without regard to the netting rule described in § 1.965–2(h)(2). Accordingly, for purposes of determining the value of stock of CFC1 at the beginning of the 2019 taxable year, USP's adjusted basis in the stock of CFC1 is $510 ($600 − $90).

(c)(2)(ii) through (c)(2)(vi) [Reserved]. For further guidance, see § 1.861–12T(c)(2)(ii) through (c)(2)(vi).

(3) *Characterization of stock of controlled foreign corporations*—(i) *Operative sections.* (A) *Operative sections other than section 904.* For purposes of applying this section to an operative section other than section 904,

stock in a controlled foreign corporation (as defined in section 957) is characterized as an asset in the relevant groupings on the basis of the asset method described in paragraph (c)(3)(ii) of this section, or the modified gross income method described in paragraph (c)(3)(iii) of this section. Stock in a controlled foreign corporation whose interest expense is apportioned on the basis of assets is characterized in the hands of its United States shareholders under the asset method described in paragraph (c)(3)(ii) of this section. Stock in a controlled foreign corporation whose interest expense is apportioned on the basis of modified gross income is characterized in the hands of its United States shareholders under the modified gross income method described in paragraph (c)(3)(iii) of this section.

(B) *Section 904 as operative section.* For purposes of applying this section to section 904 as the operative section, § 1.861–13 applies to characterize the stock of a controlled foreign corporation as an asset producing foreign source income in the separate categories described in § 1.904–5(a)(4)(v), or as an asset producing U.S. source income in the residual grouping, in the hands of the United States shareholder, and to determine the portion of the stock that gives rise to an inclusion under section 951A(a) that is treated as an exempt asset under § 1.861–8(d)(2)(ii)(C). Section 1.861–13 also provides rules for subdividing the stock in the various separate categories and the residual grouping into a section 245A subgroup and a non-section 245A subgroup in order to determine the amount of the adjustments required by section 904(b)(4) and § 1.904(b)–3(c) with respect to the section 245A subgroup, and provides rules for determining the portion of the stock that gives rise to a dividend eligible for a deduction under section 245(a)(5) that is treated as an exempt asset under § 1.861–8(d)(2)(ii)(B).

(ii) [Reserved]. For further guidance, see § 1.861–12T(c)(3)(ii).

(iii) *Modified gross income method.* Under the modified gross income method, the taxpayer characterizes the tax book value of the stock of the first-tier controlled foreign corporation based on the gross income, net of interest expense, of the controlled foreign corporation (as computed under § 1.861–9T(j) to include certain gross income, net of interest expense, of lower-tier controlled foreign corporations) within each relevant category for the taxable year of the controlled foreign corporation ending with or within the taxable year of the taxpayer. For this purpose, however, the gross income, net of interest expense, of the first-tier controlled foreign corporation includes the total amount of gross subpart F income, net of interest expense, of any lower-tier controlled foreign corporation that was excluded under the rules of § 1.861–9(j)(2)(ii)(B). The gross income, net of interest expense, of the first-tier controlled foreign corporation also includes the total amount of gross tested income, net of interest expense, of any lower-tier controlled foreign corporation that was excluded under the rules of § 1.861–9(j)(2)(ii)(C).

(4) *Characterization of stock of noncontrolled 10-percent owned foreign corporations*—(i) *In general.* Except in the case of a nonqualifying shareholder described in paragraph (c)(4)(ii) of this section, the principles of § 1.861–12(c)(3), including the relevant rules of § 1.861–13 when section 904 is the operative section, apply to characterize stock in a noncontrolled 10-percent owned foreign corporation (as defined in section 904(d)(2)(E)). Accordingly, stock in a noncontrolled 10-percent owned foreign corporation is characterized as an asset in the various separate categories on the basis of either the asset method described in § 1.861–12T(c)(3)(ii) or the modified gross income method described in § 1.861–12(c)(3)(iii). Stock in a noncontrolled 10-percent owned foreign corporation the interest expense of which is apportioned on the basis of assets is characterized in the hands of its shareholders under the asset method described in § 1.861–12T(c)(3)(ii). Stock in a noncontrolled 10-percent owned foreign corporation the interest expense of which is apportioned on the basis of gross income is characterized in the hands of its shareholders under the modified gross income method described in § 1.861–12(c)(3)(iii).

(ii) *Nonqualifying shareholders.* Stock in a noncontrolled 10-percent owned foreign corporation is characterized as a passive category asset in the hands of a shareholder that either is not a domestic corporation or is not a United States shareholder with respect to the noncontrolled 10-percent owned foreign corporation for the taxable year. Stock in a noncontrolled 10-percent owned foreign corporation is characterized as in the separate category described in section 904(d)(4)(C)(ii) in the hands of any shareholder with respect to whom look-through treatment is not substantiated. *See also* § 1.904–5(c)(4)(iii)(B). In the case of a noncontrolled 10-percent owned foreign corporation that is a passive foreign investment company with respect to a shareholder, stock in the noncontrolled 10-percent owned foreign corporation is characterized as a passive category asset in the hands of the shareholder if such shareholder does not meet the ownership requirements described in section 904(d)(2)(E)(i)(II).

(d) *Treatment of notes*—(1) *General rule.* [Reserved]. For further guidance, see § 1.861–12T(d)(1).

(2) *Characterization of related controlled foreign corporation notes.* The debt of a controlled foreign corporation is characterized in the same manner as the interest income derived from that debt obligation. See §§ 1.904–4 and 1.904–5(c)(2) for rules treating interest income as income in a separate category.

(e) through (j) [Reserved]. For further guidance, see § 1.861–12T(e) through (j).

(k) *Applicability date.* This section applies to taxable years that both begin after December 31, 2017, and end on or after December 4, 2018. Section 1.861–12(c)(2)(i)(*B*)(*1*)(*ii*) also applies to the last taxable year of a foreign corporation that begins before January 1, 2018, and with respect to a United States person, the taxable year in which or with which such taxable year of the foreign corporation ends.

■ **Par. 8.** § 1.861–13 is added to read as follows:

§ 1.861–13 Special rules for characterization of controlled foreign corporation stock.

(a) *Methodology.* For purposes of allocating and apportioning deductions for purposes of section 904 as the operative section, stock in a controlled foreign corporation owned directly or indirectly through a partnership or other pass-through entity by a United States shareholder is characterized by the United States shareholder under the rules described in this section. In general, paragraphs (a)(1) through (5) of this section characterize the stock of the controlled foreign corporation as an asset in the various statutory groupings and residual grouping based on the type of income that the stock of the controlled foreign corporation generates, has generated, or may reasonably be expected to generate when the income is included by the United States shareholder.

(1) *Step 1: Characterize stock as generating income in statutory groupings under the asset or modified gross income method*—(i) *Asset method.* United States shareholders using the asset method to characterize stock of a controlled foreign corporation must apply the asset method described in § 1.861–12T(c)(3)(ii) to assign the assets of the controlled foreign corporation to the statutory groupings described in

paragraphs (a)(1)(i)(A)(*1*) through (*10*) and (a)(1)(i)(B) of this section. If the controlled foreign corporation owns stock in a lower-tier noncontrolled 10-percent owned foreign corporation, the assets of the lower-tier noncontrolled 10-percent owned foreign corporation are assigned to a gross subpart F income grouping to the extent such assets generate income that, if distributed to the controlled foreign corporation, would be gross subpart F income of the controlled foreign corporation. *See also* § 1.861–12(c)(4).

(A) *General and passive categories.* Within each of the controlled foreign corporation's general category and passive category, each of the following subgroups within each category is a separate statutory grouping—

(*1*) Foreign source gross tested income;

(*2*) For each applicable treaty, U.S. source gross tested income that, when taken into account by a United States shareholder under section 951A, is resourced in the hands of the United States shareholder (*resourced gross tested income*);

(*3*) U.S. source gross tested income not described in paragraph (a)(1)(i)(A)(*2*) of this section;

(*4*) Foreign source gross subpart F income;

(*5*) For each applicable treaty, U.S. source gross subpart F income that, when included by a United States shareholder under section 951(a)(1), is resourced in the hands of the United States shareholder (*resourced gross subpart F income*);

(*6*) U.S. source gross subpart F income not described in paragraph (a)(1)(i)(A)(*5*) of this section;

(*7*) Foreign source gross section 245(a)(5) income;

(*8*) U.S. source gross section 245(a)(5) income;

(*9*) Any other foreign source gross income (*specified foreign source general category income* or *specified foreign source passive category income,* as the case may be); and

(*10*) Any other U.S. source gross income (*specified U.S. source general category gross income* or *specified U.S. source passive category gross income,* as the case may be).

(B) *Section 901(j) income.* For each country described in section 901(j), all gross income from sources in that country.

(ii) *Modified gross income method.* United States shareholders using the modified gross income method to characterize stock in a controlled foreign corporation must apply the modified gross income method under § 1.861–12(c)(3)(iii) to assign the modified gross income of the controlled foreign corporation to the statutory groupings described in paragraphs (a)(1)(i)(A)(*1*) through (*10*) and (a)(1)(i)(B) of this section. For this purpose, the rules described in §§ 1.861–12(c)(3)(iii) and 1.861–9T(j)(2) apply to combine gross income in a statutory grouping that is earned by the controlled foreign corporation with gross income of lower-tier controlled foreign corporations that is in the same statutory grouping. For example, foreign source general category gross tested income (net of interest expense) earned by the controlled foreign corporation is combined with its pro rata share of the foreign source general category gross tested income (net of interest expense) of lower-tier controlled foreign corporations. If the controlled foreign corporation owns stock in a lower-tier noncontrolled 10-percent owned foreign corporation, gross income of the lower-tier noncontrolled 10-percent owned foreign corporation is assigned to a gross subpart F income grouping to the extent that the income, if distributed to the upper-tier controlled foreign corporation, would be gross subpart F income of the upper-tier controlled foreign corporation. *See also* § 1.861–12(c)(4).

(2) *Step 2: Assign stock to the section 951A category.* A controlled foreign corporation is not treated as earning section 951A category income. The portion of the value of the stock of the controlled foreign corporation that is assigned to the section 951A category equals the value of the portion of the stock of the controlled foreign corporation that is assigned to the foreign source gross tested income statutory groupings within the general category (*general category gross tested income stock*) multiplied by the United States shareholder's inclusion percentage. Under § 1.861–8(d)(2)(ii)(C)(*2*)(*ii*), a portion of the value of stock assigned to the section 951A category may be treated as an exempt asset. The portion of the general category gross tested income stock that is not characterized as a section 951A category asset remains a general category asset and may result in expenses being disregarded under section 904(b)(4). See paragraph (a)(5)(ii) of this section and § 1.904(b)–3. No portion of the passive category gross tested income stock or U.S. source gross tested income stock is assigned to the section 951A category.

(3) *Step 3: Assign stock to a treaty category.* (i) *Inclusions under section 951A(a).* The portion of the value of the stock of the controlled foreign corporation that is assigned to a particular treaty category due to an inclusion of U.S. source income under section 951A(a) that was resourced under a particular treaty equals the value of the portion of the stock of the controlled foreign corporation that is assigned to the resourced gross tested income statutory grouping within each of the controlled foreign corporation's general or passive categories (*resourced gross tested income stock*) multiplied by the United States shareholder's inclusion percentage. Under § 1.861–8(d)(2)(ii)(C)(*2*)(*ii*), a portion of the value of stock assigned to a particular treaty category by reason of this paragraph (a)(3)(i) may be treated as an exempt asset. The portion of the resourced gross tested income stock that is not characterized as a treaty category asset remains a U.S. source general or passive category asset, as the case may be, that is in the residual grouping and may result in expenses being disregarded under section 904(b)(4) for purposes of determining entire taxable income under section 904(a). *See* paragraph (a)(5)(iv) of this section and § 1.904(b)–3.

(ii) *Inclusions under section 951(a)(1).* The portion of the value of the stock of the controlled foreign corporation that is assigned to a particular treaty category due to an inclusion of U.S. source income under section 951(a)(1) that was resourced under a treaty equals the value of the portion of the stock of the controlled foreign corporation that is assigned to the resourced gross subpart F income statutory grouping within each of the controlled foreign corporation's general category or passive category.

(4) *Step 4: Aggregate stock within each separate category and assign stock to the residual grouping.* The portions of the value of stock of the controlled foreign corporation assigned to foreign source statutory groupings that were not specifically assigned to the section 951A category under paragraph (a)(2) of this section (Step 2) are aggregated within the general category and the passive category to characterize the stock as general category stock and passive category stock, respectively. The portions of the value of stock of the controlled foreign corporation assigned to U.S. source statutory groupings that were not specifically assigned to a particular treaty category under paragraph (a)(3) of this section (Step 3) are aggregated to characterize the stock as U.S. source category stock, which is in the residual grouping. Stock assigned to the separate category for income described in section 901(j)(1) remains in that category.

(5) *Step 5: Determine section 245A and non-section 245A subgroups for each separate category and U.S. source category*—(i) *In general.* In the case of stock of a controlled foreign corporation that is held directly or indirectly through a partnership or other pass-through entity by a United States shareholder that is a domestic corporation, stock of the controlled foreign corporation that is general category stock, passive category stock, and U.S. source category stock is subdivided between a section 245A subgroup and a non-section 245A subgroup under paragraphs (a)(5)(ii) through (v) of this section for purposes of applying section 904(b)(4) and § 1.904(b)–3(c). Each subgroup is treated as a statutory grouping under § 1.861–8(a)(4) for purposes of allocating and apportioning deductions under §§ 1.861–8 through 1.861–14T and 1.861–17 in applying section 904 as the operative section. Deductions apportioned to each section 245A subgroup are disregarded under section 904(b)(4). *See* § 1.904(b)–3. Deductions apportioned to the statutory groupings for gross section 245(a)(5) income are not disregarded under section 904(b)(4); however, a portion of the stock assigned to those groupings is treated as exempt under § 1.861–8T(d)(2)(ii)(B).

(ii) *Section 245A subgroup of general category stock.* The portion of the general category stock of the controlled foreign corporation that is assigned to the section 245A subgroup of the general category equals the value of the general category gross tested income stock of the controlled foreign corporation that is not assigned to the section 951A category under paragraph (a)(2) of this section (Step 2), plus the value of the portion of the stock of the controlled foreign corporation that is assigned to the specified foreign source general category income statutory grouping.

(iii) *Section 245A subgroup of passive category stock.* The portion of passive category stock of the controlled foreign corporation that is assigned to the section 245A subcategory of the passive category equals the sum of—

(A) The value of the portion of the stock of the controlled foreign corporation that is assigned to the gross tested income statutory grouping within foreign source passive category income multiplied by a percentage equal to 100 percent minus the United States shareholder's inclusion percentage for passive category gross tested income; and

(B) The value of the portion of the stock of the controlled foreign corporation that was assigned to the specified foreign source passive category income statutory grouping.

(iv) *Section 245A subgroup of U.S. source category stock.* The portion of U.S. source category stock of the controlled foreign corporation that is assigned to the section 245A subgroup of the U.S. source category equals the sum of—

(A) The value of the portion of the stock of the controlled foreign corporation that is assigned to the U.S. source general category gross tested income statutory grouping multiplied by a percentage equal to 100 percent minus the United States shareholder's inclusion percentage for the general category;

(B) The value of the portion of the stock of the controlled foreign corporation that is assigned to the U.S. source passive category gross tested income statutory grouping multiplied by a percentage equal to 100 percent minus the United States shareholder's inclusion percentage for the passive category;

(C) The value of the resourced gross tested income stock of the controlled foreign corporation that is not assigned to a particular treaty category under paragraph (a)(3)(i) of this section (Step 3);

(D) The value of the portion of the stock of the controlled foreign corporation that is assigned to the specified U.S. source general category gross income statutory grouping; and

(E) The value of the portion of the stock of the controlled foreign corporation that is assigned to the specified U.S. source passive category gross income statutory grouping.

(v) *Non-section 245A subgroup.* The value of stock of a controlled foreign corporation that is not assigned to the section 245A subgroup within the general or passive category or the residual grouping is assigned to the non-section 245A subgroup within such category or grouping. The value of stock of a controlled foreign corporation that is assigned to the section 951A category, the separate category for income described in section 901(j)(1), or a particular treaty category is always assigned to a non-section 245A subgroup.

(b) *Definitions.* This paragraph (b) provides definitions that apply for purposes of this section.

(1) *Gross section 245(a)(5) income.* The term *gross section 245(a)(5) income* means all items of gross income described in section 245(a)(5)(A) and (B).

(2) *Gross subpart F income.* The term *gross subpart F income* means all items of gross income that are taken into account by a controlled foreign corporation in determining its subpart F income under section 952, except for items of gross income described in section 952(a)(5).

(3) *Gross tested income.* The term *gross tested income* has the meaning provided in § 1.951A–1(c)(1).

(4) *Inclusion percentage.* The term *inclusion percentage* has the meaning provided in § 1.960–2(c)(2).

(5) *Separate category.* The term *separate category* has the meaning provided in § 1.904–5(a)(4)(v).

(6) *Treaty category.* The term *treaty category* means a category of income earned by a controlled foreign corporation for which section 904(a), (b), and (c) are applied separately as a result of income being resourced under a treaty. See, for example, section 245(a)(10), 865(h), or 904(h)(10). A United States shareholder may have multiple treaty categories for amounts of income resourced by the United States shareholder under a treaty. *See* § 1.904–5(m)(7).

(7) *U.S. source category.* The term *U.S. source category* means the aggregate of U.S. source income in each separate category listed in section 904(d)(1).

(c) *Examples.* The following examples illustrate the application of the rules in this section.

(1) *Example 1: Asset method*—(i) *Facts*—(A) USP, a domestic corporation, directly owns all of the stock of a controlled foreign corporation, CFC1. The tax book value of CFC1's stock is $20,000. USP uses the asset method described in § 1.861–12T(c)(3)(ii) to characterize the stock of CFC1. USP's inclusion percentage is 70%.

(B) CFC1 owns the following assets with the following values as determined under §§ 1.861–9(g)(2) and 1.861–9T(g)(3): Assets that generate income described in the foreign source gross tested income statutory grouping within the general category ($4,000), assets that generate income described in the foreign source gross subpart F income statutory grouping within the general category ($1,000), assets that generate specified foreign source general category income ($3,000), and assets that generate income described in the foreign source gross subpart F income statutory grouping within the passive category ($2,000).

(C) CFC1 also owns all of the stock of CFC2, a controlled foreign corporation. The tax book value of CFC1's stock in CFC2 is $5,000. CFC2 owns the following assets with the following values as determined under §§ 1.861–9(g)(2) and 1.861–9T(g)(3): Assets that generate income described in the foreign source gross subpart F income statutory grouping within the general category ($2,250) and assets that generate specified foreign source general category income ($750).

(ii) *Analysis*—(A) *Step 1*—(*1*) *Characterization of CFC2 stock.* CFC2 has total assets of $3,000, $2,250 of which are in

the foreign source gross subpart F income statutory grouping within the general category and $750 of which are in the specified foreign source general category income statutory grouping. Accordingly, CFC2's stock is characterized as $3,750 ($2,250/$3,000 × $5,000) in the foreign source gross subpart F income statutory grouping within the general category and $1,250 ($750/$3,000 × $5,000) in the specified foreign source general category income statutory grouping.

(*2*) *Characterization of CFC1 stock.* CFC1 has total assets of $15,000, $4,000 of which are in the foreign source gross tested income statutory grouping within the general category, $4,750 of which are in the foreign source gross subpart F income statutory grouping within the general category (including the portion of CFC2 stock assigned to that statutory grouping), $4,250 of which are in the specified foreign source general category income statutory grouping (including the portion of CFC2 stock assigned to that statutory grouping), and $2,000 of which are in the foreign source gross subpart F income statutory grouping within the passive category. Accordingly, CFC1's stock is characterized as $5,333 ($4,000/$15,000 × $20,000) in the foreign source gross tested income statutory grouping within the general category, $6,333 ($4,750/$15,000 × $20,000) in the foreign source gross subpart F income statutory grouping within the general category, $5,667 ($4,250/$15,000 × $20,000) in the specified foreign source general category income statutory grouping, and $2,667 ($2,000/$15,000 × $20,000) in the foreign source gross subpart F income statutory grouping within the passive category.

(B) *Step 2.* The portion of the value of the stock of CFC1 that is general category gross tested income stock is $5,333. USP's inclusion percentage is 70%. Accordingly, under paragraph (a)(2) of this section, $3,733 of the stock of CFC1 is assigned to the section 951A category and a portion thereof may be treated as an exempt asset under § 1.861–8(d)(2)(ii)(C)(*2*)(*ii*). The remainder, $1,600, remains a general category asset.

(C) *Step 3.* No portion of the stock of CFC1 is resourced gross tested income stock or assigned to the resourced gross subpart F income statutory grouping in any treaty category. Accordingly, no portion of the stock of CFC1 is assigned to a treaty category under paragraph (a)(3) of this section.

(D) *Step 4*—(*1*) *General category stock.* The total portion of the value of the stock of CFC1 that is general category stock is $13,600, which is equal to $1,600 (the portion of the value of the general category stock of CFC1 that was not assigned to the section 951A category in Step 2) plus $5,667 (the value of the portion of the stock of CFC1 assigned to the specified foreign source income statutory grouping within the general category) plus $6,333 (the value of the portion of the stock of CFC1 assigned to the foreign source gross subpart F income statutory grouping within the general category).

(*2*) *Passive category stock.* The total portion of the value of the stock of CFC1 that is passive category stock is $2,667.

(*3*) *U.S source category stock.* No portion of the value of the stock of CFC1 is U.S. source category stock.

(E) *Step 5*—(*1*) *General category stock.* Under paragraph (a)(5)(ii) of this section, the value of the stock of CFC1 assigned to the section 245A subgroup of general category stock is $7,267, which is equal to $1,600 (the portion of the value of the general category stock of CFC1 that was not assigned to the section 951A category in Step 2) plus $5,667 (the value of the portion of the stock of CFC1 assigned to the specified foreign source general category income statutory grouping). Under paragraph (a)(5)(v) of this section, the remainder of the general category stock of CFC1, $6,333, is assigned to the non-section 245A subgroup of general category stock.

(*2*) *Passive category stock.* No portion of the passive category stock of CFC1 is in the foreign source gross tested income statutory grouping or the specified foreign source passive category income statutory grouping. Accordingly, under paragraph (a)(5)(iii) of this section, no portion of the value of the stock of CFC1 is assigned to the section 245A subgroup of passive category stock. Under paragraph (a)(5)(v) of this section, the passive category stock of CFC1, $2,667 is assigned to the non-section 245A subgroup of passive category stock.

(*3*) *Section 951A category stock.* Under paragraph (a)(5)(v) of this section, all of the section 951A category stock, $3,733, is assigned to the non-section 245A subgroup of section 951A category stock.

(F) *Summary.* For purpose of the allocation and apportionment of expenses, $13,600 of the stock of CFC1 is characterized as general category stock, $7,267 of which is in the section 245A subgroup and $6,333 of which is in the non-section 245A subgroup; $2,667 of the stock of CFC1 is characterized as passive category stock, all of which is in the non-section 245A subgroup; and $3,733 of the stock of CFC1 is characterized as section 951A category stock, all of which is in the non-section 245A subgroup.

(2) *Example 2: Asset method with noncontrolled 10-percent owned foreign corporation*—(i) *Facts.* The facts are the same as in paragraph (c)(1)(i) of this section, except that CFC1 does not own CFC2 and instead owns 20% of the stock of FC2, a foreign corporation that is a noncontrolled 10-percent owned foreign corporation. The tax book value of CFC1's stock in FC2 is $5,000. FC2 owns assets with the following values as determined under §§ 1.861–9(g)(2) and 1.861–9T(g)(3): Assets that generate specified foreign source general category income ($3,000). All of the assets of FC2 generate income that, if distributed to CFC1 as a dividend, would be foreign source gross subpart F income in the general category to CFC1.

(ii) *Analysis*—(A) *Step 1*—(*1*) *Characterization of FC2 stock.* All of the assets of FC2 generate income that, if distributed to CFC1, would be foreign source gross subpart F income in the general category to CFC1. Accordingly, under paragraph (a)(1)(i) of this section, all of CFC1's stock in FC2 ($5,000) is characterized as in the foreign source gross subpart F income statutory grouping within the general category.

(*2*) *Characterization of CFC1 stock.* CFC1 has total assets of $15,000, $4,000 of which are in the foreign source gross tested income statutory grouping within the general category, $6,000 of which are in the foreign source gross subpart F income statutory grouping within the general category (including the FC2 stock assigned to that statutory grouping), $3,000 of which are in the specified foreign source general category income statutory grouping, and $2,000 of which are in the foreign source gross subpart F income statutory grouping within the passive category. Accordingly, CFC1's stock is characterized as $5,333 ($4,000/$15,000 × $20,000) in the foreign source gross tested income statutory grouping within the general category, $8,000 ($6,000/$15,000 × $20,000) in the foreign source gross subpart F income statutory grouping within the general category, $4,000 ($3,000/$15,000 × $20,000) in the specified foreign source general category income statutory grouping, and $2,667 ($2,000/$15,000 × $20,000) in the foreign source gross subpart F income statutory grouping within the passive category.

(B) *Step 2.* The analysis is the same as in paragraph (c)(1)(ii)(B) of this section.

(C) *Step 3.* The analysis is the same as in paragraph (c)(1)(ii)(C) of this section.

(D) *Step 4*—(*1*) *General category stock.* The total portion of the value of the stock of CFC1 that is general category stock is $13,600, which is equal to $1,600 (the portion of the value of the general category stock of CFC1 that was not assigned to the section 951A category in Step 2) plus $4,000 (the value of the portion of the stock of CFC1 assigned to the specified foreign source income statutory grouping within the general category general category) plus $8,000 (the value of the portion of the stock of CFC1 assigned to the foreign source gross subpart F income statutory grouping within the general category).

(*2*) *Passive category stock.* The analysis is the same as in paragraph (c)(1)(ii)(D)(*2*) of this section.

(E) *Step 5*—(*1*) *General category stock.* Under paragraph (a)(5)(ii) of this section, the value of the stock of CFC1 assigned to the section 245A subgroup of general category stock is $5,600, which is equal to $1,600 (the portion of the value of the general category stock of CFC1 that was not assigned to the section 951A category in Step 2) plus $4,000 (the value of the portion of the stock of CFC1 assigned to the specified foreign source general category income statutory grouping). Under paragraph (a)(5)(v) of this section, the remainder of the general category stock of CFC1, $8,000, is assigned to the non-section 245A subgroup of general category stock.

(*2*) *Passive category stock.* The analysis is the same as in paragraph (c)(1)(ii)(E)(*2*) of this section.

(*3*) *Section 951A category stock.* The analysis is the same as in paragraph (c)(1)(ii)(E)(*3*) of this section.

(F) *Summary.* For purpose of the allocation and apportionment of expenses, $13,600 of the stock of CFC1 is characterized as general category stock, $5,600 of which is in the section 245A subgroup and $8,000 of which is in the non-section 245A subgroup; $2,667

of the stock of CFC1 is characterized as passive category stock, all of which is in the non-section 245A subgroup; and $3,733 of the stock of CFC1 is characterized as section 951A category stock, all of which is in the non-section 245A subgroup.

(3) *Example 3: Modified gross income method*—(i) *Facts*—(A) USP, a domestic corporation, directly owns all of the stock of a controlled foreign corporation, CFC1. The tax book value of CFC1's stock is $100,000. CFC1 owns all of the stock of CFC2, a controlled foreign corporation. USP uses the modified gross income method described in § 1.861–12(c)(3)(iii) to characterize the stock in CFC1. USP's inclusion percentage is 100%.

(B) CFC1 earns $1,500 of foreign source gross tested income within the general category and $500 of foreign source gross subpart F income within the passive category. CFC1 incurs $200 of interest expense.

(C) CFC2 earns $3,000 of foreign source gross tested income within the general category, $2,000 of foreign source gross subpart F income within the general category, and $1,000 of specified foreign source general category income. CFC2 incurs $3,000 of interest expense.

(ii) *Analysis*—(A) *Step 1*—(*1*) *Determination of CFC2 gross income (net of interest expense).* CFC2 has total gross income of $6,000. CFC2's $3,000 of interest expense is apportioned among the statutory groupings of gross income based on the gross income of CFC2 to determine the gross income (net of interest expense) of CFC2 in each statutory grouping. As a result, $1,500 ($3,000/$6,000 × $3,000) of interest expense is apportioned to foreign source gross tested income within the general category, $1,000 ($2,000/$6,000 × $3,000) of interest expense is apportioned to foreign source gross subpart F income within the general category, and $500 ($1,000/$6,000 × $3,000) of interest expense is apportioned to specified foreign source general category income. Accordingly, CFC2 has the following amounts of gross income (net of interest expense): $1,500 ($3,000 − $1,500) of foreign source gross tested income within the general category, $1,000 ($2,000 − $1,000) of foreign source gross subpart F income within the general category, and $500 ($1,000 − $500) of specified foreign source general category income.

(*2*) *Determination of CFC1 gross income (net of interest expense).* Before including the gross income consisting of subpart F income and tested income (net of interest expense) of CFC2, CFC1 has total gross income of $2,500, including $500 of CFC2's specified foreign source general category income which is combined with CFC1's items of gross income under § 1.861–9(j)(2)(ii). CFC1's $200 of interest expense is apportioned among the statutory groupings of gross income of CFC1 to determine the gross income (net of interest expense) of CFC1 in each statutory grouping. As a result, $120 ($1,500/$2,500 × $200) of interest expense is apportioned to foreign source gross tested income within the general category, $40 ($500/$2,500 × $200) to foreign source gross subpart F income within the passive category, and $40 ($500/$2,500 × $200) to specified foreign source general category income. Accordingly, CFC1 has the following amounts of gross income (net of interest expense) before including the gross income (net of interest expense) of CFC2: $1,380 ($1,500 − $120) of foreign source gross tested income within the general category, $460 ($500 − $40) of foreign source gross subpart F income within the passive category, and $460 ($500 − $40) of specified foreign source general category income. After including the gross income consisting of subpart F income and tested income (net of interest expense) of CFC2, CFC1 has the following amounts of gross income (net of interest expense): $2,880 ($1,380 + $1,500) of foreign source gross tested income within the general category, $1,000 of foreign source gross subpart F income within the general category, $460 of specified foreign source general category income, and $460 of foreign source gross subpart F income within the passive category.

(*3*) *Characterization of CFC1 stock.* CFC1 is considered to have a total of $4,800 of gross income (net of interest expense) for purposes of characterizing the stock of CFC1. Accordingly, CFC1's stock is characterized as $60,000 ($2,880/$4,800 × $100,000) in the foreign source gross tested income statutory grouping within the general category, $20,834 ($1,000/$4,800 × $100,000) in the foreign source gross subpart F income statutory grouping within the general category, $9,583 ($460/$4,800 × $100,000) in the specified foreign source general category income statutory grouping, and $9,583 ($460/$4,800 × $100,000) in the foreign source gross subpart F income statutory grouping within the passive category.

(B) *Step 2.* The portion of the value of the stock of CFC1 that is general category gross tested income stock is $60,000. USP's inclusion percentage is 100%. Accordingly, under paragraph (a)(2) of this section, all of the $60,000 of the stock of CFC1 is assigned to the section 951A category.

(C) *Step 3.* No portion of the stock of CFC1 is resourced gross tested income or assigned to the resourced gross subpart F income statutory group in any treaty category. Accordingly, no portion of the stock of CFC1 is assigned to a treaty category under paragraph (a)(3) of this section.

(D) *Step 4*—(*1*) *General category stock.* The total portion of the value of the stock of CFC1 that is general category stock is $30,417, which is equal to $20,834 (the value of the portion of the stock of CFC1 assigned to the subpart F income statutory grouping within the general category income statutory grouping) plus $9,583 (the value of the portion of the stock of CFC1 assigned to the specified foreign source general category income statutory grouping).

(*2*) *Passive category stock.* The total portion of the value of the stock of CFC1 that is passive category stock is $9,583.

(*3*) *U.S. source category stock.* No portion of the value of the stock of CFC1 is U.S. source category stock.

(E) *Step 5*—(*1*) *General category stock.* All of the value of the general category gross tested income stock of CFC1 was assigned to the section 951A category in Step 2. Accordingly, under paragraph (a)(5)(ii) of this section, the value of the stock of CFC1 assigned to the section 245A subgroup of general category stock is $9,583, which is equal to the value of the portion assigned to the specified foreign source general category income statutory grouping. Under paragraph (a)(5)(v) of this section, the remainder of the general category stock of CFC1, $20,834, is assigned to the non-section 245A subgroup of general category stock.

(*2*) *Passive category stock.* No portion of the passive category stock of CFC1 is in the foreign source gross tested income statutory grouping or the specified foreign source passive category income statutory grouping. Accordingly, under paragraph (a)(5)(iii) of this section, no portion of the value of the stock of CFC1 is assigned to the section 245A subgroup. Under paragraph (a)(5)(v) of this section, the passive category stock of CFC1, $9,534, is assigned to the non-section 245A subgroup of passive category stock.

(*3*) *Section 951A category stock.* Under paragraph (a)(5)(v) of this section, all of the section 951A category stock, $60,000, is assigned to the non-section 245A subgroup of section 951A category stock.

(F) *Summary.* For purposes of the allocation and apportionment of expenses, $60,000 of the stock of CFC1 is characterized as section 951A category stock, all of which is in the non-section 245A subgroup; $30,417 of the stock of CFC1 is characterized as general category stock, $9,583 of which is in the section 245A subgroup and $20,834 of which is in the non-section 245A subgroup; and $9,583 of the stock of CFC1 is characterized as passive category stock, all of which is in the non-section 245A subgroup.

(d) *Applicability dates.* This section applies for taxable years that both begin after December 31, 2017, and end on or after December 4, 2018.

§ 1.861–14 [Amended]

■ **Par. 9.** Section 1.861–14 is amended by:

■ 1. Removing the language ‘‘, except that section 936 corporations (as defined in § 1.861–11(d)(2)(ii)) are also included within the affiliated group to the extent provided in paragraph (d)(2) of this section’’ from the first sentence of paragraph (d)(1).

■ 2. Removing and reserving paragraph (d)(2).

■ **Par. 10.** Section 1.861–17 is amended by:

■ 1. Adding paragraph (e)(3).

■ 2. Removing and reserving paragraph (g).

■ 3. Adding paragraph (i).

The additions and revisions read as follows:

§ 1.861–17 Allocation and apportionment of research and experimental expenditures.

* * * * *

(e) * * *

(3) *Change of method for first taxable year beginning after December 31, 2017.* A taxpayer otherwise subject to the binding election described in paragraph

(e)(1) of this section may change its method once for its first taxable year beginning after December 31, 2017, without the prior consent of the Commissioner. The taxpayer's use of a new method constitutes a binding election to use the new method for its return filed for the first year for which the taxpayer uses the new method and for four taxable years thereafter.

* * * * *

(g) [Reserved]

* * * * *

(i) *Applicability date.* This section applies to taxable years that both begin after December 31, 2017, and end on or after December 4, 2018.

■ **Par. 11.** Section 1.901(j)–1 is added to read as follows:

§ 1.901(j)–1 Denial of foreign tax credit with respect to certain foreign countries.

(a) *Sourcing rule for related party payments and inclusions.* Any income paid or accrued through one or more entities is treated as income from sources within a country described in section 901(j)(2) if the income was, without regard to such entities, from sources within that country.

(b) *Applicability date.* This section applies to taxable years that end on or after December 4, 2018.

■ **Par. 12.** § 1.904–1 is revised to read as follows:

§ 1.904–1 Limitation on credit for foreign taxes.

(a) *In general.* For each separate category described in § 1.904–5(a)(4)(v), the total credit for taxes paid or accrued (including those deemed to have been paid or accrued other than by reason of section 904(c)) shall not exceed that proportion of the tax against which such credit is taken which the taxpayer's taxable income from foreign sources (but not in excess of the taxpayer's entire taxable income) in such separate category bears to his entire taxable income for the same taxable year.

(b) *Special computation of taxable income.* For purposes of computing the limitation under paragraph (a) of this section, the taxable income in the case of an individual, estate, or trust is computed without any deduction for personal exemptions under section 151 or 642(b).

(c) *Joint return.* In the case of spouses making a joint return, the applicable limitation prescribed by section 904(a) on the credit for taxes paid or accrued to foreign countries and possessions of the United States is applied with respect to the aggregate taxable income in each separate category from sources without the United States, and the aggregate taxable income from all sources, of the spouses.

(d) *Consolidated group.* For rules relating to the computation of the foreign tax credit limitation for a consolidated group, see § 1.1502–4.

(e) *Applicability dates.* This section applies to taxable years that both begin after December 31, 2017, and end on or after December 4, 2018.

■ **Par. 13.** Section 1.904–2 is amended by:

■ 1. Revising paragraphs (a) through (d).

■ 2. Removing the language ''904(d)'' and adding the language ''904(c)'' in its place in paragraph (e).

■ 3. Removing and reserving paragraph (g).

■ 4. Revising paragraphs (h) and (i).

■ 5. Adding paragraphs (j) and (k).

The revisions and additions read as follows:

§ 1.904–2 Carryback and carryover of unused foreign tax.

(a) *Credit for foreign tax carryback or carryover.* A taxpayer who chooses to claim a credit under section 901 for a taxable year is allowed a credit under that section not only for taxes otherwise allowable as a credit but also for taxes deemed paid or accrued in that year as a result of a carryback or carryover of an unused foreign tax under section 904(c). However, the taxes so deemed paid or accrued are not allowed as a deduction under section 164(a). Foreign tax paid or accrued with respect to section 951A category income, including section 951A category income that is reassigned to a separate category for income resourced under a treaty, may not be carried back or carried forward or deemed paid or accrued under section 904(c). For special rules regarding these computations in case of taxes paid, accrued, or deemed paid with respect to foreign oil and gas extraction income or foreign oil related income, see section 907(f) and the regulations under that section.

(b) *Years to which foreign taxes are carried.* If the taxpayer chooses the benefits of section 901 for a taxable year, any unused foreign tax paid or accrued in that year is carried first to the immediately preceding taxable year and then, as applicable, to each of the ten succeeding taxable years, in chronological order, but only to the extent not absorbed as taxes deemed paid or accrued under paragraph (d) of this section in a prior taxable year.

(c) *Definitions.* This paragraph (c) provides definitions that apply for purposes of this section.

(1) *Unused foreign tax.* The term *unused foreign tax* means, with respect to each separate category for any taxable year, the excess of the amount of creditable foreign tax paid or accrued, or deemed paid under section 902 (as in effect on December 21, 2017) or section 960, in such year, over the applicable foreign tax credit limitation under section 904 for the separate category in such year. Unused foreign tax does not include any amount for which a credit is disallowed, including foreign income taxes for which a credit is disallowed or reduced when the tax is paid, accrued, or deemed paid.

(2) *Separate category.* The term *separate category* has the same meaning as provided in § 1.904–5(a)(4)(v).

(3) *Excess limitation*—(i) *In general.* The term *excess limitation* means, with respect to a separate category for any taxable year (the *excess limitation year*) and an unused foreign tax carried from another taxable year (the *excess credit year*), the amount (if any) by which the limitation for that separate category with respect to that excess limitation year exceeds the sum of—

(A) The creditable foreign tax actually paid or accrued or deemed paid under section 902 (as in effect on December 21, 2017) or section 960 with respect to the separate category in the excess limitation year, and

(B) The portion of any unused foreign tax for a taxable year preceding the excess credit year that is absorbed as taxes deemed paid or accrued in the excess limitation year under paragraph (a) of this section.

(ii) *Deduction years.* Excess limitation for a taxable year absorbs unused foreign tax, regardless of whether the taxpayer chooses to claim a credit under section 901 for the year. In such case, the amount of the excess limitation, if any, for the year is determined in the same manner as though the taxpayer had chosen to claim a credit under section 901 for that year. For purposes of this determination, if the taxpayer has an overall foreign loss account, the excess limitation in a deduction year is determined based on the amount of the overall foreign loss the taxpayer would have recaptured if the taxpayer had chosen to claim a credit under section 901 for that year and had not made an election under § 1.904(f)–2(c)(2) to recapture more of the overall foreign loss account than is required under § 1.904(f)–2(c)(1).

(d) *Taxes deemed paid or accrued*—(1) *Amount deemed paid or accrued.* The amount of unused foreign tax with respect to a separate category that is deemed paid or accrued in any taxable year to which such unused foreign tax may be carried under paragraph (b) of this section is equal to the smaller of—

(i) The portion of the unused foreign tax that may be carried to the taxable year under paragraph (b) of this section, or

(ii) The amount, if any, of the excess limitation for such taxable year with respect to such unused foreign tax.

(2) *Carryback or carryover tax deemed paid or accrued in the same separate category.* Any unused foreign tax, which is deemed to be paid or accrued under section 904(c) in the year to which it is carried, is deemed to be paid or accrued with respect to the same separate category as the category to which it was assigned in the year in which it was actually paid or accrued. However, see paragraphs (h) through (j) of this section for transition rules in the case of certain carrybacks and carryovers.

(3) *No duplicate disallowance of creditable foreign tax.* Foreign income taxes for which a credit is partially disallowed, including when the tax is paid, accrued, or deemed paid, are not reduced again by reason of the unused foreign tax being deemed to be paid or accrued in the year to which it is carried under section 904(c).

* * * * *

(g) [Reserved]

(h) *Transition rules for carryovers of pre-2003 unused foreign tax and carrybacks of post-2002 unused foreign tax paid or accrued with respect to dividends from noncontrolled section 902 corporations.* For transition rules for carryovers of pre-2003 unused foreign tax, and carrybacks of post-2002 unused foreign tax, paid or accrued with respect to dividends from noncontrolled section 902 corporations, see 26 CFR 1.904–2(h) (revised as of April 1, 2018).

(i) *Transition rules for carryovers of pre-2007 unused foreign tax and carrybacks of post-2006 unused foreign tax.* For transition rules for carryovers of pre-2007 unused foreign tax, and carrybacks of post-2006 unused foreign tax, see 26 CFR 1.904–2(i) (revised as of April 1, 2018).

(j) *Transition rules for carryovers and carrybacks of pre-2018 and post-2017 unused foreign tax*—(1) *Carryover of unused foreign tax*—(i) *In general.* For purposes of this paragraph (j), the terms *post-2017 separate category, pre-2018 separate category,* and *specified separate category* have the meanings set forth in § 1.904(f)–12(j)(1). The rules of this paragraph (j)(1) apply to reallocate to the taxpayer's post-2017 separate categories for foreign branch category income, general category income, passive category income, and specified separate categories of income, any unused foreign taxes (as defined in paragraph (c)(1) of this section) that were paid or accrued or deemed paid under sections 902 and 960 with respect to income in a pre-2018 separate category.

(ii) *Allocation to the same separate category.* Except as provided in paragraph (j)(1)(iii) of this section, to the extent any unused foreign taxes paid or accrued or deemed paid with respect to a separate category of income are carried forward to a taxable year beginning after December 31, 2017, such taxes are allocated to the same post-2017 separate category as the pre-2018 separate category from which the unused foreign taxes are carried.

(iii) *Exception for certain general category unused foreign taxes*—(A) *In general.* To the extent any unused foreign taxes paid or accrued (but not taxes deemed paid) with respect to general category income are carried forward to a taxable year beginning after December 31, 2017, a taxpayer may choose to allocate those taxes to the taxpayer's post-2017 separate category for foreign branch category income to the extent those taxes would have been allocated to the taxpayer's post-2017 separate category for foreign branch category income if the taxes were paid or accrued in a taxable year beginning after December 31, 2017. Any remaining unused foreign taxes paid or accrued or deemed paid with respect to general category income carried forward to a taxable year beginning after December 31, 2017, are allocated to the taxpayer's post-2017 separate category for general category income.

(B) *Rules regarding the exception.* A taxpayer applying the exception described in paragraph (j)(1)(iii)(A) of this section (the *branch carryover exception*) must apply the exception to all of its unused foreign taxes paid or accrued with respect to general category income that are carried forward to all taxable years beginning after December 31, 2017. A taxpayer may choose to apply the branch carryover exception on a timely filed original return (including extensions) or an amended return. A taxpayer that applies the exception on an amended return must make appropriate adjustments to eliminate any double benefit arising from application of the exception to years that are not open for assessment.

(2) *Carryback of unused foreign tax*—(i) *In general.* The rules of this paragraph (j)(2) apply to any unused foreign taxes that were paid or accrued, or deemed paid under section 960, with respect to income in a post-2017 separate category.

(ii) *Passive category income and specified separate categories of income described in § 1.904–4(m).* Any unused foreign taxes paid or accrued or deemed paid with respect to passive category income or a specified separate category of income in a taxable year beginning after December 31, 2017, that are carried back to a taxable year beginning before January 1, 2018, are allocated to the same pre-2018 separate category as the post-2017 separate category from which the unused foreign taxes are carried.

(iii) *General category income and foreign branch category income.* Any unused foreign taxes paid or accrued or deemed paid with respect to general category income or foreign branch category income in a taxable year beginning after December 31, 2017, that are carried back to a taxable year beginning before January 1, 2018, are allocated to the taxpayer's pre-2018 separate category for general category income.

(k) *Applicability date.* Paragraphs (a) through (i) of this section apply to taxable years that both begin after December 31, 2017, and end on or after December 4, 2018. Paragraph (j) of this section applies to taxable years beginning after December 31, 2017. Paragraph (j)(2) of this section also applies to the last taxable year beginning before January 1, 2018.

■ **Par. 14.** Section 1.904–3 is amended by:

■ 1. Revising the section heading.

■ 2. Removing the language ''a husband and wife'' and adding the language ''spouses'' in its place in paragraphs (a), (b), (c), and (d).

■ 3. Adding a sentence to the end of paragraph (a).

■ 4. Removing the second and third sentences in paragraph (d).

■ 5. Revising paragraph (e).

■ 6. Revising paragraphs (f)(1) through (f)(3).

■ 7. Removing the language ''904(d)'' and adding the language ''904(c)'' in its place in paragraphs (f)(5)(i) and (ii).

■ 8. Removing paragraph (f)(6).

■ 9. Removing and reserving paragraph (g).

■ 10. Adding paragraph (h).

The additions and revisions read as follows:

§ 1.904–3 Carryback and carryover of unused foreign tax by spouses making a joint return.

(a) * * * The rules in this section apply separately with respect to each separate category as defined in § 1.904–5(a)(4)(v).

* * * * *

(e) *Amounts carried from or through a joint return year to or through a separate return year*—(1) *In general.* It is necessary to allocate to each spouse the spouse's share of an unused foreign tax

or excess limitation for any taxable year for which the spouses filed a joint return if—

(i) The spouses file separate returns for the current taxable year and an unused foreign tax is carried thereto from a taxable year for which they filed a joint return;

(ii) The spouses file separate returns for the current taxable year and an unused foreign tax is carried to such taxable year from a year for which they filed separate returns but is first carried through a year for which they filed a joint return; or

(iii) The spouses file a joint return for the current taxable year and an unused foreign tax is carried from a taxable year for which they filed joint returns but is first carried through a year for which they filed separate returns.

(2) *Computation and adjustments.* In the cases described in paragraph (e)(1) of this section, the separate carryback or carryover of each spouse to the current taxable year shall be computed in the manner described in § 1.904–2 but with the modifications set forth in paragraph (f) of this section. Where applicable, appropriate adjustments are made to take into account the fact that, for any taxable year involved in the computation of the carryback or the carryover, either spouse has combined foreign oil and gas income described in section 907(b) with respect to which the limitation in section 907(a) applies.

(f) * * * (1) *Separate category limitation.* The limitation in a separate category of a particular spouse for a taxable year for which a joint return is made shall be the portion of the limitation on the joint return which bears the same ratio to such limitation as such spouse's foreign source taxable income (with gross income and deductions taken into account to the same extent as taken into account on the joint return) in such separate category (but not in excess of the joint foreign source taxable income) bears to the joint foreign source taxable income in such separate category.

(2) *Unused foreign tax.* For purposes of this section, the term *unused foreign tax* means, with respect to a particular spouse and separate category for a taxable year for which a joint return is made, the excess of the foreign tax paid or accrued by that spouse with respect to that separate category over that spouse's separate category limitation.

(3) *Excess limitation.* For purposes of this section, the term *excess limitation* means, with respect to a particular spouse and separate category for a taxable year for which a joint return is made, the excess of that spouse's separate category limitation over the foreign taxes paid or accrued by such spouse with respect to such separate category for such taxable year.

* * * * *

(g) [Reserved]

(h) *Applicability date.* This section is applicable for taxable years that both begin after December 31, 2017, and end on or after December 4, 2018.

■ **Par. 15.** § 1.904–4 is amended by:

■ 1. Revising paragraph (a).

■ 2. Removing the language ''1248; or'' from paragraph (b)(2)(i)(A) and adding the language ''1248;'' in its place.

■ 3. Removing the language ''1293.'' from paragraph (b)(2)(i)(B) and adding the language ''1293;'' in its place.

■ 4. Adding paragraphs (b)(2)(i)(C) and (D).

■ 5. Revising the first and second sentences of paragraph (b)(2)(ii).

■ 6. Removing the language ''shall not be'' from the first sentence of paragraph (c)(1) and adding the language ''is not'' in its place.

■ 7. Revising the second, third, and fourth sentences of paragraph (c)(1).

■ 8. Removing the last sentence of paragraph (c)(1).

■ 9. Revising the second, third, and fourth sentences, and adding a new sentence after the fourth sentence, of paragraph (c)(3).

■ 10. Revising paragraph (c)(4).

■ 11. Revising paragraph (c)(5)(ii).

■ 12. Removing the second and third sentences of paragraphs (c)(5)(iii)(A) and (B).

■ 13. Revising the first sentence of paragraph (c)(6)(i).

■ 14. Removing the language ''deemed paid or accrued'' and adding the language ''deemed paid'' in its place in the second sentence in paragraph (c)(6)(i).

■ 15. Removing the word ''taxable'' from the last sentence of paragraph (c)(6)(i).

■ 16. Revising the first, fourth, fifth, and sixth sentences of paragraph (c)(6)(iii).

■ 17. Removing the word ''taxable'' in the second sentence of paragraph (c)(6)(iii).

■ 18. Removing the language ''deemed paid or accrued'' and adding the language ''deemed paid'' in its place in the third sentence of paragraph (c)(6)(iii).

■ 19. Revising paragraph (c)(6)(iv).

■ 20. Revising the second sentence and the sixth sentence of paragraph (c)(7)(i).

■ 21. Removing the language ''general category income'' and adding the language ''income in another separate category'' in its place in the third sentence of paragraph (c)(7)(iii).

■ 22. Adding paragraph (d) and revising paragraph (e)(1).

■ 23. Removing and reserving paragraph (e)(2)(i)(W).

■ 24. Removing the last sentence of paragraph (e)(3)(ii).

■ 25. Removing paragraph (e)(5).

■ 26. Adding paragraphs (f) and (g).

■ 27. Revising paragraphs (h)(2), (h)(5)(i), (h)(5)(ii), and paragraphs (k) through (n).

■ 28. Adding paragraphs (o), (p), and (q).

The revisions and additions read as follows:

§ 1.904–4 Separate application of section 904 with respect to certain categories of income.

(a) *In general.* A taxpayer is required to compute a separate foreign tax credit limitation for income received or accrued in a taxable year that is described in section 904(d)(1)(A) (section 951A category income), 904(d)(1)(B) (foreign branch category income), 904(d)(1)(C) (passive category income), 904(d)(1)(D) (general category income), or paragraph (m) of this section (specified separate categories). For purposes of this section, the definitions in § 1.904–5(a)(4) apply.

(b) * * *

(2) * * *

(i) * * *

(C) Distributive shares of partnership income treated as passive category income under paragraph (n)(1) of this section, and income from the sale of a partnership interest treated as passive category income under paragraph (n)(2) of this section; or

(D) Income treated as passive category income under the look-through rules in § 1.904–5.

(ii) *Exceptions.* Passive income does not include any export financing interest (as defined in paragraph (h) of this section), any high-taxed income (as defined in paragraph (c) of this section), financial services income (as defined in paragraph (e)(1)(ii) of this section), or any active rents and royalties (as defined in paragraph (b)(2)(iii) of this section). In addition, passive income does not include any income that would otherwise be passive but is excluded from passive category income under § 1.904–5(b)(1). * * *

* * * * *

(c) * * * (1) * * * Income is considered to be high-taxed income if, after allocating expenses, losses, and other deductions of the United States person to that income under paragraph (c)(2) of this section, the sum of the foreign income taxes paid or accrued, and deemed paid under section 960, by the United States person with respect to such income (reduced by any portion of such taxes for which a credit is not

allowed) exceeds the highest rate of tax specified in section 1 or 11, whichever applies (and with reference to section 15 if applicable), multiplied by the amount of such income (including the amount treated as a dividend under section 78). If, after application of this paragraph (c), income that would otherwise be passive income is determined to be high-taxed income, the income is treated as general category income, foreign branch category income, section 951A category income, or income in a specified separate category, as determined under the rules of this section, and any taxes imposed on that income are considered related to the same separate category of income under § 1.904–6. If, after application of this paragraph (c), passive income is zero or less than zero, any taxes imposed on the passive income are considered related to the same separate category of income to which the passive income (if not reduced to zero or less than zero) would have been assigned had the income been treated as high-taxed income (general category, foreign branch category, section 951A category, or a specified separate category). * * *

* * * * *

(3) * * * Paragraph (c)(4) of this section provides additional rules for inclusions under section 951(a)(1) or 951A(a) that are passive income, dividends from a controlled foreign corporation or noncontrolled 10-percent owned foreign corporation that are passive income, and income that is received or accrued by a United States person through a foreign QBU that is passive income. For purposes of this paragraph (c), a foreign QBU is a qualified business unit (as defined in section 989(a)), other than a controlled foreign corporation or noncontrolled 10-percent owned foreign corporation, that has its principal place of business outside the United States. These rules apply whether the income is received from a controlled foreign corporation of which the United States person is a United States shareholder, from a noncontrolled 10-percent owned foreign corporation of which the United States person is a United States shareholder that is a domestic corporation, or from any other person. In applying these rules, passive income is not treated as subject to a withholding tax or other foreign tax for which a credit is disallowed in full, for example, under section 901(k). * * *

(4) *Dividends and inclusions from controlled foreign corporations, dividends from noncontrolled 10-percent owned foreign corporations, and income attributable to foreign QBUs.* Except as provided in paragraph (c)(5) of this section, the rules of this paragraph (c)(4) apply to all dividends and all amounts included in gross income of a United States shareholder under section 951(a)(1) or 951A(a) with respect to the foreign corporation that (after application of the look-through rules of section 904(d)(3) and § 1.904–5) are attributable to passive income received or accrued by a controlled foreign corporation, all dividends from a noncontrolled 10-percent owned foreign corporation that are received or accrued by a United States shareholder that (after application of the look-through rules of section 904(d)(4) and § 1.904–5) are treated as passive income, and all amounts of passive income received or accrued by a United States person through a foreign QBU. The grouping rules of paragraph (c)(3)(i) through (iv) of this section apply separately to dividends, to inclusions under section 951(a)(1) and to inclusions under section 951A(a) with respect to each controlled foreign corporation of which the taxpayer is a United States shareholder, and to dividends with respect to each noncontrolled 10-percent owned foreign corporation of which the taxpayer is a United States shareholder that is a domestic corporation. The grouping rules of paragraph (c)(3)(i) through (iv) of this section also apply separately to income attributable to each foreign QBU of a controlled foreign corporation, noncontrolled 10-percent owned foreign corporation, any other look-through entity as defined in § 1.904–5(i), or any United States person.

(5) * * *

(ii) *Treatment of partnership income.* A partner's distributive share of income from a foreign or United States partnership that is treated as passive income under paragraph (n)(1)(ii) of this section (generally providing that a less than 10 percent partner's distributive share of partnership income is passive income) is treated as a single item of income and is not grouped with other amounts. A distributive share of income from a partnership that is treated as passive income under paragraph (n)(1)(i) of this section is grouped according to the rules in paragraph (c)(3) of this section, except that the portion, if any, of the distributive share of income attributable to income earned by a United States partnership through a foreign QBU is separately grouped under the rules of paragraph (c)(4) of this section.

* * * * *

(6) * * * (i) * * * The determination of whether an amount included in gross income under section 951(a)(1) or 951A(a) is high-taxed income is made in the taxable year the income is included in the gross income of the United States shareholder under section 951(a) or 951A(a) (for purposes of this paragraph (c), the *year of inclusion*). * * *

* * * * *

(iii) * * * If an item of income is considered high-taxed income in the year of inclusion and paragraph (c)(6)(i) of this section applies, then any increase in foreign income taxes imposed with respect to that item are considered to be related to the same separate category to which the income was assigned in the taxable year of inclusion. * * * The taxpayer shall treat any taxes paid or accrued, or deemed paid, on the distribution in excess of this amount as taxes related to the same category of income to which such inclusion would have been assigned had the income been treated as high-taxed income in the year of inclusion (general category income, section 951A category income, or income in a specified separate category). If these additional taxes are not creditable in the year of distribution, the carryover rules of section 904(c) apply (see section 904(c) and § 1.904–2(a) for rules disallowing carryovers in the section 951A category). For purposes of this paragraph (c)(6), the foreign tax on an inclusion under section 951(a)(1) or 951A(a) is considered increased on distribution of the earnings and profits associated with that inclusion if the total of taxes paid and deemed paid on the inclusion and the distribution (taking into account any reductions in tax and any withholding taxes) exceeds the total taxes deemed paid in the year of inclusion. * * *

(iv) *Increase in taxes paid by successors.* If passive earnings and profits previously included in income of a United States shareholder are distributed to a person that was not a United States shareholder of the distributing corporation in the year the earnings were included, any increase in foreign taxes paid or accrued, or deemed paid, on that distribution is treated as tax related to general category income (or income in a specified separate category, if applicable) in the case of earnings and profits previously included under section 951(a)(1), and is treated as tax related to section 951A category income (or income in a specified separate category, if applicable) in the case of earnings and profits previously included under section 951A(a), regardless of whether the previously-taxed income was considered high-taxed income under

section 904(d)(2)(F) in the year of inclusion.

(7) * * * (i) * * * If the inclusion is considered to be high-taxed income, then the taxpayer shall treat the inclusion as general category income, section 951A category income or income in a specified separate category as provided in paragraph (c)(1) of this section. * * * For this purpose, the foreign tax on an inclusion under section 951(a)(1) or 951A(a) shall be considered reduced on distribution of the earnings and profits associated with the inclusion if the total taxes paid and deemed paid on the inclusion and the distribution (taking into account any reductions in tax and any withholding taxes) is less than the total taxes deemed paid in the year of inclusion. * * *

* * * * *

(d) *General category income.* The term *general category income* means all income other than passive category income, foreign branch category income, section 951A category income, and income in a specified separate category. Any item that is excluded from the passive category under section 904(d)(2)(B)(iii) or § 1.904–5(b)(1) is included in general category income only to the extent that such item does not meet the definition of another separate category. General category income also includes income treated as general category income under the look-through rules referenced in § 1.904–5(a)(2).

(e) * * * (1) *In general*—(i) *Treatment of financial services income.* Financial services income that meets the definition of foreign branch category income is treated as income in that category. Financial services income of a controlled foreign corporation that is included in gross income of a United States shareholder under section 951A(a) is treated as section 951A category income in the hands of the United States shareholder. Financial services income that is neither treated as foreign branch category income nor treated as section 951A category income is treated as general category income.

(ii) *Definition of financial services income.* The term *financial services income* means income derived by a financial services entity, as defined in paragraph (e)(3) of this section, that is:

(A) Income derived in the active conduct of a banking, insurance, financing, or similar business (active financing income as defined in paragraph (e)(2) of this section);

(B) Passive income as defined in section 904(d)(2)(B) and paragraph (b) of this section as determined before the application of the exception for high-taxed income but after the application of the exception for export financing interest; or

(C) Incidental income as defined in paragraph (e)(4) of this section.

(2) * * *

(i) * * *

(W) [Reserved]

* * * * *

(f) *Foreign branch category income*—(1) *Foreign branch category income*—(i) *In general.* Except as provided in paragraph (f)(1)(ii) of this section, the term *foreign branch category income* means income of a United States person, other than a pass-through entity, that is—

(A) Income attributable to foreign branches of the United States person held directly or indirectly through disregarded entities;

(B) A distributive share of partnership income that is attributable to foreign branches held by the partnership directly or indirectly through disregarded entities, or held indirectly by the partnership through another partnership or other pass-through entity that holds the foreign branch directly or indirectly through disregarded entities; and

(C) Income from other pass-through entities determined under principles similar to those described in paragraph (f)(1)(i)(B) of this section.

(ii) *Passive category income excluded from foreign branch category income.* Income assigned to the passive category under paragraph (b) of this section is not foreign branch category income, regardless of whether the income is described in paragraph (f)(1)(i) of this section. Income that is treated as passive category income under the look-through rules in § 1.904–5 is also excluded from foreign branch category income, regardless of whether the income is attributable to a foreign branch. However, income that would be passive category income but for the application of section 904(d)(2)(B)(iii) (export financing interest and high-taxed income) or 904(d)(2)(C) (financial services income) and the regulations under those sections and also meets the definition of foreign branch category income is foreign branch category income.

(2) *Gross income attributable to a foreign branch*—(i) *In general.* Except as provided in this paragraph (f)(2), gross income is attributable to a foreign branch to the extent the gross income (as adjusted to conform to Federal income tax principles) is reflected on the separate set of books and records (as defined in § 1.989(a)–1(d)(1) and (2)) of the foreign branch. Gross income that is not attributable to the foreign branch and is therefore attributable to the foreign branch owner is treated as income in a separate category (other than the foreign branch category) under the other rules of this section.

(ii) *Income attributable to U.S. activities.* Gross income attributable to a foreign branch does not include items arising from activities carried out in the United States, regardless of whether the items are reflected on the foreign branch's separate books and records.

(iii) *Income arising from stock*—(A) *In general.* Except as provided in paragraph (f)(2)(iii)(B) of this section, gross income attributable to a foreign branch does not include items of income arising from stock of a corporation (whether foreign or domestic), including gain from the disposition of such stock or any inclusion under sections 951(a), 951A(a), or 1293(a).

(B) *Exception for dealer property.* Paragraph (f)(2)(iii)(A) of this section does not apply to gain recognized from dispositions of stock in a corporation, if the stock would be dealer property (as defined in § 1.954–2(a)(4)(v)) if the foreign branch were a controlled foreign corporation.

(iv) *Disposition of interests in certain entities*—(A) *In general.* Except as provided in paragraph (f)(2)(iv)(B) of this section, gross income attributable to a foreign branch does not include gain from the disposition of an interest in a partnership or other pass-through entity or an interest in a disregarded entity. See also paragraph (n)(2) of this section for general rules relating to the sale of a partnership interest.

(B) *Exception for sales by a foreign branch in the ordinary course of business.* The rule in paragraph (f)(2)(iv)(A) of this section does not apply to gain from the sale or exchange of an interest in a partnership or other pass-through entity or an interest in a disregarded entity if the gain is reflected on the books and records of a foreign branch and the interest is held by the foreign branch in the ordinary course of its active trade or business. An interest is considered to be held in the ordinary course of the foreign branch's active trade or business if the foreign branch engages in the same or a related trade or business as the partnership or other pass-through entity (other than through a less than 10 percent interest) or disregarded entity.

(v) *Adjustments to items of gross income reflected on the books and records.* If a principal purpose of recording or failing to record an item of gross income on the books and records of a foreign branch, or of making a

disregarded payment described in paragraph (f)(2)(vi) of this section, is the avoidance of Federal income tax, the purposes of section 904, or the purposes of section 250 (in connection with section 250(b)(3)(A)(i)(VI)), the item must be attributed to one or more foreign branches or the foreign branch owner in a manner that reflects the substance of the transaction. For purposes of this paragraph (f)(2)(v), interest received by a foreign branch from a related person is presumed to be attributable to the foreign branch owner (and not to the foreign branch) unless the interest income meets the definition of financial services income under paragraph (e)(1)(ii) of this section. For purposes of this paragraph (f)(2)(v), a related person is any person that bears a relationship to the foreign branch owner described in section 267(b) or 707.

(vi) *Attribution of gross income to which disregarded payments are allocable*—(A) *In general.* If a foreign branch makes a disregarded payment to its foreign branch owner and the disregarded payment is allocable to non-passive category gross income of the foreign branch reflected on the foreign branch's separate set of books and records under paragraph (f)(2)(i) of this section, the gross income attributable to the foreign branch is adjusted downward to reflect the allocable amount of the disregarded payment, and the general category gross income attributable to the foreign branch owner is adjusted upward by the same amount, translated (if necessary) from the foreign branch's functional currency to U.S. dollars at the spot rate, as defined in § 1.988–1(d), on the date of the disregarded payment. Similarly, if a foreign branch owner makes a disregarded payment to its foreign branch and the disregarded payment is allocable to general category gross income of the foreign branch owner that was not reflected on the separate set of books and records of any foreign branch of the foreign branch owner, the gross income attributable to the foreign branch owner is adjusted downward to reflect the allocable amount of the disregarded payment, and the gross income attributable to the foreign branch is adjusted upward by the same amount, translated (if necessary) from U.S. dollars to the foreign branch's functional currency at the spot rate, as defined in § 1.988–1(d), on the date of the disregarded payment. An adjustment to the attribution of gross income under this paragraph (f)(2)(vi) does not change the total amount, character, or source of the United States person's gross income. Similar rules apply in the case of disregarded payments between a foreign branch and another foreign branch with the same foreign branch owner.

(B) *Allocation of disregarded payments*—(*1*) *In general.* Whether a disregarded payment is allocable to gross income of a foreign branch or its foreign branch owner, and the source and separate category of the gross income to which the disregarded payment is allocable, is determined under the following rules:

(*i*) Disregarded payments from a foreign branch owner to its foreign branch are allocable to gross income attributable to the foreign branch owner to the extent a deduction for that payment, if regarded, would be allocated and apportioned to general category gross income of the foreign branch owner under the principles of §§ 1.861–8 through 1.861–14T and 1.861–17 by treating foreign source general category gross income and U.S. source general category gross income each as a statutory grouping; and

(*ii*) Disregarded payments from a foreign branch to its foreign branch owner are allocable to gross income attributable to the foreign branch to the extent a deduction for that payment, if regarded, would be allocated and apportioned to gross income of the foreign branch under the principles of §§ 1.861–8 through 1.861–14T and 1.861–17 by treating foreign source gross income in the foreign branch category and U.S. source gross income in the foreign branch category each as a statutory grouping.

(*2*) *Disregarded sales of property.* The principles of paragraph (f)(2)(vi)(B)(*1*)(*i*) and (*ii*) of this section apply in the case of disregarded payments in consideration for the transfer of property between a foreign branch and its foreign branch owner to the extent the disregarded payment, if regarded, would, for purposes of determining gross income, be subtracted from gross receipts that are regarded for Federal income tax purposes.

(*3*) *Conditions and timing of reallocation.* The gross income attributable to the foreign branch is adjusted only in the taxable year, and only to the extent, that a disregarded payment, if regarded, would be allowed as a deduction or otherwise would be taken into account (for example, as an increase to cost of goods sold).

(C) *Exclusion of certain disregarded payments.* Paragraph (f)(2)(vi)(A) of this section does not apply to the following payments, accruals, or other transfers between a foreign branch and its foreign branch owner that are disregarded for Federal income tax purposes:

(*1*) Interest and interest equivalents that, if regarded, would be described in § 1.861–9T(b);

(*2*) Remittances from the foreign branch to its foreign branch owner, except as provided in paragraph (f)(2)(vi)(D) of this section; or

(*3*) Contributions of money, securities, and other property from the foreign branch owner to its foreign branch, except as set forth in paragraph (f)(2)(vi)(D) of this section.

(D) *Certain transfers of intangible property.* For purposes of applying this paragraph (f)(2)(vi), the amount of gross income attributable to a foreign branch (and the amount of gross income attributable to its foreign branch owner) that is not passive category income must be adjusted under the principles of paragraph (f)(2)(vi)(B) of this section to reflect all transactions that are disregarded for Federal income tax purposes in which property described in section 367(d)(4) is transferred to or from a foreign branch, whether or not a disregarded payment is made in connection with the transfer. In determining the amount of gross income that is attributable to a foreign branch that must be adjusted by reason of this paragraph (f)(2)(vi)(D), the principles of sections 367(d) and 482 apply. For example, if a foreign branch owner transfers property described in section 367(d)(4), the principles of section 367(d) are applied by treating the foreign branch as a separate corporation to which the property is transferred in exchange for stock of the corporation in a transaction described in section 351.

(E) *Amount of disregarded payments.* The amount of each disregarded payment used to make an adjustment under this paragraph (f)(2)(vi) (or the absence of any adjustment) must be determined in a manner that results in the attribution of the proper amount of gross income to each of a foreign branch and its foreign branch owner under the principles of section 482, applied as if the foreign branch were a corporation.

(F) *Ordering rules.* For purposes of applying this paragraph (f)(2)(vi), adjustments related to disregarded payments from a foreign branch to its foreign branch owner are computed first, followed by adjustments related to disregarded payments from a foreign branch owner to its foreign branch.

(3) *Definitions.* The following definitions apply for purposes of this paragraph (f).

(i) *Disregarded entity.* The term *disregarded entity* means an entity described in § 301.7701–2(c)(2) of this chapter that is disregarded as an entity

separate from its owner for Federal income tax purposes.

(ii) *Disregarded payment.* The term *disregarded payment* means any amount described in paragraph (f)(3)(ii)(A) or (B) of this section.

(A) *Payments to or from a disregarded entity.* An amount described in this paragraph (f)(3)(ii)(A) is an amount that is paid to or by a disregarded entity in connection with a transaction that is disregarded for Federal income tax purposes and that is reflected on the separate set of books and records of a foreign branch.

(B) *Other disregarded amounts.* An amount described in this paragraph (f)(3)(ii)(B) is any amount reflected on the separate set of books and records of a foreign branch that would constitute an item of income, gain, deduction, or loss (other than an amount described in paragraph (f)(3)(ii)(A) of this section) if the transaction to which the amount is attributable were regarded for Federal income tax purposes.

(iii) *Foreign branch*—(A) *In general.* The term *foreign branch* means a qualified business unit (QBU), as defined in § 1.989(a)–1(b)(2)(ii) and (b)(3), that conducts a trade or business outside the United States. For an illustration of the principles of this paragraph (f)(3)(iii), see paragraph (f)(4)(i) *Example 1* of this section.

(B) *Trade or business outside the United States.* Activities carried out in the United States, whether or not such activities are described in § 1.989(a)–1(b)(3), do not constitute the conduct of a trade or business outside the United States. Activities carried out outside the United States that constitute a permanent establishment under the terms of an income tax treaty between the United States and the country in which the activities are carried out are presumed to constitute a trade or business conducted outside the United States for purposes of this paragraph (f)(3)(iii)(B). In determining whether activities constitute a trade or business under § 1.989(a)–1(c), disregarded payments are taken into account and may give rise to a trade or business, provided that the activities (together with any other activities of the QBU) would otherwise satisfy the rule in § 1.989(a)–1(c).

(C) *Activities of a partnership, estate, or trust*—(*1*) *Treatment as a foreign branch.* For purposes of this paragraph (f)(3)(iii), the activities of a partnership, estate, or trust that conducts a trade or business that satisfies the requirements of § 1.989(a)–1(b)(2)(ii)(A) (as modified by paragraph (f)(3)(iii)(B) of this section) are—

(*i*) Deemed to satisfy the requirements of § 1.989(a)–1(b)(2)(ii)(B); and

(*ii*) Comprise a foreign branch.

(*2*) *Separate set of books and records.* A foreign branch described in this paragraph (f)(3)(iii)(C) is treated as maintaining a separate set of books and records with respect to the activities described in paragraph (f)(3)(iii)(C)(*1*) of this section, and must determine, as the context requires, the items of gross income, disregarded payments, and any other items that would be reflected on those books and records in applying this paragraph (f) with respect to the foreign branch.

(iv) *Foreign branch owner.* The term *foreign branch owner* means, with respect to a foreign branch, the person (including a foreign or domestic partnership or other pass-through entity) that owns the foreign branch, either directly or indirectly through one or more disregarded entities. For this purpose, the foreign branch owner does not include the foreign branch or another foreign branch of the person that owns the foreign branch.

(v) *Remittance.* The term *remittance* means a transfer of property (within the meaning of section 317(a)) by a foreign branch that would be treated as a distribution if the foreign branch were treated as a separate corporation.

(4) *Examples.* The following examples illustrate the application of this paragraph (f).

(i) *Example 1: Determination of foreign branches and foreign branch owner*—(A) *Facts*—(*1*) P, a domestic corporation, is a partner in PRS, a domestic partnership. All other partners in PRS are unrelated to P. PRS conducts activities solely in Country A (the Country A Business), and those activities constitute a trade or business outside the United States within the meaning of paragraph (f)(3)(iii)(B) of this section. PRS reflects items of income, gain, loss, and expense of the Country A Business on the books and records of PRS's home office. PRS's functional currency is the U.S. dollar. PRS is in the business of manufacturing bicycles.

(*2*) PRS owns FDE1, a disregarded entity organized in Country B. FDE1 conducts activities in Country B (the Country B Business), and those activities constitute a trade or business outside the United States within the meaning of paragraph (f)(3)(iii)(B) of this section. FDE1 maintains a set of books and records that are separate from those of PRS, and the separate set of books and records reflects items of income, gain, loss, and expense with respect to the Country B Business. Country B Business's functional currency is the U.S. dollar. FDE1 is in the business of selling bicycles manufactured by PRS.

(*3*) FDE1 owns FDE2, a disregarded entity organized in Country C. FDE2 conducts activities in Country C (the Country C Business), and those activities constitute a trade or business outside the United States within the meaning of paragraph (f)(3)(iii)(B) of this section. FDE2 maintains a set of books and records that are separate from those of PRS and FDE1, and the separate set of books and records reflects items of income, gain, loss, and expense with respect to the Country C Business. Country C Business's functional currency is the U.S. dollar. FDE2 sells paper. FDE2's paper business is not related to FDE1's bicycle sales business, and FDE1 does not hold its interest in FDE2 in the ordinary course of its trade or business.

(B) *Analysis*—(*1*) Country A Business's activities comprise a trade or business conducted outside the United States within the meaning of § 1.989(a)–1(b)(2)(ii)(A) and (b)(3) (in each case, as modified by paragraph (f)(3)(iii) of this section). PRS does not maintain a separate set of books and records with respect to the Country A Business. However, under paragraph (f)(3)(iii)(C) of this section, the Country A Business's activities are deemed to satisfy the requirement of § 1.989(a)–1(b)(2)(ii)(B) that a QBU maintain a separate set of books and records with respect to the relevant activities. Thus, for purposes of this paragraph (f), the activities of the Country A Business constitute a QBU as defined in § 1.989–1(b)(2)(ii) and (b)(3), as modified by paragraph (f)(3)(iii) of this section, that conducts a trade or business outside the United States. Accordingly, the activities of the Country A Business constitute a foreign branch within the meaning of paragraph (f)(3)(iii) of this section. PRS, the person that owns the Country A Business, is the foreign branch owner, within the meaning of paragraph (f)(3)(iv) of this section, with respect to the Country A Business.

(*2*) Country B Business's activities comprise a trade or business outside the United States within the meaning of § 1.989(a)–1(b)(2)(ii)(A) and (b)(3) (in each case, as modified by paragraph (f)(3)(iii) of this section). PRS maintains a separate set of books and records with respect to the Country B Business, as described in § 1.989(a)–1(b)(2)(ii)(B). Thus, for purposes of this section, the activities of the Country B Business constitute a QBU as defined in § 1.989–1(b)(2)(ii) and (b)(3), as modified by paragraph (f)(3)(iii) of this section, that conducts a trade or business outside the United States. Accordingly, the activities of the Country B Business constitute a foreign branch within the meaning of paragraph (f)(3)(iii) of this section. Under paragraph (f)(3)(iv) of this section, PRS, the person that owns the Country B Business indirectly through FDE1 (a disregarded entity), but not including the activities of PRS that constitute the Country A business, is the foreign branch owner with respect to the Country B Business.

(*3*) The same analysis that applies to the Country B Business applies to the Country C Business. Accordingly, the activities of the Country C Business constitute a foreign branch within the meaning of paragraph (f)(3)(iii) of this section. PRS, the person that owns the Country C Business indirectly through FDE1 and FDE2 (disregarded entities), but not including the activities of PRS that constitute the Country A Business,

is the foreign branch owner with respect to the Country C Business.

(ii) *Example 2: Sale of foreign branch*—(A) *Facts.* The facts are the same as in paragraph (f)(4)(i)(A) of this section, except that in 2019, FDE1 sold FDE2 to an unrelated person, recording gain from the sale on its books and records. In 2020, PRS sells FDE1 to another unrelated person, recording gain from the sale on its books and records. In each year, PRS allocates a portion of the gain to P.

(B) *Analysis*—(*1*) *Sale of FDE2.* Under paragraph (f)(1)(i)(B) of this section, P's distributive share of gain recognized by PRS in connection with the sales of FDE1 and FDE2 constitutes foreign branch category income if it is attributable to a foreign branch held by PRS directly or indirectly through one or more disregarded entities. PRS's gross income from the 2019 sale of FDE2 is reflected on the separate set of books and records maintained with respect to the Country B Business (a foreign branch) operated by FDE1. Therefore, absent an exception, under paragraph (f)(2)(i) of this section PRS's gross income from the sale of FDE2 would be attributable to the Country B Business, and would constitute foreign branch category income. However, under paragraph (f)(2)(iv) of this section, gross income attributable to the Country B Business does not include gain from the sale or exchange of an interest in FDE2, a disregarded entity, unless the interest in FDE2 is held by the Country B Business in the ordinary course of its active trade or business (within the meaning of paragraph (f)(2)(iv)(B) of this section). In this case, the Country B Business does not hold FDE2 in the ordinary course of its active trade or business within the meaning of paragraph (f)(2)(iv)(B) of this section. As a result, P's distributive share of gain from the sale of FDE2 is not attributable to a foreign branch, and is not foreign branch category income.

(*2*) *Sale of FDE1.* The analysis of PRS's sale of FDE1 in 2020 is the same as the analysis for the sale of FDE2, except that PRS, through its Country A Business, holds FDE1 in the ordinary course of its active trade or business within the meaning of paragraph (f)(2)(iv)(B) of this section because the Country A Business engages in a trade or business that is related to the trade or business of FDE1. Therefore, P's distributive share of gain from the sale of FDE1 is attributable to a foreign branch, and is foreign branch category income.

(iii) *Example 3: Disregarded payment for services*—(A) *Facts.* P, a domestic corporation, owns FDE, a disregarded entity that is a foreign branch within the meaning of paragraph (f)(3)(iii) of this section. FDE's functional currency is the U.S. dollar. In 2019, P accrued and recorded on its books and records (and not FDE's books and records) $1,000 of gross income from the performance of services to unrelated parties that was not passive category income, $400 of which was foreign source income in respect of services performed outside the United States by employees of FDE and $600 of which was United States source income in respect of services performed in the United States. Absent the application of paragraph (f)(2)(vi) of this section, the $1,000 of gross income earned by P would be general category income that would not be attributable to FDE. FDE provided services in support of P's gross income from services. P compensated FDE for its services with an arm's length payment of $400, which was disregarded for Federal income tax purposes. The deduction for the payment of $400 from P to FDE would be allocated and apportioned to the $400 of P's foreign source services income if the payment were regarded for Federal income tax purposes.

(B) *Analysis.* The disregarded payment from P, a United States person, to FDE, its foreign branch, is not recorded on FDE's separate books and records (as adjusted to conform to Federal income tax principles) within the meaning of paragraph (f)(2)(i) of this section because it is disregarded for United States tax purposes. However, the disregarded payment is allocable to gross income attributable to P because a deduction for the payment, if it were regarded, would be allocated to P's $1,000 of gross services income and apportioned between U.S. and foreign source income under § 1.861–8. Under paragraph (f)(2)(vi)(A) of this section, the amount of gross income attributable to the FDE foreign branch (and the gross income attributable to P) is adjusted to take the disregarded payment into account. As such, all of P's $400 of foreign source gross income from the performance of services is attributable to the FDE foreign branch for purposes of this section. Therefore, $400 of the foreign source gross income that P earned with respect to its services in 2019 constitutes gross income that is assigned to the foreign branch category.

(g) *Section 951A category income*—(1) *In general.* Except as provided in paragraph (g)(2) of this section, the term *section 951A category income* means amounts included (directly or indirectly through a pass-through entity) in gross income of a United States person under section 951A(a).

(2) *Exceptions for passive category income.* Section 951A category income does not include any amounts included under section 951A(a) that are allocable to passive category income under § 1.904–5(c)(6). Section 951A category income also does not include any amounts treated as passive category income under paragraph (n)(2) of this section.

(h) * * *

(2) *Treatment of export financing interest.* Except as provided in paragraph (h)(3) of this section, if a taxpayer (including a financial services entity) receives or accrues export financing interest from an unrelated person, then that interest is not treated as passive category income. Instead, the interest income is treated as foreign branch category income, section 951A category income, general category income, or income in a specified separate category under the rules of this section.

* * * * *

(5) * * * (i) *Income other than interest.* If any foreign person receives or accrues income that is described in section 864(d)(7) (income on a trade or service receivable acquired from a related person in the same foreign country as the recipient) and such income would also meet the definition of export financing interest if section 864(d)(1) applied to such income (income on a trade or service receivable acquired from a related person treated as interest), then the income is considered to be export financing interest and is not treated as passive category income. The income is treated as foreign branch category income, section 951A category income, general category income, or income in a specified separate category under the rules of this section.

(ii) *Interest income.* If export financing interest is received or accrued by any foreign person and that income would otherwise be treated as related person factoring income of a controlled foreign corporation under section 864(d)(6) if section 864(d)(7) did not apply, section 904(d)(2)(B)(iii)(I) applies and the interest is not treated as passive category income. The income is treated as general category income in the hands of the controlled foreign corporation.

* * * * *

(k) *Separate category under section 904(d)(6) for items resourced under treaties*—(1) *In general.* Except as provided in paragraph (k)(4)(i) of this section, sections 904(a), (b), (c), (d), (f), and (g), and sections 907 and 960 are applied separately to any item of income that, without regard to a treaty obligation of the United States, would be treated as derived from sources within the United States, but under a treaty obligation of the United States such item of income would be treated as arising from sources outside the United States, and the taxpayer chooses the benefits of such treaty obligation.

(2) *Aggregation of items of income in each other separate category.* For purposes of applying the general rule of paragraph (k)(1) of this section, items of income in each other separate category of income that are resourced under each applicable treaty are aggregated in a single separate category for income in that separate category that is resourced under that treaty. For example, all items of general category income that would otherwise be treated as derived from sources within the United States but which the taxpayer chooses to treat as arising from sources outside the United

States pursuant to a provision of a bilateral U.S. income tax treaty are treated as income in a separate category for general category income resourced under the particular treaty. Resourced items are not combined with other income that is foreign source income under the Code, even if the other income arises from sources within the treaty country and is included in the same separate category to which the resourced income would be assigned without regard to section 904(d)(6).

(3) *Related taxes.* Foreign taxes are allocated to each separate category described in paragraph (k)(2) of this section in accordance with § 1.904–6.

(4) *Coordination with certain income tax treaty provisions*—(i) *Exception for special relief from double taxation for individual residents of treaty countries.* Section 904(d)(6)(A) and paragraph (k)(1) of this section do not apply to any item of income deemed to be from foreign sources by reason of the relief from double taxation rules in any U.S. income tax treaty that is solely applicable to United States citizens who are residents of the other Contracting State.

(ii) *U.S. competent authority assistance.* For purposes of applying paragraph (k)(1) of this section, if, under the mutual agreement procedure provisions of an applicable income tax treaty, the U.S. competent authority agrees to allow a taxpayer to treat an item of income as foreign source income, where such item of income would otherwise be treated as derived from sources within the United States, then the taxpayer is considered to have chosen the benefits of such treaty obligation to treat the item as foreign source income.

(5) *Coordination with other Code provisions.* Section 904(d)(6)(A) and paragraph (k)(1) of this section do not apply to any item of income to which any of sections 245(a)(10), 865(h), or 904(h)(10) applies. *See* paragraph (l) of this section.

(l) *Priority rule.* Income that meets the definitions of a specified separate category and another category of income described in section 904(d)(1) is subject to the separate limitation described in paragraph (m) of this section and is not treated as general category income, foreign branch category income, passive category income, or section 951A category income.

(m) *Income treated as allocable to a specified separate category.* If section 904(a), (b), and (c) are applied separately to any category of income under the Internal Revenue Code and regulations (for example, under section 245(a)(10), 865(h), 901(j), 904(d)(6), or 904(h)(10), and the regulations under those sections), that category of income is treated for all purposes of the Internal Revenue Code and regulations as if it were a separate category listed in section 904(d)(1). For purposes of this section, a separate category that is treated as if it were listed in section 904(d)(1) by reason of the first sentence in this paragraph (m) is referred to as a *specified separate category.*

(n) *Income from partnerships and other pass-through entities*—(1) *Distributive shares of partnership income*—(i) *In general.* Except as provided in paragraph (n)(1)(ii) of this section, a partner's distributive share of partnership income is characterized as passive category income to the extent that the distributive share is a share of income earned or accrued by the partnership in the passive category. A partner's distributive share of partnership income that is not described in the first sentence of this paragraph is treated as foreign branch category income, section 951A category income, general category income, or income in a specified separate category under the rules of this section. Similar principles apply for a person's share of income from any other pass-through entity.

(ii) *Less than 10 percent partners partnership interests*—(A) *In general.* Except as provided in paragraph (n)(1)(ii)(B) of this section, if any limited partner or corporate general partner owns less than 10 percent of the value in a partnership, the partner's distributive share of partnership income from the partnership is passive income to the partner (subject to the high-taxed income exception of section 904(d)(2)(B)(iii)(II)), and the partner's distributive share of partnership deductions from the partnership is allocated and apportioned under the principles of section 1.861–8 only to the partner's passive income from that partnership. See also § 1.861–9(e)(4) for rules for apportioning partnership interest expense.

(B) *Exception for partnership interest held in the ordinary course of business.* If a partnership interest described in paragraph (n)(1)(ii)(A) of this section is held in the ordinary course of a partner's active trade or business, the rules of paragraph (n)(1)(i) of this section apply for purposes of characterizing the partner's distributive share of the partnership income. A partnership interest is considered to be held in the ordinary course of a partner's active trade or business if the partner (or a member of the partner's affiliated group of corporations (within the meaning of section 1504(a) and without regard to section 1504(b)(3))) engages (other than through a less than 10 percent interest in a partnership) in the same or a related trade or business as the partnership.

(2) *Income from the sale of a partnership interest*—(i) *In general.* To the extent a partner recognizes gain on the sale of a partnership interest, that income shall be treated as passive category income to the partner, unless the income is considered to be high-taxed under section 904(d)(2)(B)(iii)(II) and paragraph (c) of this section.

(ii) *Exception for sale by 25-percent owner.* Except as provided in paragraph (f)(2)(iv) of this section, in the case of a sale of an interest in a partnership by a partner that is a 25-percent owner of the partnership, determined by applying section 954(c)(4)(B) and substituting ''partner'' for ''controlled foreign corporation'' every place it appears, for purposes of determining the separate category to which the income recognized on the sale of the partnership interest is assigned such partner is treated as selling the proportionate share of the assets of the partnership attributable to such interest.

(3) *Value of a partnership interest.* For purposes of paragraphs (n)(1) and (2) of this section, a partner will be considered as owning 10 percent of the value of a partnership for a particular year if the partner, together with any person that bears a relationship to the partner described in section 267(b) or 707, owns 10 percent of the capital and profits interest of the partnership. For this purpose, value will be determined at the end of the partnership's taxable year.

(o) *Separate category of section 78 gross up.* The amount included in income under section 78 by reason of taxes deemed paid under section 960 is assigned to the separate category to which the taxes are allocated under § 1.904–6(b).

(p) *Separate category of foreign currency gain or loss.* Foreign currency gain or loss recognized under section 986(c) with respect to a distribution of previously taxed earnings and profits (as described in section 959 or 1293(c)) is assigned to the separate category or categories of the previously taxed earnings and profits from which the distribution is made. See § 1.987–6(b) for rules on assigning section 987 gain or loss on a remittance from a section 987 QBU to a separate category or categories.

(q) *Applicability dates.* This section applies for taxable years that both begin after December 31, 2017, and end on or after December 4, 2018.

■ **Par. 16.** § 1.904–5 is amended by:

■ 1. Revising paragraphs (a), (b), and (c)(1).
■ 2. Revising the third and fourth sentences of paragraph (c)(2)(i).
■ 3. Removing the language ''noncontrolled section 902 corporation'' and adding the language ''noncontrolled 10-percent owned foreign corporation'' in its place in the heading and text of paragraph (c)(2)(iii).
■ 4. Revising paragraph (c)(3).
■ 5. Revising the first sentence, and removing the language ''paragraph'' and adding the language ''paragraph (c)(4)'' in its place in the second sentence, of paragraph (c)(4)(i).
■ 6. Revising paragraph (c)(4)(iii).
■ 7. Adding paragraphs (c)(5) and (6).
■ 8. Revising paragraphs (d)(1) and (2).
■ 9. Removing and reserving paragraph (f)(1).
■ 10. Removing paragraph (f)(3).
■ 11. Removing the language ''section 904(d)(3) and this section'' and adding the language ''paragraph (c) of this section'' in its place in the first sentence of paragraph (g).
■ 12. Removing the last sentence of paragraph (g).
■ 13. Revising paragraph (h).
■ 14. Removing the language ''paragraphs (i)(2), (3), and (4)'' and adding the language ''paragraphs (i)(2) and (3)'' in its place in the first sentence of paragraph (i)(1).
■ 15. Removing the language ''noncontrolled section 902 corporation'' and adding the language ''noncontrolled 10-percent owned foreign corporation'' in its place in the second sentence of paragraph (i)(1).
■ 16. Removing the language ''paragraph (i)(4)'' and adding the language ''paragraph (i)(3)'' in its place in the second sentence of paragraph (i)(1).
■ 17. Revising the sixth and seventh sentences of paragraph (i)(1).
■ 18. Revising paragraph (i)(2) and (3).
■ 19. Removing and reserving paragraph (i)(4).
■ 20. Removing the last sentence of paragraph (j).
■ 21. Adding the language ''under § 1.904–4'' after the language ''characterized'' in the first sentence of paragraph (k)(1).
■ 22. Revising paragraph (k)(2)(iii).
■ 23. Removing the language ''noncontrolled section 902 corporation'' and adding the language ''noncontrolled 10-percent owned foreign corporation'' in its place in paragraph (m)(1).
■ 24. Removing the language ''or amount treated as a dividend, including'' and adding the language ''which, for purposes of this paragraph (m), includes'' in its place in the third sentence of paragraph (m)(1).
■ 25. Removing the language ''951(a)(1)(A),'' and adding the language ''951(a)(1)(A), 951A(a),'' in its place in the fourth sentence of paragraph (m)(1).
■ 26. Revising paragraphs (m)(2)(ii), (m)(4)(i), and the first sentence of paragraph (m)(5)(i).
■ 27. Removing the language ''section 902(a) and section 960(a)(1)'' and adding the language ''section 960'' in its place in paragraph (m)(6).
■ 28. Removing the language ''904(g)(6)'' from the first sentence of paragraph (m)(7)(i) and adding the language ''904(h)(6)'' in its place.
■ 29. Removing the language ''904(g)'' from the first sentence of paragraph (m)(7)(i) and adding the language ''904(h)'' in its place.
■ 30. Removing the language ''(d) and (f)'' from the second sentence of paragraph (m)(7)(i) and adding the language ''(d), (f), and (g)'' in its place.
■ 31. Removing the language ''902,'' from the second sentence of paragraph (m)(7)(i).
■ 32. Removing the language ''noncontrolled section 902 corporation'' and adding the language ''noncontrolled 10-percent owned foreign corporation'' in its place, and by removing the language ''section 904(d)(1)'' and adding ''§ 1.904–4'' in its place in the first sentence of paragraph (n).
■ 33. Revising the last sentence of paragraph (n).
■ 34. Revising paragraph (o).

The additions and revisions read as follows:

§ 1.904–5 Look-through rules as applied to controlled foreign corporations and other entities.

(a) *Scope and definitions.* (1) *Look-through rules under section 904(d)(3) to passive category income.* Paragraph (c) of this section provides rules for determining the extent to which dividends, interest, rents, and royalties received or accrued by certain eligible persons, and inclusions under sections 951(a)(1) and 951A(a), are treated as passive category income. Paragraph (g) of this section provides rules applying the principles of paragraph (c) of this section to foreign source interest, rents, and royalties paid by a United States corporation to a related corporation. Paragraph (h) of this section provides rules for assigning a partnership payment to a partner described in section 707 to the passive category. Paragraph (i) of this section provides rules applying the principles of this section to assign distributions and payments from certain related entities to the passive category or to treat the distributions and payments as not in the passive category.

(2) *Other look-through rules under section 904(d).* Under section 904(d)(4) and paragraph (c)(4)(iii) of this section, certain dividends from noncontrolled 10-percent owned foreign corporations are treated as income in a separate category. Under section 904(d)(3)(H) and paragraph (j) of this section, certain inclusions under section 1293 are treated as income in a separate category. Paragraph (i) of this section provides rules applying the principles of this section to assign distributions from certain related entities to separate categories.

(3) *Other rules provided in this section.* Paragraph (b) of this section provides operative rules for this section. Paragraph (d) of this section provides rules addressing exceptions to passive category income for certain purposes in the case of controlled foreign corporations that meet the requirements of section 954(b)(3)(A) (de minimis rule) or section 954(b)(4) (high-tax exception). Paragraph (e) of this section provides rules for characterizing a controlled foreign corporation's foreign base company income and gross insurance income when section 954(b)(3)(B) (full inclusion rule) applies. Paragraph (f) of this section modifies the look-through rules for certain types of income. Paragraph (k) of this section provides ordering rules for applying the look-through rules. Paragraph (l) of this section provides examples illustrating the application of certain rules in this section. Paragraphs (m) and (n) of this section provide rules related to the resourcing rules described in section 904(h).

(4) *Definitions.* For purposes of this section, the following definitions apply:

(i) The term *controlled foreign corporation* has the meaning given such term by section 957 (taking into account the special rule for certain captive insurance companies contained in section 953(c)).

(ii) The term *look-through rules* means the rules described in this section that assign income to a separate category based on the separate category of the income to which it is allocable.

(iii) The term *noncontrolled 10-percent owned foreign corporation* has the meaning provided in section 904(d)(2)(E)(i).

(iv) The term *pass-through entity* means a partnership, S corporation, or any other person (whether domestic or foreign) other than a corporation to the extent that the income or deductions of the person are included in the income of one or more direct or indirect owners or beneficiaries of the person. For example, if a domestic trust is subject to Federal income tax on a portion of its

income and its owners are subject to tax on the remaining portion, the domestic trust is treated as a domestic pass-through entity with respect to such remaining portion.

(v) The term *separate category* means, as the context requires, any category of income described in 904(d)(1)(A), (B), (C), or (D), any specified separate category of income as defined in § 1.904–4(m), or any category of earnings and profits to which income described in such provisions is attributable.

(vi) The term *United States shareholder* has the meaning given such term by section 951(b) (taking into account the special rule for certain captive insurance companies contained in section 953(c)), except that for purposes of this section, a United States shareholder includes any member of the controlled group of the United States shareholder. For this purpose the controlled group is any member of the affiliated group within the meaning of section 1504(a)(1) except that ''more than 50 percent'' is substituted for ''at least 80 percent'' wherever it appears in section 1504(a)(2). When used in reference to a noncontrolled 10-percent owned foreign corporation described in section 904(d)(2)(E)(i)(II), the term *United States shareholder* also means a taxpayer that meets the stock ownership requirements described in section 904(d)(2)(E)(i)(II).

(b) *Operative rules*—(1) *Assignment of income not assigned under the look-through rules.* Except as provided by the look-through rules, dividends, interest, rents, and royalties received or accrued by a taxpayer from a controlled foreign corporation in which the taxpayer is a United States shareholder are excluded from passive category income. Income excluded from the passive category under this paragraph (b)(1) is assigned to another separate category (other than the passive category) under the rules in § 1.904–4.

(2) *Priority and ordering of look-through rules.* Except as provided in § 1.904–4(l), to the extent the look-through rules assign income to a separate category, the income is assigned to that separate category rather than the separate category to which the income would have been assigned under § 1.904–4 (not taking into account § 1.904–4(l)). See paragraph (k) of this section for ordering rules for applying the look-through rules.

(c) * * * (1) *Scope.* Subject to the exceptions in paragraph (f) of this section, paragraphs (c)(2) through (c)(6) (other than paragraph (c)(4)(iii)) of this section provide look-through rules with respect to interest, rents, royalties, dividends, and inclusions under section 951(a)(1) and 951A(a) that are received or accrued from a controlled foreign corporation in which the taxpayer is a United States shareholder. Paragraph (c)(4)(iii) of this section provides a look-through rule for dividends received from a noncontrolled 10-percent owned foreign corporation by a domestic corporation that is a United States shareholder in the foreign corporation.

(2) * * * (i) * * * Related person interest is treated as passive category income to the extent it is allocable to passive category income of the controlled foreign corporation. If related person interest is received or accrued from a controlled foreign corporation by two or more persons, the amount of interest received or accrued by each person that is allocable to passive category income is determined by multiplying the amount of related person interest allocable to passive category income by a fraction. * * *

* * * * *

(3) *Rents and royalties.* Any rents or royalties received or accrued from a controlled foreign corporation in which the taxpayer is a United States shareholder are treated as passive category income to the extent they are allocable to passive category income of the controlled foreign corporation under the principles of §§ 1.861–8 through 1.861–14T.

(4) * * * (i) * * * Except as provided in paragraph (d)(2) of this section, any dividend paid or accrued out of the earnings and profits of any controlled foreign corporation is treated as passive category income in proportion to the ratio of the portion of earnings and profits attributable to passive category income to the total amount of earnings and profits of the controlled foreign corporation. * * *

* * * * *

(iii) *Look-through rule for dividends from noncontrolled 10-percent owned foreign corporations*—(A) *In general.* Except as provided in paragraph (c)(4)(iii)(B) of this section, any dividend that is distributed by a noncontrolled 10-percent owned foreign corporation and received or accrued by a domestic corporation that is a United States shareholder of such foreign corporation is treated as income in a separate category in proportion to the ratio of the portion of earnings and profits attributable to income in such category to the total amount of earnings and profits of the noncontrolled 10-percent owned foreign corporation.

(B) *Inadequate substantiation.* A dividend distributed by a noncontrolled 10-percent owned foreign corporation is treated as income in the separate category described in section 904(d)(4)(C)(ii) if the Commissioner determines that the look-through characterization of the dividend cannot reasonably be determined based on the available information.

* * * * *

(5) *Inclusions under section 951(a)(1)(A)*—(i) Any amount included in gross income under section 951(a)(1)(A) is treated as passive category income to the extent the amount included is attributable to income received or accrued by the controlled foreign corporation that is passive category income. All other amounts included in gross income under section 951(a)(1)(A) are treated as general category income or income in a specified separate category under the rules in § 1.904–4. For rules concerning a distributive share of partnership income, see § 1.904–4(n). For rules concerning the gross up under section 78, see § 1.904–4(o). For rules concerning inclusions under section 951(a)(1)(B), see paragraph (c)(4)(i) of this section.

(ii) [Reserved]

(6) *Inclusions under section 951A(a).* Any amount included in gross income under section 951A(a) is treated as passive category income to the extent the amount included is attributable to income received or accrued by the controlled foreign corporation that is passive category income. All other amounts included in gross income under section 951A(a) are treated as section 951A category income or income in a specified separate category under the rules in § 1.904–4. For rules concerning a distributive share of partnership income, see § 1.904–4(n). For rules concerning the gross up under section 78, see § 1.904–4(o).

(d) * * * (1) *De minimis amount of subpart F income.* If the sum of a controlled foreign corporation's gross foreign base company income (determined under section 954(a) without regard to section 954(b)(5)) and gross insurance income (determined under section 953(a)) for the taxable year is less than the lesser of 5 percent of gross income or $1,000,000, then none of that income is treated as passive category income. In addition, if the test in the first sentence of this paragraph is satisfied, for purposes of paragraphs (c)(2)(ii)(D) and (E) of this section (apportionment of interest expense to passive income using the asset method), any passive category assets are not treated as passive category assets but are treated as assets in the general category or a specified separate category. The

determination in the first sentence is made before the application of the exception for certain income subject to a high rate of foreign tax described in paragraph (d)(2) of this section.

(2) *Exception for certain income subject to high foreign tax.* Except as provided in § 1.904–4(c)(7)(iii) (relating to reductions in tax upon distribution), for purposes of the dividend look-through rule of paragraph (c)(4)(i) of this section, an item of net income that would otherwise be passive income (after application of the priority rules of § 1.904–4(l)) and that is received or accrued by a controlled foreign corporation is not treated as passive category income, and the earnings and profits attributable to such income is not treated as passive category earnings and profits, if the taxpayer establishes to the satisfaction of the Secretary under section 954(b)(4) that the income was subject to an effective rate of income tax imposed by a foreign country greater than 90 percent of the maximum rate of tax specified in section 11 (with reference to section 15, if applicable). Such income is treated as general category income or income in a specified separate category under the rules in § 1.904–4. The first sentence of this paragraph has no effect on amounts (other than dividends) paid or accrued by a controlled foreign corporation to a United States shareholder of such controlled foreign corporation to the extent those amounts are allocable to passive category income of the controlled foreign corporation.

* * * * *

(f) * * * (1) [Reserved]

* * * * *

(h) *Application of look-through rules to payments from a partnership or other pass-through entity.* Payments to a partner described in section 707 (*e.g.,* payments to a partner not acting in capacity as a partner) are characterized as passive category income to the extent that the payment is attributable under the principles of § 1.861–8 and this section to passive category income of the partnership, if the payments are interest, rents, or royalties that would be characterized under the controlled foreign corporation look-through rules of paragraph (c) of this section if the partnership were a foreign corporation, and the partner who receives the payment owns 10 percent or more of the value of the partnership (as determined under § 1.904–4(n)(3)). A payment by a partnership to a member of the controlled group (as defined in paragraph (a)(4)(vi) of this section) of the partner is characterized under the look-through rules of this paragraph (h) if the payment would be a section 707 payment entitled to look-through treatment if it were made to the partner. Similar principles apply for a payment from any other pass-through entity. The rules in this paragraph (h) do not apply with respect to interest to the extent the interest income is assigned to a separate category under the specified partnership loan rules described in § 1.861–9(e)(8).

(i) * * * (1) * * * For purposes of this paragraph (i)(1), indirect ownership of stock is determined under section 318 and the regulations under that section. In the case of a partnership or other pass-through entity, indirect ownership and value is determined under the rules in paragraph (i)(2) of this section.

(2) *Indirect ownership and value of a partnership interest.* A person is considered as owning, directly or indirectly, more than 50 percent of the value of a partnership if the person, together with other any person that bears a relationship to the first person that is described in section 267(b) or 707, owns more than 50 percent of the capital and profits interests of the partnership. For this purpose, value will be determined at the end of the partnership's taxable year. Similar principles apply for a person that owns a pass-through entity other than a partnership.

(3) *Special rule for dividends between certain foreign corporations.* Solely for purposes of dividend payments between controlled foreign corporations, noncontrolled 10-percent owned foreign corporations, or a controlled foreign corporation and a noncontrolled 10-percent owned foreign corporation, the two foreign corporations are considered related look-through entities if the same person is a United States shareholder of both foreign corporations.

(4) [Reserved]

* * * * *

(k) * * *

(2) * * *

(iii) Inclusions under sections 951(a)(1)(A) and 951A(a) and distributive shares of partnership income;

* * * * *

(m) * * *

(2) * * *

(ii) *Interest payments from noncontrolled 10-percent owned foreign corporations.* If interest is received or accrued by a shareholder from a noncontrolled 10-percent owned foreign corporation (where the shareholder is a domestic corporation that is a United States shareholder of such noncontrolled 10-percent owned foreign corporation), the rules of paragraph (m)(2)(i) of this section apply in determining the portion of the interest payment that is from sources within the United States, except that the related party interest rules of paragraph (c)(2)(ii)(C) of this section do not apply.

* * * * *

(4) * * * (i) *Rule.* Any dividend or distribution treated as a dividend under this paragraph (m) (including an amount included in gross income under section 951(a)(1)(B)) that is received or accrued by a United States shareholder from a controlled foreign corporation, or any dividend that is received or accrued by a domestic corporation from a noncontrolled 10-percent owned foreign corporation with respect to which the shareholder is a United States shareholder, are treated as income in a separate category derived from sources within the United States in proportion to the ratio of the portion of the earnings and profits of the controlled foreign corporation or noncontrolled 10-percent owned foreign corporation in the corresponding separate category from United States sources to the total amount of earnings and profits of the controlled foreign corporation or noncontrolled 10-percent owned foreign corporation in that separate category.

* * * * *

(5) * * * (i) * * * Any amount included in the gross income of a United States shareholder of a controlled foreign corporation under section 951(a)(1)(A), 951A, or in the gross income of a domestic corporation that is a United States shareholder of a noncontrolled 10-percent owned foreign corporation described in section 904(d)(2)(E)(i)(II) that is a qualified electing fund under section 1293 is treated as income subject to a separate category that is derived from sources within the United States to the extent the amount is attributable to income of the controlled foreign corporation or qualified electing fund, respectively, in the corresponding category of income from sources within the United States. * * *

* * * * *

(n) * * * Section 904(d)(3), (d)(4), and (h), and this section are then applied for purposes of characterizing and sourcing income received, accrued, or included by a United States shareholder of the foreign corporation that is attributable or allocable to income or earnings and profits of the foreign corporation.

(o) *Applicability dates.* This section is applicable for taxable years that both begin after December 31, 2017, and end on or after December 4, 2018.

■ **Par. 17.** § 1.904–6 is amended by:

■ 1. Revising the first sentence, and adding two sentences after the fourth sentence, of paragraph (a)(1)(i).
■ 2. Removing the language ''(unless it is a withholding tax that is not the final tax payable on the income as described in § 1.904–4(d))'' and adding the language ''(as defined in section 901(k)(1)(B))'' in its place in the new seventh sentence of paragraph (a)(1)(i).
■ 3. Revising paragraph (a)(1)(iv).
■ 4. Adding paragraphs (a)(2) and (3).
■ 5. Revising paragraph (b).
■ 6. Adding paragraph (d).

The revisions and additions read as follows:

§ 1.904–6 Allocation and apportionment of taxes.

(a) * * * (1) * * * (i) * * * The amount of foreign taxes paid or accrued with respect to a separate category (as defined in § 1.904–5(a)(4)(v)) of income (including United States source income within the separate category) includes only those taxes that are related to income in that separate category. * * * Income included in the foreign tax base is calculated under foreign law, but characterized as income in a separate category under United States tax principles. For example, a foreign tax imposed on an amount realized on the disposition of controlled foreign corporation stock that is characterized as a capital gain under foreign law but as a dividend under section 1248 is generally assigned to the general category, not the passive category. * * *

* * * * *

(iv) *Base and timing differences.* If, under the law of a foreign country or possession of the United States, a tax is imposed on a type of item that does not constitute income under Federal income tax principles (a *base difference*), such as gifts or life insurance proceeds, that tax is treated as imposed with respect to income in the separate category described in section 904(d)(2)(H)(i). If, under the law of a foreign country or possession of the United States, a tax is imposed on an item of income that constitutes income under Federal income tax principles but is not recognized for Federal income tax purposes in the current year (a *timing difference*), that tax is allocated and apportioned to the appropriate separate category or categories to which the tax would be allocated and apportioned if the income were recognized under Federal income tax principles in the year in which the tax was imposed. If the amount of an item of income as computed for foreign tax purposes is positive but is greater than the amount of income that is currently recognized for Federal income tax purposes, for example, due to a difference in depreciation conventions or the timing of recognition of gross income, or because of a permanent difference between U.S. and foreign tax law in the amount of deductions that are allowed to reduce gross income, the tax is allocated or apportioned to the separate category to which the income is assigned, and no portion of the tax is attributable to a base difference. In addition, a tax imposed on a distribution that is excluded from gross income under section 959(a) or section 959(b) is treated as attributable to a timing difference (and not a base difference) and is treated as tax imposed on the earnings and profits from which the distribution was paid.

(2) *Special rules for foreign branches*—(i) *In general.* Except as provided in this paragraph (a)(2), any foreign tax reflected on the books and records of a foreign branch under the principles of § 1.987–2(b) is allocated and apportioned under the rules of paragraph (a)(1) of this section.

(ii) *Disregarded reallocation transactions*—(A) *Foreign branch to foreign branch owner.* In the case of a disregarded payment from a foreign branch to a foreign branch owner that is treated as a disregarded reallocation transaction that results in foreign branch category income being reallocated to the general category, any foreign tax imposed solely by reason of that payment, such as a withholding tax imposed on the disregarded payment, is allocated and apportioned to the general category.

(B) *Foreign branch owner to foreign branch.* In the case of a disregarded payment from a foreign branch owner to a foreign branch that is treated as a disregarded reallocation transaction that results in general category income being reallocated to the foreign branch category, any foreign tax imposed solely by reason of that transaction is allocated and apportioned to the foreign branch category.

(iii) *Other disregarded payments*—(A) *Foreign branch to foreign branch owner.* In the case of a disregarded payment from a foreign branch to a foreign branch owner that is not a disregarded reallocation transaction, foreign tax imposed solely by reason of that disregarded payment is allocated and apportioned to a separate category under the principles of paragraph (a)(1) of this section based on the nature of the item (determined under Federal income tax principles) that is included in the foreign tax base. For example, if a remittance of an appreciated asset results in gain recognition under foreign law, the tax imposed on that gain is treated as attributable to a timing difference with respect to recognition of the gain, and is allocated and apportioned to the separate category to which gain on a sale of that asset would have been assigned if it were recognized for Federal income tax purposes. However, a gross basis withholding tax on a remittance is attributable to a timing difference in taxation of the income out of which the remittance is made, and is allocated and apportioned to the separate category or categories to which a section 987 gain or loss would be assigned under § 1.987–6(b).

(B) *Foreign branch owner to foreign branch.* In the case of a disregarded payment from a foreign branch owner to a foreign branch that is not a disregarded reallocation transaction, any foreign tax imposed solely by reason of that disregarded payment is allocated and apportioned to the foreign branch category.

(iv) *Definitions.* The following definitions apply for purposes of this paragraph (a)(2):

(A) *Disregarded reallocation transaction.* The term *disregarded reallocation transaction* means a disregarded payment or a transfer described in § 1.904–4(f)(2)(vi)(D) that results in an adjustment to the gross income attributable to the foreign branch under § 1.904–4(f)(2)(vi)(A).

(B) The terms *disregarded payment, foreign branch, foreign branch owner,* and *remittance* have the same meaning given to those terms in § 1.904–4(f)(3).

(3) *Taxes imposed on high-taxed income.* For rules on the treatment of taxes imposed on high-taxed income, see § 1.904–4(c).

(b) *Allocation and apportionment of deemed paid taxes and certain creditable foreign tax expenditures*—(1) *Taxes deemed paid under section 960(a) or (d).* If a domestic corporation that is a United States shareholder includes any amount in gross income under sections 951(a)(1)(A) or 951A(a), any foreign tax deemed paid with respect to such amount under section 960(a) or (d) is allocated to the separate category to which the inclusion is assigned.

(2) *Taxes deemed paid under section 960(b)(1).* If a domestic corporation that is a United States shareholder receives a distribution of previously taxed earnings and profits from a first-tier corporation that is excluded from the domestic corporation's income under section 959(a) and § 1.959–1, any foreign tax deemed paid under section 960(b)(1) with respect to such distribution is allocated to the same separate category as the annual PTEP account and PTEP group (as defined in

§ 1.960–3(c)) from which the distribution is made.

(3) *Taxes deemed paid under section 960(b)(2).* If a controlled foreign corporation receives a distribution of previously taxed earnings and profits from an immediately lower-tier corporation that is excluded from such controlled foreign corporation's gross income under section 959(b) and § 1.959–2, any foreign tax deemed paid under section 960(b)(2) with respect to such distribution is allocated to the same separate category as the annual PTEP account and PTEP group (as defined in § 1.960–3(c)) from which the distribution is made. *See also* § 1.960–3(c)(2).

(4) *Creditable foreign tax expenditures*—(i) *In general.* Except as provided in paragraph (b)(4)(ii) of this section, creditable foreign tax expenditures (CFTEs) allocated to a partner under § 1.704–1(b)(4)(viii)(*a*) are allocated for purposes of this section to the same separate category as the separate category to which the taxes were allocated in the hands of the partnership under the rules of paragraph (a) of this section.

(ii) *Foreign branch category.* CFTEs allocated to a partner in a partnership under § 1.704–1(b)(4)(viii)(*a*) are allocated and apportioned to the foreign branch category of the partner to the extent that:

(A) The CFTEs are allocated and apportioned by the partnership under the rules of paragraph (a) of this section to the general category;

(B) In the hands of the partnership, the CFTEs are related to general category income attributable to a foreign branch (as described in § 1.904–4(f)(2)) under the principles of paragraph (a) of this section; and

(C) The partner's distributive share of the income described in paragraph (b)(4)(ii)(B) of this section is foreign branch category income of the partner under § 1.904–4(f)(1)(i)(B).

* * * * *

(d) *Applicability dates.* This section is applicable for taxable years that both begin after December 31, 2017, and end on or after December 4, 2018.

■ **Par. 18.** Section 1.904(b)–3 is added to read as follows:

§ 1.904(b)–3 Disregard of certain dividends and deductions under section 904(b)(4).

(a) *Disregard of certain dividends and deductions*—(1) *In general.* For purposes of section 904(a), in the case of a domestic corporation which is a United States shareholder with respect to a specified 10-percent owned foreign corporation (as defined in section 245A(b)), the domestic corporation's foreign source taxable income in a separate category and entire taxable income is determined without regard to the following items:

(i) Any dividend for which a deduction is allowed under section 245A;

(ii) Deductions properly allocable or apportioned to gross income in the section 245A subgroup as determined under paragraphs (b) and (c)(1) of this section; and

(iii) Deductions properly allocable or apportioned to stock of specified 10-percent owned foreign corporations in the section 245A subgroup as determined under paragraphs (b) and (c) of this section.

(2) *Deductions properly allocable or apportioned to the residual grouping.* Deductions that are properly allocable or apportioned to gross income or stock in the section 245A subgroup of the residual grouping (consisting of U.S. source income) are disregarded solely for purposes of determining entire taxable income under section 904(a).

(b) *Determining properly allocable or apportioned deductions.* The amount of deductions properly allocable or apportioned to gross income or stock described in paragraphs (a)(1)(ii) and (iii) of this section is determined by subdividing the United States shareholder's gross income and assets in each separate category described in § 1.904–5(a)(4)(v) into a section 245A subgroup and a non-section 245A subgroup. Gross income and assets in the residual grouping for U.S. source income are also subdivided into a section 245A subgroup and a non-section 245A subgroup. Each section 245A subgroup is treated as a statutory grouping under § 1.861–8(a)(4). Deductions properly allocable or apportioned to dividends or stock described in paragraphs (a)(1)(ii) and (iii) of this section only include those deductions that are allocated and apportioned under §§ 1.861–8 through 1.861–14T and 1.861–17 to the section 245A subgroups. The deduction allowed under section 245A(a) for dividends is allocated and apportioned solely among the section 245A subgroups on the basis of the relative amounts of gross income from such dividends in each section 245A subgroup.

(c) *Income and assets in the 245A subgroups*—(1) *In general.* For purposes of applying the allocation and apportionment rules under §§ 1.861–8 through 1.861–14T and 1.861–17 to the deductions of a United States shareholder, the only gross income included in a section 245A subgroup is dividend income for which a deduction is allowed under section 245A. The only asset included in a section 245A subgroup is the portion of the value of stock of each specified 10-percent owned foreign corporation that is assigned to the section 245A subgroup determined under paragraph (c)(2) of this section.

(2) *Assigning stock to a subgroup.* The value of stock of a specified 10-percent owned foreign corporation is characterized as an asset in a separate category described in § 1.904–5(a)(4)(v) or the residual grouping for U.S. source income under the rules of § 1.861–12(c). If the specified 10-percent owned foreign corporation is not a controlled foreign corporation, all of the value of its stock (other than the portion of stock assigned to the statutory groupings for gross section 245(a)(5) income under §§ 1.861–12(c)(4) and 1.861–13) in each separate category and in the residual grouping for U.S. source income is assigned to the section 245A subgroup in such separate category or residual grouping. If the specified 10-percent owned foreign corporation is a controlled foreign corporation, a portion of the value of stock in each separate category and in the residual grouping for U.S. source income is subdivided between a section 245A and non-section 245A subgroup under § 1.861–13(a)(5).

(d) *Coordination with OFL and ODL rules.* Section 904(b)(4) and this section apply before the operation of the overall foreign loss rules in section 904(f) and the overall domestic loss rules in section 904(g).

(e) *Example.* The following example illustrates the application of this section.

(1) *Facts*—(i) *Income and assets of USP.* USP is a domestic corporation. USP owns a factory in the United States with a tax book value of $21,000. USP also directly owns all of the stock of each of the following three controlled foreign corporations: CFC1, CFC2, and CFC3. USP's tax book value in each of CFC1, CFC2, and CFC3 is $10,000. USP incurs $1,500 of interest expense and earns $1,600 of U.S. source gross income. Under section 951A and the section 951A regulations (as defined in § 1.951A–1(a)(1)), USP's GILTI inclusion amount is $2,200. USP's deduction under section 250 is $1,100 (''section 250 deduction''), all of which is by reason of section 250(a)(1)(B)(i). No portion of USP's section 250 deduction is reduced by reason of section 250(a)(2)(B). None of the CFCs makes any distributions.

(ii) *Characterization of CFC stock.* After application of § 1.861–13(a), USP determined that $7,300 of the stock of each of CFC1, CFC2, and CFC3 is assigned to the section 951A category (''section 951A category stock'') in the non-section 245A subgroup and the remaining $2,700 of the stock of each of CFC1, CFC2, and CFC3 is assigned to the general category (''general category stock'') in the section 245A subgroup. Additionally,

under § 1.861–8(d)(2)(ii)(C)(*2*), $3,650 of the stock of each of CFC1, CFC2, and CFC3 that is section 951A category stock is an exempt asset. Accordingly, with respect to the stock of its controlled foreign corporations in the aggregate, USP has $10,950 of section 951A category stock in a non-section 245A subgroup; $8,100 of general category stock in a section 245A subgroup; and $10,950 of stock that is an exempt asset.

(iii) *Apportioning of expenses.* Taking into account USP's factory and its stock in CFC1, CFC2, and CFC3, the tax book value of USP's assets for purposes of apportioning expenses is $40,050 (excluding the $10,950 of exempt assets). Under § 1.861–9T(g), USP's $1,500 of interest expense is apportioned as follows: $410 ($1,500 × $10,950/$40,050) to section 951A category income, $303 ($1,500 × $8,100/$40,050) to general category income, and the remaining $787 ($1,500 × $21,000/$40,050) to the residual U.S. source grouping. Under § 1.861–8(e)(14), all of USP's section 250 deduction is allocated and apportioned to section 951A category income.

(2) *Analysis*—(i) *USP's pre-credit U.S. tax.* USP's worldwide taxable income is $1,200, which equals its GILTI inclusion amount of $2,200 plus its U.S. source gross income of $1,600, less its deduction under section 250 of $1,100 and its interest expense of $1,500. For purposes of applying section 904(a), before taking into account any foreign tax credit under section 901, USP's federal income tax liability is 21% of $1,200, or $252.

(ii) *Application of section 904(b)(4).* Under section 904(d)(1), USP applies section 904(a) separately to each separate category of income.

(A) *General category income.* Before application of section 904(b)(4) and the rules in this section, USP's foreign source taxable income in the general category is a loss of $303, which equals $0 (USP's foreign source general category income) less $303 (interest expense apportioned to general category income), and USP's worldwide taxable income is $1,200. Under paragraph (d) of this section, the rules in section 904(f) and (g) apply after section 904(b)(4) and the rules in this section. Under paragraphs (b) and (c)(1) of this section, USP has no deductions properly allocable or apportioned to gross income in the section 245A subgroup because USP has no dividend income in the general category for which a deduction is allowed under section 245A. Under paragraphs (b) and (c) of this section, USP has $303 of deductions for interest expense that are properly allocable or apportioned to stock of specified 10-percent owned foreign corporations in the section 245A subgroup because USP's only general category assets are the general category stock of CFC1, CFC2, and CFC3, all of which are in the section 245A subgroup. Therefore, under paragraph (a) of this section, USP's foreign source taxable income in the general category and its worldwide taxable income are determined without regard to the $303 of deductions for interest expense. Accordingly, USP's foreign source taxable income in the general category is $0 and its worldwide taxable income is $1,503, and therefore, there is no separate limitation loss for purposes of section 904(f). Under section 904(a) and (d)(1) USP's foreign tax credit limitation for the general category is $0.

(B) *Section 951A category income.* Before application of section 904(b)(4) and the rules in this section, USP's foreign source taxable income in the section 951A category is $690, which equals $2,200 (USP's GILTI inclusion amount) less $1,100 (USP's section 250 deduction) less $410 (interest apportioned to section 951A category income). Under paragraphs (b) and (c)(1) of this section, USP has no deductions properly allocable and apportioned to gross income in a section 245A subgroup of the section 951A category. Under paragraphs (b) and (c) of this section, USP has no deductions properly allocable and apportioned to stock of specified 10-percent owned foreign corporations in a section 245A subgroup of section 951A category stock because no portion of section 951A category stock is assigned to a section 245A subgroup. *See* § 1.861–13(a)(5)(v). Therefore, under paragraph (a) of this section no adjustment is made to USP's foreign source taxable income in the section 951A category. However, the adjustments to USP's worldwide taxable income described in paragraph (e)(2)(ii)(A) of this section apply for purposes of calculating USP's foreign tax credit limitation for the section 951A category. Accordingly, USP's foreign source taxable income in the section 951A category is $690 and its worldwide taxable income is $1,503. Under section 904(a) and (d)(1), USP's foreign tax credit limitation for the section 951A category is $116 ($252 × $690/$1,503).

(f) *Applicability date.* Except as provided in this paragraph (f), this section applies to taxable years beginning after December 31, 2017. For a taxable year that both begins before January 1, 2018, and ends after December 31, 2017, this section applies without regard to the rules relating to inclusions arising under section 951A.

■ **Par. 19.** § 1.904(f)–12 is amended by adding and reserving paragraph (i) and adding paragraph (j) to read as follows:

§ 1.904(f)–12 Transition rules.

* * * * *

(i) [Reserved]

(j) *Recapture in years beginning after December 31, 2017, of separate limitation losses, overall foreign losses, and overall domestic losses incurred in years beginning before January 1, 2018*—(1) *Definitions*—(i) The term *pre-2018 separate categories* means the separate categories of income described in section 904(d) and any specified separate categories of income, as applicable to taxable years beginning before January 1, 2018.

(ii) The term *post-2017 separate categories* means the separate categories of income described in section 904(d) and any specified separate categories of income, as applicable to taxable years beginning after December 31, 2018.

(iii) The term *specified separate category* has the meaning set forth in § 1.904–4(m)).

(2) *Losses related to pre-2018 passive category income or a specified separate category of income*—(i) *Allocation of separate limitation loss or overall foreign loss account incurred in a pre-2018 separate category for passive category income or a specified separate category of income.* To the extent that a taxpayer has a balance in any separate limitation loss or overall foreign loss account in a pre-2018 separate category for passive category income or a specified separate category of income at the end of the taxpayer's last taxable year beginning before January 1, 2018, the amount of such balance is allocated on the first day of the taxpayer's next taxable year to the same post-2017 separate category as the pre-2018 separate category of the separate limitation loss or overall foreign loss account.

(ii) *Recapture of separate limitation loss or overall domestic loss that reduced pre-2018 passive category income or a specified separate category of income.* To the extent that at the end of the taxpayer's last taxable year beginning before January 1, 2018, a taxpayer has a balance in any separate limitation loss or overall domestic loss account which offset pre-2018 separate category income that was passive category income or income in a specified separate category, such loss is recaptured in subsequent taxable years as income in the same post-2017 separate category as the pre-2018 separate category of income that was offset by the loss.

(3) *Losses related to pre-2018 general category income*—(i) *Allocation of separate limitation loss or overall foreign loss account incurred in a pre-2018 separate category for general category income.* To the extent that a taxpayer has a balance in any separate limitation loss or overall foreign loss account in a pre-2018 separate category for general category income at the end of the taxpayer's last taxable year beginning before January 1, 2018, the amount of such balance is allocated on the first day of the taxpayer's next taxable year to the taxpayer's post-2017 separate category for general category income, or, if the taxpayer applies the exception described in § 1.904–2(j)(1)(iii), on a pro rata basis to the taxpayer's post-2017 separate categories for general category and foreign branch category income, based on the proportion in which any unused foreign taxes in the same pre-2018 separate category for general category income are allocated under § 1.904–2(j)(1)(iii)(A). If

the taxpayer has no unused foreign taxes in the pre-2018 separate category for general category income, then any loss account balance in that category is allocated to the post-2017 separate category for general category income.

(ii) *Recapture of separate limitation loss or overall domestic loss that reduced pre-2018 general category income.* To the extent that a taxpayer's separate limitation loss or overall domestic loss offset pre-2018 separate category income that was general category income, the balance in the loss account at the end of the taxpayer's last taxable year beginning before January 1, 2018, is recaptured in subsequent taxable years as income in the post-2017 separate category for general category income, or, if the taxpayer applies the exception described in § 1.904–2(j)(1)(iii), on a pro rata basis as income in the post-2017 separate categories for general category and foreign branch category income, based on the proportion in which any unused foreign taxes in the pre-2018 separate category for general category income are allocated under § 1.904–2(j)(1)(iii)(A). If the taxpayer has no unused foreign taxes in the pre-2018 separate category for general category income, then the loss account balance shall be recaptured in subsequent taxable years solely as income in the post-2017 separate category for general category income.

(4) *Treatment of foreign losses that are part of net operating losses incurred in pre-2018 taxable years which are carried forward to post-2017 taxable years.* A foreign loss that is part of a net operating loss incurred in a taxable year beginning before January 1, 2018, which is carried forward, pursuant to section 172, to a taxable year beginning after December 31, 2017, will be carried forward under the rules of § 1.904(g)–3(b)(2). For purposes of applying those rules, the portion of a net operating loss carryforward that is attributable to a foreign loss from the pre-2018 separate category for passive category income or a specified separate category of income will be treated as a loss in the same post-2017 separate category as the pre-2018 separate category. The portion of a net operating loss carryforward that is attributable to a foreign loss from the pre-2018 separate category for general category income must be treated as a loss in the post-2017 separate category for general or branch category income under the allocation principles of paragraph (j)(3)(i) of this section.

(5) *Applicability date.* This paragraph (j) applies to taxable years beginning after December 31, 2017.

§ 1.952–1 [Amended]

■ **Par. 20.** Section 1.952–1 is amended by removing the language ''§ 1.904–5(a)(1)'' and adding in its place the language ''§ 1.904–5(a)(4)(v)'' in the first sentence of paragraph (e)(5).

■ **Par. 21.** Section 1.954–1 is amended by:

■ 1. Removing the language ''§ 1.904–5(a)(1)'' and adding in its place the language ''§ 1.904–5(a)(4)(v)'' in the introductory text of paragraph (c)(1)(iii)(A).

■ 2. Removing the language ''section 960'' and adding in its place the language ''section 960(a) and § 1.960–2(b)(1)'' in the first sentence of paragraph (d)(3)(i).

■ 3. Removing the language ''section 960'' and adding in its place the language ''section 960(a)'' in the second sentence of paragraph (d)(3)(i).

■ 4. Revising the last sentence of paragraph (d)(3)(i).

■ 5. Adding a sentence at the end of paragraph (d)(3)(i).

■ 6. Removing the language ''section 960'' and adding in its place the language ''section 960(a) and § 1.960–2(b)(1)'' in paragraph (d)(3)(ii).

■ 7. Adding a sentence at the end of paragraph (d)(3)(ii).

■ 8. Removing paragraph (g)(4).

■ 9. Adding paragraph (h).

The revision and additions read as follows:

§ 1.954–1 Foreign base company income.

* * * * *

(d) * * *

(3) * * *

(i) * * * Except as provided in the next sentence, the amount of foreign income taxes paid or accrued with respect to a net item of income, determined in the manner provided in this paragraph (d), is not affected by a subsequent reduction in foreign income taxes attributable to a distribution to shareholders of all or part of such income. To the extent the foreign income taxes paid or accrued by the controlled foreign corporation are reasonably certain to be returned by the foreign jurisdiction imposing such taxes to a shareholder, directly or indirectly, through any means (including, but not limited to, a refund, credit, payment, discharge of an obligation, or any other method) on a subsequent distribution to such shareholder, the foreign income taxes are not treated as paid or accrued for purposes of this paragraph (d)(3)(i).

(ii) * * * However, notwithstanding the rules in § 1.904–4(c)(7), to the extent the foreign income taxes paid or accrued by the controlled foreign corporation are reasonably certain to be returned by the foreign jurisdiction imposing such taxes to a shareholder, directly or indirectly, through any means (including, but not limited to, a refund, credit, payment, discharge of an obligation, or any other method) on a subsequent distribution to such shareholder, the foreign income taxes are not treated as paid or accrued for purposes of this paragraph (d)(3)(ii).

* * * * *

(h) *Applicability dates*—(1) *Paragraphs (d)(3)(i) and (ii).* Paragraphs (d)(3)(i) and (ii) of this section apply to taxable years of a controlled foreign corporation ending on or after December 4, 2018.

(2) *Paragraph (g).* Paragraph (g) of this section applies to taxable years of a controlled foreign corporation beginning on or after July 23, 2002.

■ **Par. 22.** Section 1.960–1 is revised to read as follows:

§ 1.960–1 Overview, definitions, and computational rules for determining foreign income taxes deemed paid under section 960(a), (b), and (d).

(a) *Overview*—(1) *Scope of §§ 1.960–1 through 1.960–3.* This section and §§ 1.960–2 and 1.960–3 provide rules to associate foreign income taxes of a controlled foreign corporation with the income that a domestic corporation that is a United States shareholder of the controlled foreign corporation takes into account in determining a subpart F inclusion or GILTI inclusion amount of the domestic corporation, as well as to associate foreign income taxes of a controlled foreign corporation with distributions of previously taxed earnings and profits. These regulations provide the exclusive rules for determining the foreign income taxes deemed paid by a domestic corporation. Therefore, only foreign income taxes of a controlled foreign corporation that are associated under these rules with a subpart F inclusion or GILTI inclusion amount of a domestic corporation that is a United States shareholder of the controlled foreign corporation, or with previously taxed earnings and profits, are eligible to be deemed paid. This section provides definitions and computational rules for determining foreign income taxes deemed paid under section 960(a), (b), and (d). Section 1.960–2 provides rules for computing the amount of foreign income taxes deemed paid by a domestic corporation that is a United States shareholder of a controlled foreign corporation under section 960(a) and (d). Section 1.960–3 provides rules for computing the amount of foreign income taxes deemed paid by a domestic corporation that is a United States shareholder of a controlled foreign corporation, or by a controlled

foreign corporation, under section 960(b).

(2) *Scope of this section.* Paragraph (b) of this section provides definitions for purposes of this section and §§ 1.960–2 and 1.960–3. Paragraph (c) of this section provides computational rules to coordinate the various calculations under this section and §§ 1.960–2 and 1.960–3. Paragraph (d) of this section provides rules for computing the income in an income group within a section 904 category, and for associating foreign income taxes with an income group. Paragraph (e) of this section provides a rule for the creditability of taxes associated with the residual income group. Paragraph (f) of this section provides an example illustrating the application of this section.

(b) *Definitions.* The following definitions apply for purposes of this section and §§ 1.960–2 and 1.960–3.

(1) *Annual PTEP account.* The term *annual PTEP account* has the meaning set forth in § 1.960–3(c)(1).

(2) *Controlled foreign corporation.* The term *controlled foreign corporation* means a foreign corporation described in section 957(a).

(3) *Current taxable year.* The term *current taxable year* means the U.S. taxable year of a controlled foreign corporation that is an inclusion year, or during which the controlled foreign corporation receives a section 959(b) distribution or makes a section 959(a) distribution or a section 959(b) distribution.

(4) *Current year taxes.* The term *current year taxes* means foreign income taxes paid or accrued by a controlled foreign corporation in a current taxable year. Foreign income taxes accrue when all the events have occurred that establish the fact of the liability and the amount of the liability can be determined with reasonable accuracy. *See* §§ 1.446–1(c)(1)(ii)(A) and 1.461–4(g)(6)(iii)(B) (economic performance exception for certain foreign taxes). Withholding taxes described in section 901(k)(1)(B) that are withheld from a payment accrue when the payment is made. Foreign income taxes calculated on the basis of net income recognized in a foreign taxable year accrue on the last day of the foreign taxable year. Accordingly, current year taxes include foreign withholding taxes that are withheld from payments made to the controlled foreign corporation during the current taxable year, and foreign income taxes that accrue in the controlled foreign corporation's current taxable year in which or with which its foreign taxable year ends. Additional payments of foreign income taxes resulting from a redetermination of foreign tax liability, including contested taxes that accrue when the contest is resolved, ''relate back'' and are considered to accrue as of the end of the foreign taxable year to which the taxes relate.

(5) *Foreign income taxes.* The term *foreign income taxes* means income, war profits, and excess profits taxes as defined in § 1.901–2(a), and taxes included in the term income, war profits, and excess profits taxes by reason of section 903 and § 1.903–1(a), that are imposed by a foreign country or a possession of the United States, including any such taxes that are deemed paid by a controlled foreign corporation under section 960(b). Income, war profits, and excess profits taxes do not include amounts excluded from the definition of those taxes pursuant to section 901 and the regulations under that section. See, for example, section 901(f), (g), and (i). Foreign income taxes also do not include taxes paid by a controlled foreign corporation for which a credit is disallowed at the level of the controlled foreign corporation. See, for example, sections 245A(e)(3), 901(k)(1), (l), and (m), 909, and 6038(c)(1)(B). Foreign income taxes, however, include taxes that may be deemed paid but for which a credit is reduced or disallowed at the level of the United States shareholder. See, for example, sections 901(e), 901(j), 901(k)(2), 908, 965(g), and 6038(c)(1)(A).

(6) *Foreign taxable year.* The term *foreign taxable year* has the meaning set forth in section 7701(a)(23), applied by substituting ''under foreign law'' for the phrase ''under subtitle A.''

(7) *GILTI inclusion amount.* The term *GILTI inclusion amount* has the meaning set forth in § 1.951A–1(c)(1) (or, in the case of a member of a consolidated group, § 1.1502–51(b)).

(8) *Gross tested income.* The term *gross tested income* has the meaning set forth in § 1.951A–2(c)(1).

(9) *Inclusion percentage.* The term *inclusion percentage* has the meaning set forth in § 1.960–2(c)(2).

(10) *Inclusion year.* The term *inclusion year* means the U.S. taxable year of a controlled foreign corporation which ends during or with the taxable year of a United States shareholder of the controlled foreign corporation in which the United States shareholder includes an amount in income under section 951(a)(1) or 951A(a) with respect to the controlled foreign corporation.

(11) *Income group.* The term *income group* means a group of income described in paragraph (d)(2)(ii) of this section.

(12) *Partnership CFC.* The term *partnership CFC* has the meaning set forth in § 1.951A–5(e)(2).

(13) *Passive category.* The term *passive category* means the separate category of income described in section 904(d)(1)(C) and § 1.904–4(b).

(14) *Previously taxed earnings and profits.* The term *previously taxed earnings and profits* means earnings and profits described in section 959(c)(1) or (2), including earnings and profits described in section 959(c)(2) by reason of section 951A(f)(1) and § 1.951A–6(b)(1).

(15) *PTEP group.* The term *PTEP group* has the meaning set forth in § 1.960–3(c)(2).

(16) *PTEP group taxes.* The term *PTEP group taxes* has the meaning set forth in § 1.960–3(d)(1).

(17) *Recipient controlled foreign corporation.* The term *recipient controlled foreign corporation* has the meaning set forth in § 1.960–3(b)(2).

(18) *Reclassified previously taxed earnings and profits.* The term *reclassified previously taxed earnings and profits* has the meaning set forth in § 1.960–3(c)(4).

(19) *Reclassified PTEP group.* The term *reclassified PTEP group* has the meaning set forth in § 1.960–3(c)(4).

(20) *Residual income group.* The term *residual income group* has the meaning set forth in paragraph (d)(2)(ii)(D) of this section.

(21) *Section 904 category.* The term *section 904 category* means a separate category of income described in § 1.904–5(a)(4)(v).

(22) *Section 951A category.* The term *section 951A category* means the separate category of income described in section 904(d)(1)(A) and § 1.904–4(g).

(23) *Section 959 distribution.* The term *section 959 distribution* means a section 959(a) distribution or a section 959(b) distribution.

(24) *Section 959(a) distribution.* The term *section 959(a) distribution* means a distribution excluded from the gross income of a United States shareholder under section 959(a).

(25) *Section 959(b) distribution.* The term *section 959(b) distribution* means a distribution excluded from the gross income of a controlled foreign corporation for purposes of section 951(a) under section 959(b).

(26) *Section 959(c)(2) PTEP group.* The term *section 959(c)(2) PTEP group* has the meaning set forth in § 1.960–3(c)(4).

(27) *Subpart F inclusion.* The term *subpart F inclusion* has the meaning set forth in § 1.960–2(b)(1).

(28) *Subpart F income.* The term *subpart F income* has the meaning set forth in section 952 and § 1.952–1(a).

(29) *Subpart F income group.* The term *subpart F income group* has the meaning set forth in paragraph (d)(2)(ii)(B)(*1*) of this section.

(30) *Tested foreign income taxes.* The term *tested foreign income taxes* has the meaning set forth in § 1.960–2(c)(3).

(31) *Tested income.* The term *tested income* means the amount with respect to a controlled foreign corporation that is described in section 951A(c)(2)(A) and § 1.951A–2(b)(1).

(32) *Tested income group.* The term *tested income group* has the meaning set forth in paragraph (d)(2)(ii)(C) of this section.

(33) *United States shareholder.* The term *United States shareholder* has the meaning set forth in section 951(b).

(34) *U.S. shareholder partner.* The term *U.S. shareholder partner* has the meaning set forth in § 1.951A–5(e)(3).

(35) *U.S. shareholder partnership.* The term *U.S. shareholder partnership* has the meaning set forth in § 1.951A–5(e)(4).

(36) *U.S. taxable year.* The term *U.S. taxable year* has the same meaning as that of the term *taxable year* set forth in section 7701(a)(23).

(c) *Computational rules*—(1) *In general.* For purposes of computing foreign income taxes deemed paid by either a domestic corporation that is a United States shareholder with respect to a controlled foreign corporation under § 1.960–2 or 1.960–3 or by a controlled foreign corporation under § 1.960–3 for the current taxable year, the following rules apply in the following order, beginning with the lowest-tier controlled foreign corporation in a chain with respect to which the domestic corporation is a United States shareholder:

(i) First, items of gross income of the controlled foreign corporation for the current taxable year other than a section 959(b) distribution are assigned to section 904 categories and included in income groups within those section 904 categories under the rules in paragraph (d)(2) of this section. The receipt of a section 959(b) distribution by the controlled foreign corporation is accounted for under § 1.960–3(c)(3).

(ii) Second, deductions (other than for current year taxes) of the controlled foreign corporation for the current taxable year are allocated and apportioned to reduce gross income in the section 904 categories and the income groups within a section 904 category. See paragraph (d)(3)(i) of this section. Additionally, the functional currency amounts of current year taxes of the controlled foreign corporation for the current taxable year are allocated and apportioned to reduce gross income in the section 904 categories and the income groups within a section 904 category, and to reduce earnings and profits in any PTEP groups that were increased as provided in paragraph (c)(1)(i) of this section. See paragraph (d)(3)(ii) of this section. For purposes of computing foreign taxes deemed paid, current year taxes allocated and apportioned to income groups and PTEP groups in the section 904 categories are translated into U.S. dollars in accordance with section 986(a). See paragraph (c)(3) of this section.

(iii) Third, current year taxes deemed paid under section 960(a) and (d) by the domestic corporation with respect to income of the controlled foreign corporation are computed under the rules of § 1.960–2. In addition, foreign income taxes deemed paid under section 960(b)(2) with respect to the receipt of a section 959(b) distribution by the controlled foreign corporation are computed under the rules of § 1.960–3(b).

(iv) Fourth, any previously taxed earnings and profits of the controlled foreign corporation resulting from subpart F inclusions and GILTI inclusion amounts with respect to the controlled foreign corporation's current taxable year are separated from other earnings and profits of the controlled foreign corporation and added to an annual PTEP account, and a PTEP group within the PTEP account, under the rules of § 1.960–3(c).

(v) Fifth, paragraphs (c)(1)(i) through (iv) of this section are repeated for each next higher-tier controlled foreign corporation in the chain.

(vi) Sixth, with respect to the highest-tier controlled foreign corporation in a chain that is owned directly (or indirectly through a partnership) by the domestic corporation, foreign income taxes that are deemed paid under section 960(b)(1) in connection with the receipt of a section 959(a) distribution by the domestic corporation are computed under the rules of § 1.960–3(b).

(2) *Inclusion of current year items.* For a current taxable year, the items of income and deductions (including for taxes), and the U.S. dollar amounts of current year taxes, that are included in the computations described in this section and assigned to income groups and PTEP groups for the taxable year are the items that the controlled foreign corporation accrues and takes into account during the current taxable year.

(3) *Functional currency and translation.* The computations described in this paragraph (c) that relate to income and earnings and profits are made in the functional currency of the controlled foreign corporation (as determined under section 985), and references to taxes deemed paid are to U.S. dollar amounts (translated in accordance with section 986(a)).

(d) *Computing income in a section 904 category and an income group within a section 904 category*—(1) *Scope.* This paragraph (d) provides rules for assigning gross income (including gains) of a controlled foreign corporation for the current taxable year to a section 904 category and income group within a section 904 category, and for allocating and apportioning deductions (including losses and current year taxes) and the U.S. dollar amount of current year taxes of the controlled foreign corporation for the current taxable year among the section 904 categories, income groups within a section 904 category, and PTEP groups. For rules regarding maintenance of previously taxed earnings and profits in an annual PTEP account, and assignment of those previously taxed earnings and profits to PTEP groups, see § 1.960–3.

(2) *Assignment of gross income to section 904 categories and income groups within a category*—(i) *Assigning items of gross income to section 904 categories.* Items of gross income of the controlled foreign corporation for the current taxable year are first assigned to a section 904 category of the controlled foreign corporation under §§ 1.904–4 and 1.904–5, and under § 1.960–3(c)(1) in the case of gross income relating to a section 959(b) distribution received by the controlled foreign corporation. Income of a controlled foreign corporation, other than gross income relating to a section 959(b) distribution, cannot be assigned to the section 951A category or the foreign branch category. *See* § 1.904–4(f) and (g).

(ii) *Grouping gross income within a section 904 category*—(A) *In general.* Gross income within a section 904 category is assigned to an income group under the rules of this paragraph (d)(2)(ii), or to a PTEP group under the rules of § 1.960–3(c)(3). Gross income other than a section 959(b) distribution is assigned to a subpart F income group, tested income group, or residual income group.

(B) *Subpart F income groups*—(*1*) *In general.* The term *subpart F income group* means an income group within a section 904 category that consists of income that is described in paragraph (d)(2)(ii)(B)(*2*) of this section. Gross income that is treated as a single item of income under § 1.954–1(c)(1)(iii) is in a separate subpart F income group under paragraph (d)(2)(ii)(B)(*2*)(*i*) of this section. Items of gross income that give

rise to income described in paragraph (d)(2)(ii)(B)(*2*)(*ii*) of this section are aggregated and treated as gross income in a separate subpart F income group. Similarly, items of gross income that give rise to income described in each one of paragraphs (d)(2)(ii)(B)(*2*)(*iii*) through (*v*) of this section are aggregated and treated as gross income in a separate subpart F income group.

(*2*) *Income in subpart F income groups.* The income included in subpart F income groups is:

(*i*) Items of foreign base company income treated as a single item of income under § 1.954–1(c)(1)(iii);

(*ii*) Insurance income described in section 952(a)(1);

(*iii*) Income subject to the international boycott factor described in section 952(a)(3);

(*iv*) Income from certain bribes, kickbacks and other payments described in section 952(a)(4); and

(*v*) Income subject to section 901(j) described in section 952(a)(5).

(C) *Tested income groups.* The term *tested income group* means an income group that consists of tested income within a section 904 category. Items of gross tested income in each section 904 category are aggregated and treated as gross income in a separate tested income group.

(D) *Residual income group.* The term *residual income group* means the income group within a section 904 category that consists of income not described in paragraph (d)(2)(ii)(B) or (C) of this section.

(E) *Examples.* The following examples illustrate the application of this paragraph (d)(2)(ii).

(*1*) *Example 1: Subpart F income groups*—(*i*) *Facts.* CFC, a controlled foreign corporation, is incorporated in Country X. CFC uses the ''u'' as its functional currency. At all relevant times, 1u=$1. CFC earns from sources outside of Country X portfolio dividend income of 100,000u, portfolio interest income of 1,500,000u, and 70,000u of royalty income that is not derived from the active conduct of a trade or business. CFC also earns 50,000u from the sale of personal property to a related person for use outside of Country X that gives rise to foreign base company sales income under section 954(d). Finally, CFC earns 45,000u for performing consulting services outside of Country X for related persons that gives rise to foreign base company services income under section 954(e). None of the income is taxed by Country X. The dividend income is subject to a 15 percent third-country withholding tax after application of the applicable income tax treaty. The interest income and the royalty income are subject to no third-country withholding tax. CFC incurs no expenses.

(*ii*) *Analysis.* Under paragraph (d)(2)(i) of this section and § 1.904–4, the interest income, dividend income, and royalty income are passive category income and the sales and consulting income are general category income. Under paragraph (d)(2)(ii)(B) of this section, CFC has a separate subpart F income group within the passive category with respect to the 100,000u of dividend income, which is foreign personal holding company income described in § 1.954–1(c)(1)(iii)(A)(*1*)(*i*) (dividends, interest, rents, royalties and annuities) that falls within a single group of income under § 1.904–4(c)(3)(i) for passive income that is subject to withholding tax of fifteen percent or greater. CFC also has a separate subpart F income group within the passive category with respect to the 1,500,000u of interest income and the 70,000u of royalty income (in total 1,570,000u) which together are foreign personal holding company income described in § 1.954–1(c)(1)(iii)(A)(*1*)(*i*) (dividends, interest, rents, royalties and annuities) that falls within a single group of income under § 1.904–4(c)(3)(iii) for passive income that is subject to no withholding tax or other foreign tax. With respect to its 50,000u of sales income, CFC has a separate subpart F income group with respect to foreign base company sales income described in § 1.954–1(c)(1)(iii)(A)(*2*)(*i*) within the general category. With respect to its 45,000u of services income, CFC has a separate subpart F income group with respect to foreign base company services income described in § 1.954–1(c)(1)(iii)(A)(*2*)(*ii*) within the general category.

(*2*) *Example 2: Tested income groups*—(*i*) *Facts.* CFC, a controlled foreign corporation, is incorporated in Country X. CFC uses the ''u'' as its functional currency. At all relevant times, 1u=$1. CFC earns 500u from the sale of goods to unrelated parties. CFC also earns 75u for performing consulting services for unrelated parties. All of its income is gross tested income. CFC incurs no deductions.

(*ii*) *Analysis.* Under paragraph (d)(2)(i) of this section and section 904 and § 1.904–4, the sales income and services income are both general category income. Under paragraph (d)(2)(ii)(C) of this section, with respect to the 500u of sales income and 75u services income (in total 575u), CFC has one tested income group within the general category.

(3) *Allocation and apportionment of deductions among section 904 categories, income groups within a section 904 category, and certain PTEP groups*—(i) *In general.* Gross income of the controlled foreign corporation in each income group within each section 904 category is reduced by deductions (including losses) of the controlled foreign corporation for the current taxable year under the following rules.

(A) First, the rules of sections 861 through 865 and 904(d) and the regulations under those sections (taking into account the rules of section 954(b)(5) and § 1.954–1(c), and section 951A(c)(2)(A)(ii) and § 1.951A–2(c)(3), as appropriate) apply to allocate and apportion to reduce gross income (or create a loss) in each section 904 category and income group within a section 904 category any deductions of the controlled foreign corporation that are definitely related to less than all of the controlled foreign corporation's gross income as a class. See paragraph (d)(3)(ii) of this section for special rules for allocating and apportioning current year taxes to section 904 categories, income groups, and PTEP groups.

(B) Second, related person interest expense is allocated to and apportioned among the subpart F income groups within the passive category under the principles of § 1.904–5(c)(2) and § 1.954–1(c)(1)(i).

(C) Third, any remaining deductions are allocated and apportioned to reduce gross income (or create a loss) in the section 904 categories and income groups within each section 904 category under the rules referenced in paragraph (d)(3)(i)(A) of this section. No deductions of the controlled foreign corporation for the current taxable year other than a deduction for current year taxes imposed solely by reason of the receipt of a section 959(b) distribution are allocated or apportioned to reduce earnings and profits in a PTEP group.

(ii) *Allocation and apportionment of current year taxes*—(A) *In general.* Current year taxes are allocated and apportioned among the section 904 categories under the rules of § 1.904–6(a)(1)(i) and (ii) on the basis of the amount of taxable income computed under foreign law in each section 904 category that is included in the foreign tax base. Current year taxes in a section 904 category are then allocated and apportioned among the income groups within a section 904 category under the principles of § 1.904–6(a)(1)(i) and (ii). If the amount of previously taxed earnings and profits in a PTEP group is increased in the current taxable year of the controlled foreign corporation under § 1.960–3(c)(3) by reason of the receipt of a section 959(b) distribution, then for purposes of allocating and apportioning current year taxes that are imposed solely by reason of the receipt of the section 959(b) distribution under this paragraph (d)(3)(ii)(A), the PTEP group is treated as an income group within the section 904 category. In applying § 1.904–6(a)(1)(i) and (ii) for purposes of this paragraph (d)(3)(ii)(A), the gross items of income and deduction calculated under foreign law that are included in a section 904 category, income group, or PTEP group that is treated as an income group are the items that are included in taxable income under foreign law for the foreign taxable year of the controlled foreign corporation that ends with or within the controlled foreign corporation's current

taxable year. For purposes of determining foreign income taxes deemed paid under the rules in §§ 1.960–2 and 1.960–3, the U.S. dollar amounts of current year taxes are assigned to the section 904 categories, income groups, and PTEP groups, if any, to which the current year taxes are allocated and apportioned.

(B) *Base and timing differences*—(*1*) *In general.* Current year taxes that are attributable to a base difference described in § 1.904–6(a)(1)(iv) are not allocated and apportioned to any subpart F income group, tested income group or PTEP group, but are treated as related to income in the residual income group. Except as provided in paragraph (d)(3)(ii)(B)(*2*) of this section, current year taxes that are attributable to a timing difference described in § 1.904–6(a)(1)(iv) are treated as related to the appropriate section 904 category and income group within a section 904 category to which the particular tax would be assigned if the income on which the tax is imposed were recognized under Federal income tax principles in the year in which the tax was imposed.

(*2*) *Tax on previously taxed earnings and profits.* Current year taxes imposed solely by reason of the controlled foreign corporation's receipt of a section 959(b) distribution are not allocated and apportioned under the general rule for timing differences but are allocated or apportioned to a PTEP group. Current year taxes imposed with respect to previously taxed earnings and profits by reason of any other timing difference are allocated or apportioned, under the general rule described in paragraph (d)(3)(ii)(B)(*1*) of this section, to the income group to which the income that gave rise to the previously taxed earnings and profits was assigned in the inclusion year. For example, a net basis tax imposed on a controlled foreign corporation's receipt of a section 959(b) distribution by the corporation's country of residence is allocated or apportioned to a PTEP group. Similarly, a withholding tax imposed with respect to a controlled foreign corporation's receipt of a section 959(b) distribution is allocated and apportioned to a PTEP group. In contrast, a withholding tax imposed on a disregarded payment from a disregarded entity to its controlled foreign corporation owner is treated as a timing difference and is never treated as related to a PTEP group, even if all of the controlled foreign corporation's earnings are previously taxed earnings and profits, because the tax is not imposed solely by reason of a section 959(b) distribution. Such a withholding tax, however, may be treated as related to a subpart F income group or tested income group under the general rule for timing differences.

(e) *No deemed paid credit for current year taxes related to residual income group.* Current year taxes paid or accrued by a controlled foreign corporation that are allocated and apportioned under paragraph (d)(3)(ii) of this section to a residual income group cannot be deemed paid under section 960 for any taxable year.

(f) *Example.* The following example illustrates the application of this section and § 1.960–3.

(1) *Facts*—(i) *Income of CFC1 and CFC2.* CFC1, a controlled foreign corporation, conducts business in Country X. CFC1 uses the ''u'' as its functional currency. At all relevant times, 1u=$1. CFC1 owns all of the stock of CFC2, a controlled foreign corporation. CFC1 and CFC2 both use the calendar year as their U.S. and foreign taxable years. In 2019, CFC1 earns 2,000,000u of gross income that is foreign oil and gas extraction income, within the meaning of section 907(c)(1), and 2,000,000u of interest income from unrelated persons, for both U.S. and Country X tax law purposes. Country X exempts interest income from tax. In 2019, CFC1 also receives a section 959(b) distribution from CFC2 of 4,000,000u of previously taxed earnings and profits attributable to an inclusion under section 965(a) for CFC2's 2017 U.S. taxable year. The inclusion under section 965(a) was income in the general category. There are no PTEP group taxes associated with the previously taxed earnings and profits distributed by CFC2 at the level of CFC2. The section 959(b) distribution is treated as a dividend taxable to CFC1 under Country X law. In 2019, CFC2 earns no gross income and receives no distributions.

(ii) *Pre-tax deductions of CFC1 and CFC2.* For both U.S. and Country X tax purposes, in 2019, CFC1 incurs 1,500,000u of deductible expenses other than current year taxes that are allocable to all gross income. For U.S. tax purposes, under §§ 1.861–8 through 1.861–14T, 750,000u of such deductions are apportioned to each of CFC1's foreign oil and gas extraction income and interest income. Under Country X law, 1,000,000u of deductions are allocated and apportioned to the 4,000,000u treated as a dividend, and 500,000u of deductions are allocated and apportioned to the 2,000,000u of foreign oil and gas extraction income. Under Country X law, no deductions are allocable to the interest income. Country X imposes tax of 900,000u on a base of 4,500,000u (6,000,000u gross income − 1,500,000u deductions) consisting of 3,000,000u (4,000,000u − 1,000,000u) attributable to CFC1's section 959(b) distribution and 1,500,000u (2,000,000u − 500,000u) attributable to CFC1's foreign oil and gas extraction income. In 2019, CFC2 has no expenses (including current year taxes).

(iii) *United States shareholders of CFC1.* All of the stock of CFC1 is owned (within the meaning of section 958(a)) by corporate United States shareholders that use the calendar year as their U.S. taxable year. In 2019, the United States shareholders of CFC1 include in gross income subpart F inclusions in the passive category totaling $1,250,000 with respect to 1,250,000u of subpart F income of CFC1.

(2) *Analysis*—(i) *CFC2.* Under paragraph (c)(1) of this section, the computational rules of paragraph (c)(1) of this section are applied beginning with CFC2. However, CFC2 has no gross income or expenses in 2019 (the ''current taxable year''). Accordingly, the computational rules described in paragraph (c)(1)(i) through (iv) of this section are not relevant with respect to CFC2. Under paragraph (c)(1)(v) of this section, the rules in paragraph (c)(1)(i) through (iv) of this section are then applied to CFC1.

(ii) *CFC1.* (A) *Step 1.* Under paragraph (c)(1)(i) of this section, CFC1's items of gross income for the current taxable year are assigned to section 904 categories and included in income groups within those section 904 categories. In addition, CFC1's receipt of a section 959(b) distribution is assigned to a PTEP group. Under paragraph (d)(2)(i) of this section and § 1.904–4, the interest income is passive category income and the foreign oil and gas extraction income is general category income. Under paragraph (d)(2)(ii) of this section, the 2,000,000u of interest income is assigned to a subpart F income group (the ''subpart F income group'') within the passive category because it is foreign personal holding company income described in § 1.954–1(c)(1)(iii)(A)(*1*)(*i*) that falls within a single group of income under § 1.904–4(c)(3)(iii) for passive income that is subject to no withholding tax or other foreign tax. The 2,000,000u of foreign oil and gas extraction income is assigned to the residual income group within the general category. Under § 1.960–3(c), the 4,000,000u section 959(b) distribution is assigned to the PTEP group described in § 1.960–3(c)(2)(vii) within the 2017 annual PTEP account (the ''PTEP group'') within the general category.

(B) *Step 2*—(*1*) *Allocation and apportionment of deductions for expenses other than taxes.* Under paragraph (c)(1)(ii) of this section, CFC1's deductions for the current taxable year are allocated and apportioned among the section 904 categories, income groups within a section 904 category, and any PTEP groups that were increased as provided in paragraph (c)(1)(i) of this section. Under paragraph (d)(3)(i) of this section and § 1.861–8 through 1.861–14T, 750,000u of deductions are allocated and apportioned to the residual income group within the general category, and 750,000u of deductions are allocated and apportioned to the subpart F income group within the passive category. Therefore, CFC1 has 1,250,000u (2,000,000u − 750,000u) of pre-tax income attributable to the residual income group within the general category and 1,250,000u (2,000,000u − 750,000u) of pre-tax income attributable to the subpart F income group within the passive category. For U.S. tax purposes, no deductions other than current year taxes are allocated and apportioned to the 4,000,000u in CFC1's PTEP group.

(*2*) *Allocation and apportionment of current year taxes.* Under paragraph (c)(1)(ii) of this section, CFC1's current year taxes are allocated and apportioned among the section 904 categories, income groups within a section 904 category, and any PTEP groups that were increased as provided in paragraph (c)(1)(i) of this section. Under paragraphs (d)(3)(i) and (ii) of this section, for purposes of allocating and apportioning taxes to reduce the income in a section 904 category, an income group, or PTEP group, § 1.904–6(a)(1) and (ii) are applied to determine the amount of taxable income computed under Country X law in each section 904 category, income group, and PTEP group that is included in the Country X tax base. For Country X purposes, 1,000,000u of deductions are apportioned to CFC1's PTEP group within the general category, 500,000u of deductions are apportioned to the residual income group within the general category, and no deductions are apportioned to the subpart F income group in the passive category. Therefore, for Country X purposes, CFC1 has 3,000,000u of income attributable to the PTEP group within the general category, 1,500,000u of income attributable to the residual income group within the general category, and no income attributable to the subpart F income group within the passive category. Under paragraph (d)(3)(ii) of this section, 600,000u (3,000,000u/4,500,000u × 900,000u) of the 900,000u current year taxes paid by CFC1 are related to the PTEP group within the general category, and 300,000u (1,500,000u/4,500,000u × 900,000u) are related to the residual income group within the general category. No current year taxes are allocated or apportioned to the subpart F income group within the passive category because the interest expense is exempt from Country X tax. Thus, for U.S. tax purposes, CFC1 has 3,400,000u of previously taxed earnings and profits (4,000,000u − 600,000u) in the PTEP group within the general category, 1,250,000u of income in the subpart F income group within the passive category, and 950,000u of income (1,250,000u − 300,000u) in the residual income group within the general category. For purposes of determining foreign taxes deemed paid under section 960, CFC1 has $600,000 of foreign income taxes in the PTEP group within the general category and $300,000 of current year taxes in the residual income group within the general category. Under paragraph (e) of this section, the United States shareholders of CFC1 cannot claim a credit with respect to the $300,000 of taxes on CFC1's income in the residual income group.

(C) *Step 3.* Under paragraph (c)(1)(iii) of this section, the United States shareholders of CFC1 compute current year taxes deemed paid under section 960(a) and (d) and the rules of § 1.960–2. None of the Country X tax is allocated to CFC1's subpart F income group. Therefore, there are no current year taxes deemed paid by CFC1's United States shareholders with respect to their passive category subpart F inclusions. See § 1.960–2(b)(5) and (c)(7) for examples of the application of section 960(a) and (d) and the rules in § 1.960–2. Additionally, under paragraph (c)(1)(iii) of this section, foreign income taxes deemed paid under section 960(b)(2) by CFC1 are determined with respect to the section 959(b) distribution from CFC2 under the rules of § 1.960–3. There are no PTEP group taxes associated with the previously taxed earnings and profits distributed by CFC2 in the hands of CFC2. Therefore, there are no foreign income taxes deemed paid by CFC1 under section 960(b)(2) with respect to the section 959(b) distribution from CFC2. See § 1.960–3(e) for examples of the application of section 960(b) and the rules in § 1.960–3.

(D) *Step 4.* Under paragraph (c)(1)(iv) of this section, previously taxed earnings and profits resulting from subpart F inclusions and GILTI inclusion amounts with respect to CFC1's current taxable year are separated from CFC1's other earnings and profits and added to an annual PTEP account and PTEP group within the PTEP account, under the rules of § 1.960–3(c). The United States shareholders of CFC1 include in gross income subpart F inclusions totaling $1,250,000 with respect to 1,250,000u of subpart F income of CFC1, and the subpart F inclusions are passive category income. Therefore, under § 1.960–3(c)(2), 1,250,000u of previously taxed earnings and profits resulting from the subpart F inclusions is added to CFC1's PTEP group described in § 1.960–3(c)(2)(x) within the 2019 annual PTEP account within the passive category.

(E) *Step 5.* Paragraph (c)(1)(v) of this section does not apply because CFC1 is the highest-tier controlled foreign corporation in the chain.

(F) *Step 6.* Paragraph (c)(1)(vi) of this section does not apply because CFC1 did not make a section 959(a) distribution.

■ **Par. 23.** Section 1.960–2 is revised to read as follows:

§ 1.960–2 Foreign income taxes deemed paid under sections 960(a) and (d).

(a) *Scope.* Paragraph (b) of this section provides rules for computing the amount of foreign income taxes deemed paid by a domestic corporation that is a United States shareholder of a controlled foreign corporation under section 960(a). Paragraph (c) of this section provides rules for computing the amount of foreign income taxes deemed paid by a domestic corporation that is a United States shareholder of a controlled foreign corporation under section 960(d).

(b) *Foreign income taxes deemed paid under section 960(a)*—(1) *In general.* If a domestic corporation that is a United States shareholder of a controlled foreign corporation includes in gross income under section 951(a)(1)(A) its pro rata share of the subpart F income of the controlled foreign corporation (a *subpart F inclusion*), the domestic corporation is deemed to have paid the amount of the controlled foreign corporation's foreign income taxes that are properly attributable to the items of income in a subpart F income group of the controlled foreign corporation that give rise to the subpart F inclusion of the domestic corporation that is attributable to the subpart F income group. For each section 904 category, the domestic corporation is deemed to have paid foreign income taxes equal to the sum of the controlled foreign corporation's foreign income taxes that are properly attributable to the items of income in the subpart F income groups to which the subpart F inclusion is attributable. See § 1.904–6(b)(1) for rules on assigning the foreign income tax to a section 904 category. No foreign income taxes are deemed paid under section 960(a) with respect to an inclusion under section 951(a)(1)(B).

(2) *Properly attributable.* The amount of the controlled foreign corporation's foreign income taxes that are properly attributable to the items of income in the subpart F income group of the controlled foreign corporation to which a subpart F inclusion is attributable equals the domestic corporation's proportionate share of the current year taxes of the controlled foreign corporation that are allocated and apportioned under § 1.960–1(d)(3)(ii) to the subpart F income group. No other foreign income taxes are considered properly attributable to an item of income of the controlled foreign corporation.

(3) *Proportionate share*—(i) *In general.* A domestic corporation's proportionate share of the current year taxes of a controlled foreign corporation that are allocated and apportioned under § 1.960–1(d)(3)(ii) to a subpart F income group within a section 904 category of the controlled foreign corporation is equal to the total U.S. dollar amount of current year taxes that are allocated and apportioned under § 1.960–1(d)(3)(ii) to the subpart F income group multiplied by a fraction (not to exceed one), the numerator of which is the portion of the domestic corporation's subpart F inclusion that is attributable to the subpart F income group and the denominator of which is the total net income in the subpart F income group, both determined in the functional currency of the controlled foreign corporation. If the numerator or denominator of the fraction is zero or less than zero, then the proportionate share of the current year taxes that are allocated and apportioned under § 1.960–1(d)(3)(ii) to the subpart F income group is zero.

(ii) *Effect of qualified deficits.* Neither an accumulated deficit nor any prior year deficit in the earnings and profits of a controlled foreign corporation reduces its net income in a subpart F income group. Accordingly, any such deficit does not affect the denominator

of the fraction described in paragraph (b)(3)(i) of this section. However, the first sentence of this paragraph (b)(3)(ii) does not affect the application of section 952(c)(1)(B) for purposes of determining the domestic corporation's subpart F inclusion. Any reduction to the domestic corporation's subpart F inclusion under section 952(c)(1)(B) is reflected in the numerator of the fraction described in paragraph (b)(3)(i) of this section.

(iii) *Effect of current year E&P limitation or chain deficit.* To the extent that an amount of income in a subpart F income group is excluded from the subpart F income of the controlled foreign corporation under section 952(c)(1)(A) or (C), the net income in the subpart F income group that is the denominator of the fraction described in paragraph (b)(3)(i) of this section is reduced (but not below zero) by the amount excluded. The domestic corporation's subpart F inclusion that is the numerator of the fraction described in paragraph (b)(3)(i) of this section is based on the controlled foreign corporation's subpart F income computed with the application of section 952(c)(1)(A) and (C).

(4) *Domestic partnerships.* For purposes of applying this paragraph (b), in the case of a domestic partnership that is a U.S. shareholder partnership with respect to a partnership CFC, the distributive share of a U.S. shareholder partner of the U.S. shareholder partnership's subpart F inclusion with respect to the partnership CFC is treated as a subpart F inclusion of the U.S. shareholder partner with respect to the partnership CFC.

(5) *Example.* The following example illustrates the application of this paragraph (b).

(i) *Facts.* USP, a domestic corporation, owns 80% of the stock of CFC, a controlled foreign corporation. The remaining portion of the stock of CFC is owned by an unrelated person. USP and CFC both use the calendar year as their U.S. taxable year, and CFC also uses the calendar year as its foreign taxable year. CFC uses the ''u'' as its functional currency. At all relevant times, 1u=$1. For its U.S. taxable year ending December 31, 2018, after the application of the rules in § 1.960–1(d) the income of CFC after foreign taxes is assigned to the following income groups: 1,000,000u of dividend income in a subpart F income group within the passive category (''subpart F income group 1''); 2,400,000u of gain from commodities transactions in a subpart F income group within the passive category (''subpart F income group 2''); and 1,800,000u of foreign base company services income in a subpart F income group within the general category (''subpart F income group 3''). CFC has current year taxes, translated into U.S. dollars, of $740,000 that are allocated and apportioned as follows: $50,000 to subpart F income group 1; $240,000 to subpart F income group 2; and $450,000 to subpart F income group 3. USP has a subpart F inclusion with respect to CFC of 4,160,000u = $4,160,000, of which 800,000u is attributable to subpart F income group 1, 1,920,000u to subpart F income group 2, and 1,440,000u to subpart F income group 3.

(ii) *Analysis*—(A) *Passive category.* Under paragraphs (b)(2) and (3) of this section, the amount of CFC's current year taxes that are properly attributable to items of income in subpart F income group 1 to which a subpart F inclusion is attributable equals USP's proportionate share of the current year taxes that are allocated and apportioned under § 1.960–1(d)(3)(ii) to subpart F income group 1, which is $40,000 ($50,000 × 800,000u/1,000,000u). Under paragraphs (b)(2) and (3) of this section, the amount of CFC's current year taxes that are properly attributable to items of income in subpart F income group 2 to which a subpart F inclusion is attributable equals USP's proportionate share of the current year taxes that are allocated and apportioned under § 1.960–1(d)(3)(ii) to subpart F income group 2, which is $192,000 ($240,000 × 1,920,000u/2,400,000u). Accordingly, under paragraph (b)(1), USP is deemed to have paid $232,000 ($40,000 + $192,000) of passive category foreign income taxes of CFC with respect to its $2,720,000 subpart F inclusion in the passive category.

(B) *General category.* Under paragraphs (b)(2) and (3) of this section, the amount of CFC's current year taxes that are properly attributable items of income in subpart F income group 3 to which a subpart F inclusion is attributable equals USP's proportionate share of the foreign income taxes that are allocated and apportioned under § 1.960–1(d)(3)(ii) to subpart F income group 3, which is $360,000 ($450,000 × 1,440,000u/1,800,000u). CFC has no other subpart F income groups within the general category. Accordingly, under paragraph (b)(1) of this section, USP is deemed to have paid $360,000 of general category foreign income taxes of CFC with respect to its $1,440,000 subpart F inclusion in the general category.

(c) *Foreign income taxes deemed paid under section 960(d)*—(1) *In general.* If a domestic corporation that is a United States shareholder of one or more controlled foreign corporations includes an amount in gross income under section 951A(a) and § 1.951A–1(b), the domestic corporation is deemed to have paid an amount of foreign income taxes equal to 80 percent of the product of its inclusion percentage multiplied by the sum of all tested foreign income taxes in the tested income group within each section 904 category of the controlled foreign corporation or corporations.

(2) *Inclusion percentage.* The term *inclusion percentage* means, with respect to a domestic corporation that is a United States shareholder of one or more controlled foreign corporations, the domestic corporation's GILTI inclusion amount divided by the aggregate amount described in section 951A(c)(1)(A) and § 1.951A–1(c)(2)(i) with respect to the United States shareholder.

(3) *Tested foreign income taxes.* The term *tested foreign income taxes* means, with respect to a domestic corporation that is a United States shareholder of a controlled foreign corporation, the amount of the controlled foreign corporation's foreign income taxes that are properly attributable to tested income taken into account by the domestic corporation under section 951A and § 1.951A–1.

(4) *Properly attributable.* The amount of the controlled foreign corporation's foreign income taxes that are properly attributable to tested income taken into account by the domestic corporation under section 951A(a) and § 1.951A–1(b) equals the domestic corporation's proportionate share of the current year taxes of the controlled foreign corporation that are allocated and apportioned under § 1.960–1(d)(3)(ii) to the tested income group within each section 904 category of the controlled foreign corporation. No other foreign income taxes are considered properly attributable to tested income.

(5) *Proportionate share.* A domestic corporation's proportionate share of current year taxes of a controlled foreign corporation that are allocated and apportioned under § 1.960–1(d)(3)(ii) to a tested income group within a section 904 category of the controlled foreign corporation is the U.S. dollar amount of current year taxes that are allocated and apportioned under § 1.960–1(d)(3)(ii) to a tested income group within a section 904 category of the controlled foreign corporation multiplied by a fraction (not to exceed one), the numerator of which is the portion of the tested income of the controlled foreign corporation in the tested income group within the section 904 category that is included in computing the domestic corporation's aggregate amount described in section 951A(c)(1)(A) and § 1.951A–1(c)(2)(i), and the denominator of which is the income in the tested income group within the section 904 category, both determined in the functional currency of the controlled foreign corporation. If the numerator or denominator of the fraction is zero or less than zero, the domestic corporation's proportionate share of the current year taxes allocated and apportioned under § 1.960–1(d)(3)(ii) to the tested income group is zero.

(6) *Domestic partnerships.* See § 1.951A–5 for rules regarding the determination of the GILTI inclusion amount of a U.S. shareholder partner.

(7) *Examples.* The following examples illustrate the application of this paragraph (c).

(i) *Example 1: Directly owned controlled foreign corporation*—(A) *Facts.* USP, a domestic corporation, owns 100% of the stock of a number of controlled foreign corporations, including CFC1. USP and CFC1 each use the calendar year as their U.S. taxable year. CFC1 uses the ''u'' as its functional currency. At all relevant times, 1u=$1. For its U.S. taxable year ending December 31, 2018, after application of the rules in § 1.960–1(d), the income of CFC1 is assigned to a single income group: 2,000u of income from the sale of goods in a tested income group within the general category (''tested income group''). CFC1 has current year taxes, translated into U.S. dollars, of $400 that are all allocated and apportioned to the tested income group. For its U.S. taxable year ending December 31, 2018, USP has a GILTI inclusion amount determined by reference to all of its controlled foreign corporations, including CFC1, of $6,000, and an aggregate amount described in section 951A(c)(1)(A) and § 1.951A–1(c)(2)(i) of $10,000. All of the income in CFC1's tested income group is included in computing USP's aggregate amount described in section 951A(c)(1)(A) and § 1.951A–1(c)(2)(i).

(B) *Analysis.* Under paragraph (c)(5) of this section, USP's proportionate share of the current year taxes that are allocated and apportioned under § 1.960–1(d)(3)(ii) to CFC1's tested income group is $400 ($400 × 2,000u/2,000u). Therefore, under paragraph (c)(4) of this section, the amount of current year taxes properly attributable to tested income taken into account by USP under section 951A(a) and § 1.951A–1(b) is $400. Under paragraph (c)(3) of this section, USP's tested foreign income taxes with respect to CFC1 are $400. Under paragraph (c)(2) of this section, USP's inclusion percentage is 60% ($6,000/$10,000). Accordingly, under paragraph (c)(1) of this section, USP is deemed to have paid $192 of the foreign income taxes of CFC1 (80% × 60% × $400).

(ii) *Example 2: Controlled foreign corporation owned through domestic partnership*—(A) *Facts*—(*1*) US1, a domestic corporation, owns 95% of PRS, a domestic partnership. The remaining 5% of PRS is owned by US2, a domestic corporation that is unrelated to US1. PRS owns all of the stock of CFC1, a controlled foreign corporation. In addition, US1 owns all of the stock of CFC2, a controlled foreign corporation. US1, US2, PRS, CFC1, and CFC2 all use the calendar year as their taxable year. CFC1 and CFC2 both use the ''u'' as their functional currency. At all relevant times, 1u=$1. For its U.S. taxable year ending December 31, 2018, after application of the rules in § 1.960–1(d), the income of CFC1 is assigned to a single income group: 300u of income from the sale of goods in a tested income group within the general category (''CFC1's tested income group''). CFC1 has current year taxes, translated into U.S. dollars, of $100 that are all allocated and apportioned to CFC1's tested income group. The income of CFC2 is also assigned to a single income group: 200u of income from the sale of goods in a tested income group within the general category (''CFC2's tested income group''). CFC2 has current year taxes, translated into U.S. dollars, of $20 that are allocated and apportioned to CFC2's tested income group.

(*2*) In the same year, US1 is a U.S. shareholder partner with respect to CFC1, a partnership CFC, and accordingly, determines its GILTI inclusion amount under § 1.951A–5(c), as if US1 owned (within the meaning of section 958(a)) 95% of the stock of CFC1. Taking into account both CFC1 and CFC2, US1 has a GILTI inclusion amount in the general category of $485, and an aggregate amount described in section 951A(c)(1)(A) and § 1.951A–1(c)(2)(i) within the general category of $485. 285u (95% × 300u) of the income in CFC1's tested income group and 200u of the income in CFC2's tested income group is included in computing US1's aggregate amount described in section 951A(c)(1)(A) and § 1.951A–1(c)(2)(i) within the general category. Because US2 is not a U.S. shareholder partner with respect to CFC1, US2 does not take into account CFC1's tested income in determining its GILTI inclusion amount. However, under § 1.951A–5(b)(2), US2 includes in income $15, its distributive share of PRS's GILTI inclusion amount.

(B) *Analysis*—(*1*) *US1*—(*i*) *CFC1.* Under paragraph (c)(5) and (6) of this section, US1's proportionate share of the current year taxes that are allocated and apportioned under § 1.960–1(d)(3)(ii) to CFC1's tested income group is $95 ($100 × 285u/300u). Therefore, under paragraph (c)(4) of this section, the amount of the current year taxes properly attributable to tested income taken into account by US1 under section 951A(a) and § 1.951A–1(b) is $95. Under paragraph (c)(3) of this section, US1's tested foreign income taxes with respect to CFC1 are $95. Under paragraph (c)(2) of this section, US1's inclusion percentage is 100% ($485/$485). Accordingly, under paragraph (c)(1) of this section, US1 is deemed to have paid $76 of the foreign income taxes of CFC1 (80% × 100% × $95).

(*ii*) *CFC2.* Under paragraph (c)(5) of this section, US1's proportionate share of the foreign income taxes that are allocated and apportioned under § 1.960–1(d)(3)(ii) to CFC2's tested income group is $20 ($20 × 200u/200u). Therefore, under paragraph (c)(4) of this section, the amount of foreign income taxes properly attributable to tested income taken into account by US1 under section 951A(a) and § 1.951A–1(b) is $20. Under paragraph (c)(3) of this section, US1's tested foreign income taxes with respect to CFC2 are $20. Under paragraph (c)(2) of this section, US1's inclusion percentage is 100% ($485/$485). Accordingly, under paragraph (c)(1) of this section, US1 is deemed to have paid $16 of the foreign income taxes of CFC2 (80% × 100% × $20).

(*2*) *US2.* US2 is not a United States shareholder of CFC1 or CFC2. Accordingly, under paragraph (c)(1) of this section, US2 is not deemed to have paid any of the foreign income taxes of CFC1 or CFC2.

■ **Par. 24.** Section 1.960–3 is revised to read as follows:

§ 1.960–3 Foreign income taxes deemed paid under section 960(b).

(a) *Scope.* Paragraph (b) of this section provides rules for computing the amount of foreign income taxes deemed paid by a domestic corporation that is a United States shareholder of a controlled foreign corporation, or by a controlled foreign corporation, under section 960(b). Paragraph (c) of this section provides rules for the establishment and maintenance of PTEP groups within an annual PTEP account. Paragraph (d) of this section defines the term PTEP group taxes. Paragraph (e) of this section provides examples illustrating the application of this section.

(b) *Foreign income taxes deemed paid under section 960(b)*—(1) *Foreign income taxes deemed paid by a domestic corporation with respect to a section 959(a) distribution.* If a controlled foreign corporation makes a distribution to a domestic corporation that is a United States shareholder with respect to the controlled foreign corporation and that distribution is, in whole or in part, a section 959(a) distribution with respect to a PTEP group within a section 904 category, the domestic corporation is deemed to have paid the amount of the foreign corporation's foreign income taxes that are properly attributable to the section 959(a) distribution with respect to the PTEP group and that have not been deemed to have been paid by a domestic corporation under section 960 for the current taxable year or any prior taxable year. See § 1.965–5(c)(1)(iii) for rules disallowing credits in relation to a distribution of certain previously taxed earnings and profits resulting from the application of section 965. For each section 904 category, the domestic corporation is deemed to have paid foreign income taxes equal to the sum of the controlled foreign corporation's foreign income taxes that are properly attributable to section 959(a) distributions with respect to all PTEP groups within the section 904 category. See § 1.904–6(b)(2) for rules on assigning the foreign income tax to a section 904 category.

(2) *Foreign income taxes deemed paid by a controlled foreign corporation with respect to a section 959(b) distribution.* If a controlled foreign corporation (*distributing controlled foreign corporation*) makes a distribution to another controlled foreign corporation (*recipient controlled foreign corporation*) and the distribution is, in whole or in part, a section 959(b) distribution from a PTEP group within a section 904 category, the recipient controlled foreign corporation is

deemed to have paid the amount of the distributing controlled foreign corporation's foreign income taxes that are properly attributable to the section 959(b) distribution from the PTEP group and that have not been deemed to have been paid by a domestic corporation under section 960 for the current taxable year or any prior taxable year. See § 1.904–6(b)(3) for rules on assigning the foreign income tax to a section 904 category.

(3) *Properly attributable.* The amount of foreign income taxes that are properly attributable to a section 959 distribution from a PTEP group within a section 904 category equals the domestic corporation's or recipient controlled foreign corporation's proportionate share of the PTEP group taxes with respect to the PTEP group within the section 904 category. No other foreign income taxes are considered properly attributable to a section 959 distribution.

(4) *Proportionate share.* A domestic corporation's or recipient controlled foreign corporation's proportionate share of the PTEP group taxes with respect to a PTEP group within a section 904 category is equal to the total amount of the PTEP group taxes with respect to the PTEP group multiplied by a fraction (not to exceed one), the numerator of which is the amount of the section 959 distribution from the PTEP group, and the denominator of which is the total amount of previously taxed earnings and profits in the PTEP group, both determined in the functional currency of the controlled foreign corporation. If the numerator or denominator of the fraction is zero or less than zero, then the proportionate share of the PTEP group taxes with respect to the PTEP group is zero.

(5) *Domestic partnerships.* For purposes of applying this paragraph (b), in the case of a domestic partnership that is a U.S. shareholder partnership with respect to a partnership CFC, the distributive share of a U.S. shareholder partner of a U.S. shareholder partnership's section 959(a) distribution from the partnership CFC is treated as a section 959(a) distribution received by the U.S. shareholder partner from the partnership CFC.

(c) *Accounting for previously taxed earnings and profits*—(1) *Establishment of annual PTEP account.* A separate, annual account (*annual PTEP account*) must be established for the previously taxed earnings and profits of the controlled foreign corporation to which inclusions under section 951(a) and GILTI inclusion amounts of United States shareholders of the CFC are attributable. Each account must correspond to the inclusion year of the previously taxed earnings and profits and to the section 904 category to which the inclusions under section 951(a) or GILTI inclusion amounts were assigned at the level of the United States shareholders. Accordingly, a controlled foreign corporation may have an annual PTEP account in the section 951A category or a treaty category (as defined in § 1.861–13(b)(6)), even though income of the controlled foreign corporation that gave rise to the previously taxed earnings and profits cannot initially be assigned to the section 951A category or a treaty category.

(2) *PTEP groups within an annual PTEP account.* The amount in an annual PTEP account is further assigned to one or more of the following groups of previously taxed earnings and profits (each, a *PTEP group*) within the account:

(i) Earnings and profits described in section 959(c)(1)(A) by reason of section 951(a)(1)(B) and not by reason of the application of section 959(a)(2);

(ii) Earnings and profits described in section 959(c)(1)(A) that were initially described in section 959(c)(2) by reason of section 965(a);

(iii) Earnings and profits described in section 959(c)(1)(A) that were initially described in section 959(c)(2) by reason of section 965(b)(4)(A);

(iv) Earnings and profits described in section 959(c)(1)(A) that were initially described in section 959(c)(2) by reason of section 951A;

(v) Earnings and profits described in section 959(c)(1)(A) that were initially described in section 959(c)(2) by reason of section 951(a)(1)(A) (other than as a result of the application of section 965);

(vi) Earnings and profits described in section 959(c)(1)(B);

(vii) Earnings and profits described in section 959(c)(2) by reason of section 965(a);

(viii) Earnings and profits described in section 959(c)(2) by reason of section 965(b)(4)(A);

(ix) Earnings and profits described in section 959(c)(2) by reason of section 951A;

(x) Earnings and profits described in section 959(c)(2) by reason of section 951(a)(1)(A) (other than as a result of the application of section 965).

(3) *Accounting for distributions of previously taxed earnings and profits.* With respect to a recipient controlled foreign corporation that receives a section 959(b) distribution, such distribution amount is added to the annual PTEP account, and PTEP group within the annual PTEP account, that corresponds to the inclusion year and section 904 category of the annual PTEP account, and PTEP group within the annual PTEP account, from which the distributing controlled foreign corporation is treated as making the distribution under section 959 and the regulations under that section. Similarly, with respect to a controlled foreign corporation that makes a section 959 distribution, such distribution amount reduces the annual PTEP account, and PTEP group within the annual PTEP account, that corresponds to the inclusion year and section 904 category of the annual PTEP account, and PTEP group within the annual PTEP account, from which the controlled foreign corporation is treated as making the distribution under section 959 and the regulations under that section. Earnings and profits in a PTEP group are reduced by the amount of current year taxes that are allocated and apportioned to the PTEP group under § 1.960–1(d)(3)(ii), and the U.S. dollar amount of the taxes are added to an account of PTEP group taxes under the rules in paragraph (d)(1) of this section.

(4) *Accounting for reclassifications of earnings and profits described in section 959(c)(2) to earnings and profits described in section 959(c)(1).* If an amount of previously taxed earnings and profits that is in a PTEP group described in paragraphs (c)(2)(vii) through (x) of this section (each, a *section 959(c)(2) PTEP group*) is reclassified as previously taxed earnings and profits described in section 959(c)(1) (*reclassified previously taxed earnings and profits*), the section 959(c)(2) PTEP group is reduced by the functional currency amount of the reclassified previously taxed earnings and profits. This amount is added to the corresponding PTEP group described in paragraphs (c)(2)(ii) through (v) of this section (each, a *reclassified PTEP group*) in the same section 904 category and same annual PTEP account as the reduced section 959(c)(2) PTEP group.

(d) *PTEP group taxes*—(1) *In general.* The term *PTEP group taxes* means the U.S. dollar amount of foreign income taxes (translated in accordance with section 986(a)) that are paid, accrued, or deemed paid with respect to an amount in each PTEP group within an annual PTEP account. The foreign income taxes that are paid, accrued, or deemed paid with respect to a PTEP group within an annual PTEP account of a controlled foreign corporation are—

(i) The sum of—

(A) The current year taxes paid or accrued by the controlled foreign corporation that are allocated and apportioned to the PTEP group under § 1.960–1(d)(3)(ii);

(B) Foreign income taxes that are deemed paid under section 960(b)(2) and paragraph (b)(2) of this section by the controlled foreign corporation with respect to a section 959(b) distribution received by the controlled foreign corporation, the amount of which is added to the PTEP group under paragraph (c)(3) of this section; and

(C) In the case of a reclassified PTEP group of the controlled foreign corporation, reclassified PTEP group taxes that are attributable to the section 959(c)(2) PTEP group that corresponds to the reclassified PTEP group;

(ii) Reduced by—

(A) Foreign income taxes that were deemed paid under section 960(b)(2) and paragraph (b)(2) of this section by another controlled foreign corporation that received a section 959(b) distribution from the controlled foreign corporation, the amount of which is subtracted from the controlled foreign corporation's PTEP group under paragraph (c)(3) of this section;

(B) Foreign income taxes that were deemed paid under section 960(b)(1) and paragraph (b)(1) of this section by a domestic corporation that is a United States shareholder of the controlled foreign corporation that received a section 959(a) distribution from the controlled foreign corporation, the amount of which is subtracted from the controlled foreign corporation's PTEP group under paragraph (c)(3) of this section; and

(C) In the case of a section 959(c)(2) PTEP group of the controlled foreign corporation, reclassified PTEP group taxes.

(2) *Reclassified PTEP group taxes.* Reclassified PTEP group taxes are foreign income taxes that are initially included in PTEP group taxes with respect to a section 959(c)(2) PTEP group under paragraph (d)(1)(i)(A) or (B) of this section multiplied by a fraction, the numerator of which is the portion of the previously taxed earnings and profits in the section 959(c)(2) PTEP group that become reclassified previously taxed earnings and profits, and the denominator of which is the total previously taxed earnings and profits in the section 959(c)(2) PTEP group.

(3) *Foreign income taxes deemed paid with respect to PTEP groups established for pre-2018 inclusion years.* Foreign income taxes paid or accrued with respect to an annual PTEP account, and a PTEP group within such account, that was established for an inclusion year that begins before January 1, 2018, are treated as PTEP group taxes of a controlled foreign corporation for purposes of this section only if those foreign income taxes were—

(i) Paid or accrued in a taxable year of the controlled foreign corporation that began before January 1, 2018;

(ii) Not included in a controlled foreign corporation's post-1986 foreign income taxes (as defined in section 902(c)(2) as in effect on December 21, 2017) used to compute foreign taxes deemed paid under section 902 (as in effect on December 21, 2017) in any taxable year that began before January 1, 2018; and

(iii) Not treated as deemed paid under section 960(a)(3) (as in effect on December 21, 2017) by a domestic corporation that was a United States shareholder of the controlled foreign corporation.

(e) *Examples.* The following examples illustrate the application of this section.

(1) *Example 1: Establishment of PTEP groups and PTEP accounts*—(i) *Facts.* USP, a domestic corporation, owns all of the stock of CFC1, a controlled foreign corporation. CFC1 owns all of the stock of CFC2, a controlled foreign corporation. USP, CFC1, and CFC2 each use the calendar year as their U.S. taxable year. CFC1 and CFC2 use the ''u'' as their functional currency. At all relevant times, 1u=$1. With respect to CFC2, USP includes in gross income a subpart F inclusion of 1,000,000u=$1,000,000 for the taxable year ending December 31, 2018. The inclusion is with respect to passive category income. In its U.S. taxable year ending December 31, 2019, CFC2 distributes 1,000,000u to CFC1. CFC2 has no earnings and profits except for the 1,000,000u of previously taxed earnings and profits resulting from USP's 2018 taxable year subpart F inclusion. CFC2's country of organization, Country X, imposes a withholding tax on CFC1 of 300,000u on CFC2's distribution to CFC1. Under § 1.960–1(d)(3)(ii), CFC1's 300,000u of current year taxes are allocated and apportioned to the PTEP group within the annual PTEP account within the section 904 category to which the 1,000,000u of previously taxed earnings and profits are assigned.

(ii) *Analysis*—(A) Under paragraph (c)(1) of this section, a separate annual PTEP account in the passive category for the 2018 taxable year is established for CFC2 as a result of USP's subpart F inclusion. Under paragraph (c)(2) of this section, this account contains one PTEP group, which is described in paragraph (c)(2)(x) of this section.

(B) Under paragraph (c)(3) of this section, in the 2019 taxable year, the 1,000,000u related to the section 959(b) distribution from CFC2 is added to CFC1's annual PTEP account for the 2018 taxable year in the passive category and to the PTEP group within such account described in paragraph (c)(2)(x) of this section. Similarly, CFC2's 2018 taxable year annual PTEP account within the passive category, and the PTEP group within such account described in paragraph (c)(2)(x) of this section, is reduced by the amount of the 1,000,000u section 959(b) distribution to CFC1. Additionally, CFC1's annual PTEP account for the 2018 taxable year in the passive category, and the PTEP group within such account described in paragraph (c)(2)(x) of this section, is reduced by the 300,000u of withholding taxes imposed on CFC1 by Country X. Therefore, CFC1's annual PTEP account for the 2018 taxable year within the passive category and the PTEP group within such account described in paragraph (c)(2)(x) of this section is 700,000u.

(C) Under paragraph (d)(1) of this section, the 300,000u of withholding tax is translated into U.S. dollars and $300,000 is added to the PTEP group taxes with respect to CFC1's PTEP group described in paragraph (c)(2)(x) of this section within the annual PTEP account for the 2018 taxable year within the passive category.

(2) *Example 2: Foreign income taxes deemed paid under section 960(b)*—(i) *Facts.* USP, a domestic corporation, owns 100% of the stock of CFC1, which in turn owns 60% of the stock of CFC2, which in turn owns 100% of the stock of CFC3. USP, CFC1, CFC2, and CFC3 all use the calendar year as their U.S. taxable year. CFC1, CFC2, and CFC3 all use the ''u'' as their functional currency. At all relevant times, 1u=$1. On July 1, 2020, CFC2 distributes 600u to CFC1 and the entire distribution is a section 959(b) distribution (''distribution 1''). On October 1, 2020, CFC1 distributes 800u to USP and the entire distribution is a section 959(a) distribution (''distribution 2''). CFC1 and CFC2 make no other distributions in the year ending December 31, 2020, earn no other income, and incur no taxes on distribution 1 or distribution 2. Before taking into account distribution 1, CFC2 has 1,000u in a PTEP group described in paragraph (c)(2)(x) of this section within an annual PTEP account for the 2016 taxable year within the general category. The previously taxed earnings and profits in CFC2's PTEP group relate to subpart F income of CFC3 that was included by USP in 2016. CFC3 distributed the earnings and profits to CFC2 before the 2020 taxable year and, solely as a result of the distribution of the previously taxed earnings and profits, CFC2 incurred withholding and net basis tax, resulting in $150 of PTEP group taxes with respect to the PTEP group. Before taking into account distribution 1 and distribution 2, CFC1 has 200u in a PTEP group described in paragraph (c)(2)(ix) of this section within an annual PTEP account for the 2018 taxable year within the section 951A category. The previously taxed earnings and profits in CFC1's PTEP group relate to the portion of a GILTI inclusion amount that was included by USP in 2018 and allocated to CFC2 under section 951A(f)(2) and § 1.951A–6(b)(2). CFC2 distributed the earnings and profits to CFC1 before the 2020 taxable year and, solely as a result of the distribution of the previously taxed earnings and profits, CFC1 incurred withholding and net basis tax, resulting in $25 of PTEP group taxes with respect to the PTEP group.

(ii) *Analysis*—(A) *Foreign income taxes deemed paid by CFC1.* With respect to distribution 1 from CFC2 to CFC1, under paragraph (b)(4) of this section CFC1's proportionate share of PTEP group taxes with

respect to CFC2's PTEP group described in paragraph (c)(2)(x) of this section within an annual PTEP account for the 2016 taxable year within the general category is $90 ($150 × 600u/1,000u). Under paragraph (b)(3) of this section, the amount of foreign income taxes that are properly attributable to distribution 1 is $90. Accordingly, under paragraph (b)(2) of this section, CFC1 is deemed to have paid $90 of general category foreign income taxes of CFC2 with respect to its 600u section 959(b) distribution in the general category.

(B) *Adjustments to PTEP accounts of CFC1 and CFC2.* Under paragraph (c)(3) of this section, the 600u related to distribution 1 is added to CFC1's PTEP group described in paragraph (c)(2)(x) of this section within an annual PTEP account for the 2016 taxable year within the general category. Similarly, CFC2's PTEP group described in paragraph (c)(2)(x) of this section within an annual PTEP account for the 2016 taxable year within the general category is reduced by 600u, the amount of the section 959(b) distribution to CFC1. Additionally, under paragraph (d) of this section, CFC1's PTEP group taxes with respect to its PTEP group described in paragraph (c)(2)(x) of this section within an annual PTEP account for the 2016 taxable year within the general category are increased by $90 and CFC2's PTEP group described in paragraph (c)(2)(x) of this section within an annual PTEP account for the 2016 taxable year within the general category are reduced by $90.

(C) *Foreign income taxes deemed paid by USP.* With respect to distribution 2 from CFC1 to USP, because CFC1 has PTEP groups in more than one section 904 category, this section is applied separately to each section 904 category (that is, distribution 2 of 800u is applied separately to the 200u of CFC1's PTEP group described in paragraph (c)(2)(ix) of this section and 600u of CFC1's PTEP group described in paragraph (c)(2)(x) of this section).

(*1*) *Section 951A category.* Under paragraph (b)(4) of this section, USP's proportionate share of PTEP group taxes with respect to CFC1's PTEP group described in paragraph (c)(2)(ix) of this section within an annual PTEP account for the 2018 taxable year within the section 951A category is $25 ($25 × 200u/200u). Under paragraph (b)(3) of this section, the amount of foreign income taxes within the section 951A category that are properly attributable to distribution 2 is $25. Accordingly, under paragraph (b)(1) of this section USP is deemed to have paid $25 of section 951A category foreign income taxes of CFC1 with respect to its 200u section 959(a) distribution in the section 951A category.

(*2*) *General category.* Under paragraph (b)(4) of this section, USP's proportionate share of PTEP group taxes with respect to CFC1's PTEP group described in paragraph (c)(2)(x) of this section within an annual PTEP account for the 2016 taxable year within the general category is $90 ($90 × 600u/600u). Under paragraph (b)(3) of this section, the amount of foreign income taxes that are properly attributable to distribution 2 is $90. Accordingly, under paragraph (b)(1), USP is deemed to have paid $90 of general category foreign income taxes of CFC1 with respect to its 600u section 959(a) distribution in the general category.

■ **Par. 25.** Section 1.960–4 is amended by:

■ 1. Removing the language ''960(b)(1)'' and adding the language ''960(c)(1)'' in its place wherever it appears.

■ 2. Adding two sentences at the end of paragraph (a)(1).

■ 3. Revising the last sentence of paragraph (d).

The addition and revision read as follows:

§ 1.960–4 Additional foreign tax credit in year of receipt of previously taxed earnings and profits.

(a) * * * (1) * * * For purposes of this section, an amount included in gross income under section 951A(a) is treated as an amount included in gross income under section 951(a). The amount of the increase in the foreign tax credit limitation allowed by this section is determined with regard to each separate category of income described in § 1.904–5(a)(4)(v).

* * * * *

(d) * * * For purposes of this paragraph (d), the term ''foreign income taxes'' includes foreign income taxes paid or accrued, foreign income taxes deemed paid or accrued under section 904(c), and foreign income taxes deemed paid under section 960, for the taxable year of inclusion.

* * * * *

§ 1.960–5 [Amended]

■ **Par. 26.** Section 1.960–5 is amended by removing the language ''951(a)'' and adding the language ''951(a) or 951A(a)'' in its place in paragraph (a)(1).

§ 1.960–6 [Amended]

■ **Par. 27.** Section 1.960–6 is amended by removing the language ''960(b)(1)'' and adding the language ''960(c)(1)'' in its place in paragraph (a).

■ **Par. 28.** Section 1.960–7 is revised to read as follows:

§ 1.960–7 Applicability dates.

Applicability dates. Sections 1.960–1 through 1.960–6 apply to a taxable year of a foreign corporation beginning after December 31, 2017, and a taxable year of a domestic corporation that is a United States shareholder of the foreign corporation in which or with which such taxable year of such foreign corporation ends.

■ **Par. 29.** Section 1.965–5, as proposed to be added at 83 FR 39562 (August 9, 2018), is amended by adding paragraph (c)(1)(iii) to read as follows:

§ 1.965–5 Allowance of a credit or deduction for foreign income taxes.

* * * * *

(c) * * *

(1) * * *

(iii) *Foreign income taxes deemed paid under section 960(b) (as applicable to taxable years of controlled foreign corporations beginning after December 31, 2017, and to taxable years of United States persons in which or with which such taxable years of foreign corporations end).* No credit is allowed for the applicable percentage of foreign income taxes deemed paid under section 960(b) (as in effect for a taxable year of a controlled foreign corporation beginning after December 31, 2017, and a taxable year of a United States person in which or with which such controlled foreign corporation's taxable year ends) and § 1.960–3(b)(1) with respect to distributions to the domestic corporation of section 965(a) previously taxed earnings and profits or section 965(b) previously taxed earnings and profits. The foreign income taxes deemed paid under § 1.960–3(b)(1) with respect to a distribution to the domestic corporation of section 965(a) previously taxed earnings and profits or section 965(b) previously taxed earnings and profits is equal to the foreign income taxes properly attributable to a distribution from the distributing controlled foreign corporation's individual PTEP groups described in § 1.960–3(c)(2)(ii), (iii), (vii), or (viii). For purposes of this paragraph (c)(1)(iii), the terms ''properly attributable'' and ''PTEP group'' have the meanings set forth in § 1.960–3(b)(3) and (c)(2) respectively. In addition, foreign income taxes that would have been deemed paid under section 960(a)(1) (as in effect on December 21, 2017) with respect to the portion of a section 965(a) earnings amount that was reduced under § 1.965–1(b)(2) or § 1.965–8(b) are not eligible to be deemed paid under section 960(b) and § 1.960–3(b)(1) or any other section of the Code.

* * * * *

■ **Par. 30.** Section 1.965–7, as proposed to be added at 83 FR 39564 (August 9, 2018), is amended by adding three sentences at the end of paragraph (e)(1)(i) and adding paragraph (e)(1)(iv) to read as follows:

§ 1.965–7 Elections, payment, and other special rules.

* * * * *

(e) * * *

(1) * * *

(i) * * * If the section 965(n) election creates or increases a net operating loss under section 172 for the taxable year, then the taxable income of the person

for the taxable year cannot be less than the amount described in paragraph (e)(1)(ii) of this section. The amount of deductions equal to the amount by which a net operating loss is created or increased for the taxable year by reason of the section 965(n) election (the ''deferred amount'') is not taken into account in computing taxable income or the separate foreign tax credit limitations under section 904 for that year. The source and separate category (as defined in § 1.904–5(a)(4)(v)) components of the deferred amount are determined in accordance with paragraph (e)(1)(iv) of this section.

* * * * *

(iv) *Effect of section 965(n) election*—(A) *In general.* The section 965(n) election for a taxable year applies solely for purposes of determining the amount of net operating loss under section 172 for the taxable year and determining the amount of taxable income for the taxable year (computed without regard to the deduction allowable under section 172) that may be reduced by net operating loss carryovers or carrybacks to such taxable year under section 172. Paragraph (e)(1)(iv)(B) of this section provides a rule for coordinating the section 965(n) election's effect on section 172 with the computation of the separate foreign tax credit limitations under section 904.

(B) *Ordering rule for allocation and apportionment of deductions for purposes of the section 904 limitation.* The effect of a section 965(n) election with respect to a taxable year on the computation of the separate foreign tax credit limitations under section 904 is computed as follows and in the following order.

(*1*) Deductions that would have been allowed for the taxable year but for the section 965(n) election, other than the amount of any net operating loss carryover or carryback to that year that is not allowed by reason of the section 965(n) election, are allocated and apportioned under §§ 1.861–8 through 1.861–17 to the relevant statutory and residual groupings, taking into account the amount described in paragraph (e)(1)(ii) of this section. The source and separate category of the net operating loss carryover or carryback to the taxable year, if any, is determined under the rules of § 1.904(g)–3(b), taking into account the amount described in paragraph (e)(1)(ii) of this section. If the amount of the net operating loss carryover or carryback to the taxable year is reduced by reason of the section 965(n) election to an amount less than the U.S. source loss component of the net operating loss, the potential carryovers (or carrybacks) of the separate limitation losses that are part of the net operating loss are proportionately reduced as provided in § 1.904(g)–3(b)(3)(ii).

(*2*) If a net operating loss is created or increased for the taxable year by reason of the section 965(n) election, the deferred amount (as defined in paragraph (e)(1)(i) of this section) is not allowed as a deduction for the taxable year. See paragraph (e)(1)(i) of this section. The deferred amount (which is the corresponding addition to the net operating loss for the taxable year) comprises a ratable portion of the deductions (other than the deduction allowed under section 965(c)) allocated and apportioned to each statutory and residual grouping under paragraph (e)(1)(iv)(B)(*1*) of this section. Such ratable portion equals the deferred amount multiplied by a fraction, the numerator of which is the deductions allocated and apportioned to the statutory or residual grouping under paragraph (e)(1)(iv)(B)(*1*) of this section (other than the section 965(c) deduction) and the denominator of which is the total deductions (other than the section 965(c) deduction) described in paragraph (e)(1)(iv)(B)(*1*) of this section. Accordingly, the fraction described in the previous sentence takes into account the deferred amount.

(*3*) Taxable income and the separate foreign tax credit limitations under section 904 for the taxable year are computed without taking into account any deferred amount. Deductions allocated and apportioned to the statutory and residual groupings under paragraph (e)(1)(iv)(B)(*1*)) of this section, to the extent deducted in the taxable year rather than deferred to create or increase a net operating loss, are combined with income in the statutory and residual groupings to which those deductions are assigned in order to compute the amount of separate limitation income or loss in each separate category and U.S. source income or loss for the taxable year. Section 904(b), (f), and (g) are then applied to determine the applicable foreign tax credit limitations for the taxable year.

* * * * *

Kirsten Wielobob,

Deputy Commissioner for Services and Enforcement.

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Part III

Department of Commerce

National Oceanic and Atmospheric Administration

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Geophysical Surveys in the Atlantic Ocean; Notice

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE283

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Geophysical Surveys in the Atlantic Ocean

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

ACTION: Notice; issuance of five incidental harassment authorizations.

SUMMARY: In accordance with the regulations implementing the Marine Mammal Protection Act (MMPA) as amended, notification is hereby given that we have issued incidental harassment authorizations (IHA) to five separate applicants to incidentally harass marine mammals during geophysical survey activities in the Atlantic Ocean.

DATES: These authorizations are effective for one year from the date of effectiveness.

FOR FURTHER INFORMATION CONTACT: Ben Laws, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Availability

Electronic copies of the applications and supporting documents, as well as a list of the references cited in this document, may be obtained online at: *www.fisheries.noaa.gov/action/incidental-take-authorization-oil-and-gas-industry-geophysical-survey-activity-atlantic.* In case of problems accessing these documents, please call the contact listed above.

Background

Section 101(a)(5)(D) of the MMPA (16 U.S.C. 1361 *et seq.*) directs the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specific geographic region if certain findings are made and notice of a proposed authorization is provided to the public for review.

An authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth.

NMFS has defined ''negligible impact'' in 50 CFR 216.103 as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.

The MMPA states that the term ''take'' means to harass, hunt, capture, or kill, or attempt to harass, hunt, capture, or kill any marine mammal.

Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

Summary of Requests

In 2014, the Bureau of Ocean Energy Management (BOEM) produced a Programmatic Environmental Impact Statement (PEIS) to evaluate potential significant environmental effects of geological and geophysical (G&G) activities on the Mid- and South Atlantic Outer Continental Shelf (OCS), pursuant to requirements of the National Environmental Policy Act (NEPA). BOEM's PEIS and associated Record of Decision are available online at: *www.boem.gov/Atlantic-G-G-PEIS/.* G&G activities include geophysical surveys in support of hydrocarbon exploration, as are planned by the five IHA applicants discussed herein.

In 2014–15, we received multiple separate requests for authorization for take of marine mammals incidental to geophysical surveys in support of hydrocarbon exploration in the Atlantic Ocean. The applicants are companies that provide services, such as geophysical data acquisition, to the oil and gas industry. Upon review of these requests, we submitted questions, comments, and requests for additional information to the individual applicant companies. As a result of these interactions, the applicant companies provided revised versions of the applications that we determined were adequate and complete. Adequate and complete applications were received from ION GeoVentures (ION) on June 24, 2015, Spectrum Geo Inc. (Spectrum) on July 6, 2015, and from TGS–NOPEC Geophysical Company (TGS) on July 21, 2015.

We subsequently posted these applications for public review and sought public input (80 FR 45195; July 29, 2015). The comments and information received during this public review period informed development of the proposed IHAs (82 FR 26244; June 6, 2017), and all letters received are available online at *www.fisheries.noaa.gov/action/incidental-take-authorization-oil-and-gas-industry-geophysical-survey-activity-atlantic.* Following conclusion of this opportunity for public review, we received revised applications from Spectrum on September 18, 2015, and from TGS on February 10, 2016. We received additional information from ION on February 29, 2016. We also received adequate and complete applications from two additional applicants: WesternGeco, LLC (Western) on February 17, 2016, and CGG on May 26, 2016. Full details regarding these timelines were described in our **Federal Register** Notice of Proposed IHAs (82 FR 26244; June 6, 2017).

On June 26, 2018, Spectrum notified NMFS of a modification to their survey plan. Spectrum's letter and related information is available online, as is their preceding adequate and complete application. The descriptions and analyses contained herein were complete at the time we received notification of the modification. Therefore, we present those descriptions and analyses, including those related to Spectrum's request (as detailed in their 2015 application), intact as originally developed. However, we provide detail regarding Spectrum's modified survey plan, our evaluation of the modification to the specified activity, and our finding that the determinations made in regard to Spectrum's previously proposed specified activity remain appropriate and valid in a standalone section entitled ''Spectrum Survey Plan Modification'' at the end of this notice.

All issued authorizations are valid for the statutory maximum of one year. All applicants plan to conduct two-dimensional (2D) marine seismic surveys using airgun arrays. Generally speaking, these surveys may occur within the U.S. Exclusive Economic Zone (EEZ) (*i.e.,* to 200 nautical miles (nmi)) from Delaware to approximately Cape Canaveral, Florida, and corresponding with BOEM's Mid- and South Atlantic OCS planning areas, as well as additional waters out to 350 nmi from shore. Please see the applications for specific details of survey design. The use of airgun arrays is expected to

produce underwater sound at levels that have the potential to result in harassment of marine mammals. Multiple cetacean species with the expected potential to be present during all or a portion of the planned surveys are described below.

Because the specified activity, specific geographic region, and planned dates of activity are substantially similar for the five separate requests for authorization, we have determined it appropriate to provide a joint notice for issuance of the five authorizations. However, while we provide relevant information together, we consider the potential impacts of the specified activities independently and make determinations specific to each request for authorization, as required by the MMPA.

Description of the Specified Activities

In this section, we provide a generalized discussion that is broadly applicable to all five requests for authorization, with project-specific portions indicated.

Overview

The five applicants plan to conduct deep penetration seismic surveys using airgun arrays as an acoustic source. Seismic surveys are one method of obtaining geophysical data used to characterize the subsurface structure, in this case in support of hydrocarbon exploration. The planned surveys are 2D surveys, designed to acquire data over large areas in order to screen for potential hydrocarbon prospectivity. To contrast, three-dimensional surveys may use similar acoustic sources but are designed to cover smaller areas with greater resolution (*e.g.,* with closer survey line spacing). A deep penetration survey uses an acoustic source suited to provide data on geological formations that may be thousands of meters (m) beneath the seafloor, as compared with a survey that may be intended to evaluate shallow subsurface formations or the seafloor itself (*e.g.,* for hazards).

An airgun is a device used to emit acoustic energy pulses into the seafloor, and generally consists of a steel cylinder that is charged with high-pressure air. The firing pressure of an array is typically 2,000 pounds per square inch (psi). Release of the compressed air into the water column generates a signal that reflects (or refracts) off of the seafloor and/or subsurface layers having acoustic impedance contrast. When fired, a brief (~0.1 second (s)) pulse of sound is emitted by all airguns nearly simultaneously. The airguns do not fire during the intervening periods, with the array typically fired on a fixed distance (or shot point) interval. This interval may vary depending on survey objectives, but a typical interval for a 2D survey in relatively deep water might be 25 m (approximately every 10 s, depending on vessel speed). Vessel speed when towing gear is typically 4–5 knots (kn). The return signal is recorded by a listening device and later analyzed with computer interpretation and mapping systems used to depict the subsurface. In this case, towed streamers contain hydrophones that would record the return signal.

Individual airguns are available in different volumetric sizes, and for deep penetration seismic surveys are towed in arrays (*i.e.,* a certain number of airguns of varying sizes in a certain arrangement) designed according to a given company's method of data acquisition, seismic target, and data processing capabilities. A typical large airgun array, as was considered in BOEM's PEIS (BOEM, 2014a), may have a total volume of approximately 5,400 cubic inches (in^3). The notional array modeled by BOEM consists of 18 airguns in three identical strings of six airguns each, with individual airguns ranging in volume from 105–660 in^3. Sound levels for airgun arrays are typically modeled or measured at some distance from the source and a nominal source level then back-calculated. Because these arrays constitute a distributed acoustic source rather than a single point source (*i.e.,* the ''source'' is actually comprised of multiple sources with some pre-determined spatial arrangement), the highest sound levels measurable at any location in the water will be less than the nominal source level. A common analogy is to an array of light bulbs; at sufficient distance the array will appear to be a single point source of light but individual sources, each with less intensity than that of the whole, may be discerned at closer distances. In addition, the effective source level for sound propagating in near-horizontal directions (*i.e.,* directions likely to impact most marine mammals in the vicinity of an array) is likely to be substantially lower than the nominal source level applicable to downward propagation because of the directional nature of the sound from the airgun array. The horizontal propagation of sound is reduced by noise cancellation effects created when sound from neighboring airguns on the same horizontal plane partially cancel each other out.

Survey protocols generally involve a predetermined set of survey, or track, lines. The seismic acquisition vessel (source vessel) will travel down a linear track for some distance until a line of data is acquired, then turn and acquire data on a different track. In addition to the line over which data acquisition is desired, full-power operation may include run-in and run-out. Run-in is approximately 1 kilometer (km) of full-power source operation before starting a new line to ensure equipment is functioning properly, and run-out is additional full-power operation beyond the conclusion of a trackline (typically half the distance of the acquisition streamer behind the source vessel) to ensure that all data along the trackline are collected by the streamer. Line turns typically require two to three hours due to the long, trailing streamers (approximately 10 km). Spacing and length of tracks vary by survey. Survey operations often involve the source vessel, supported by a chase vessel. Chase vessels typically support the source vessel by protecting the hydrophone streamer from damage (*e.g.,* from other vessels) and otherwise lending logistical support (*e.g.,* returning to port for fuel, supplies, or any necessary personnel transfers). Chase vessels do not deploy acoustic sources for data acquisition purposes; the only potential effects of the chase vessels are those associated with normal vessel operations.

Dates and Duration

All issued IHAs are valid for the statutory maximum of one year from the date of effectiveness. The IHAs are effective upon written notification from the applicant to NMFS, but not beginning later than one year from the date of issuance or extending beyond two years from the date of issuance. However, the expected temporal extent of survey activity varies by company and may be subject to unpredictability due to inclement weather days, equipment maintenance and/or repair, transit to and from ports to survey locations, and other contingencies. Spectrum originally planned a 6-month data acquisition program (February through July), consisting of an expected 165 days of seismic operations. This plan has been modified and now consists of an estimated 108 days of operations. Please see ''Spectrum Survey Plan Modification'' for further information. TGS plans a full year data acquisition program, with an estimated 308 days of seismic operations. ION plans a six-month data acquisition program (July through December), with an estimated 70 days of seismic data collection. Western plans a full year data acquisition program, with an estimated 208 days of seismic operations. CGG plans a six-month data acquisition program (July through

December), with an estimated 155 days of seismic operations. Seismic operations typically occur 24 hours per day.

Specific Geographic Region

The planned survey activities would occur off the Atlantic coast of the United States, within BOEM's Mid-Atlantic and South Atlantic OCS planning areas (*i.e.,* from Delaware to Cape Canaveral, FL), and out to 350 nmi (648 km) (see Figure 1, reproduced from BOEM, 2014a). The seaward limit of the region is based on the maximum constraint line for the extended continental shelf (ECS) under the United Nations Convention on the Law of the Sea. Until such time as an ECS is established by the United States, the region between the U.S. EEZ boundary and the ECS maximum constraint line (*i.e.,* 200–350 nmi from shore) is part of the global commons, and BOEM determined it appropriate to include this area within the area of interest for geophysical survey activity.

The specific survey areas differ within this region; please see maps provided in the individual applications (Spectrum: Figure 1; Western: Figures 1–1 to 1–4; TGS: Figures 1–1 to 1–4; ION: Figure 1; CGG: Figure 3) (however, please see ''Spectrum Survey Plan Modification'' for further information). The specific geographic region has not changed compared with what was described in our Notice of Proposed IHAs (82 FR 26244; June 6, 2017), nor has substantive new information regarding the region become available. Therefore, we do not reprint that discussion here; for additional detail regarding the specific geographic region, please see our Notice of Proposed IHAs.

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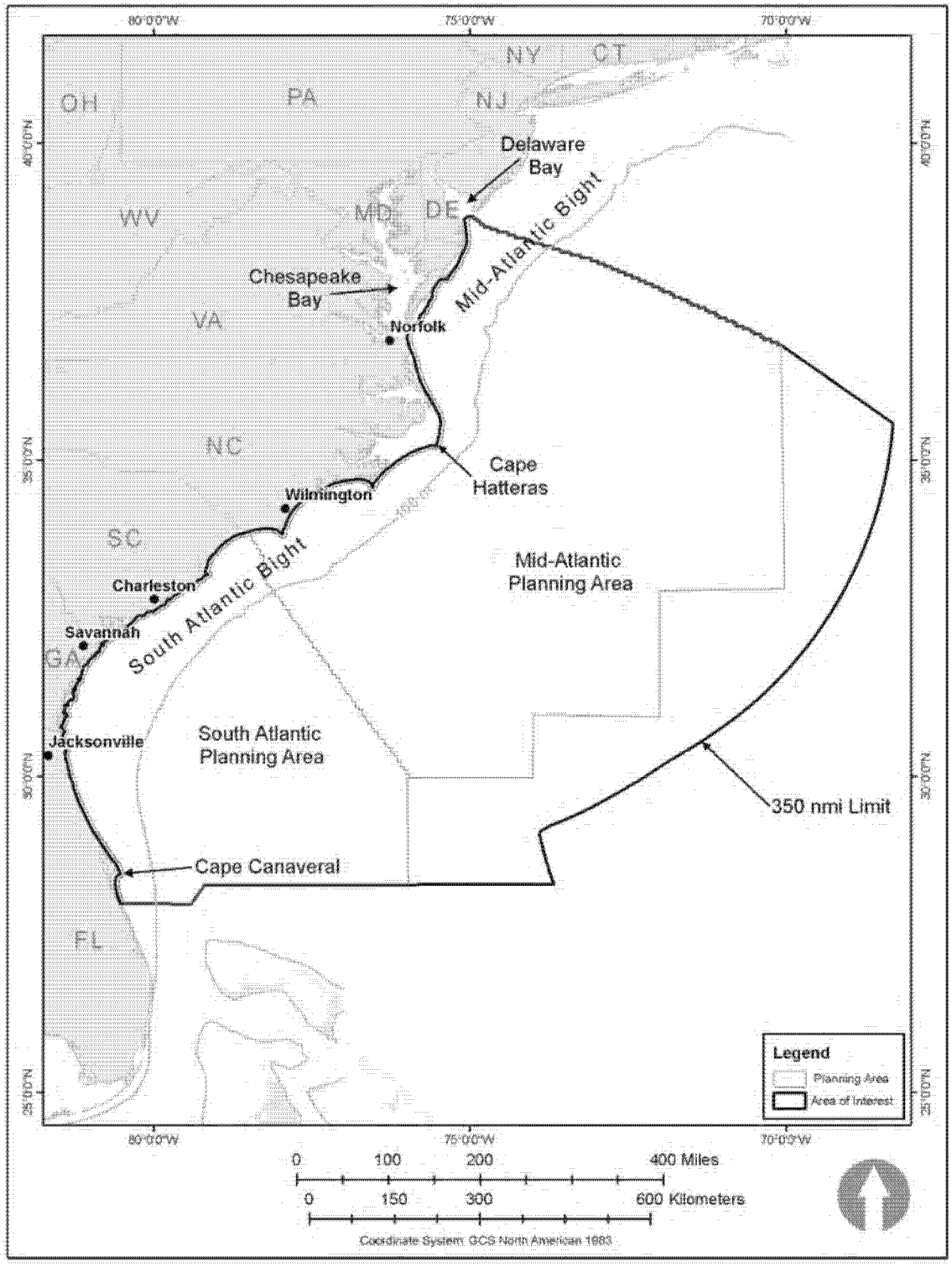

Figure 1. Specific Geographic Region.

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Detailed Description of Activities

Survey descriptions, as summarized from specific applications, are provided here. Please see Table 1 for a summary of airgun array characteristics. With the exception of Spectrum, the planned surveys have not changed from those described in our Notice of Proposed IHAs (82 FR 26244; June 6, 2017) Please see ''Spectrum Survey Plan Modification'' for further information. For full detail, please see the individual IHA applications and our Notice of Proposed IHAs. Note that all applicants expect there to be limited additional operations associated with equipment testing, startup, line changes, and repeat coverage of any areas where initial data quality is sub-standard. Therefore, there

could be some small amount of use of the acoustic source not accounted for in the total estimated line-km for each survey; however, this activity is difficult to quantify in advance and would represent an insignificant increase in effort.

ION—ION's survey is planned to occur from Delaware to northern Florida (~38.5° N to ~27.9° N) (see Figure 1 of ION's application), and consists of ~13,062 km of survey line. The acoustic source planned for deployment is a 36-airgun array with a total volume of 6,420 in^3. The array would consist of airguns ranging in volume from 40 in^3 to 380 in^3. The airguns would be configured as four identical linear arrays or ''strings'' (see Figure 3 of ION's application). The four airgun strings would be towed at 10-m depth, and would fire every 50 m or 20–24 s, depending on exact vessel speed. ION provided modeling results for their array, including notional source signatures, 1/3-octave band source levels as a function of azimuth angle, and received sound levels as a function of distance and direction at 16 representative sites in the survey area. For more detail, please see Figures 4–6 and Appendix A of ION's application.

Spectrum—Spectrum's survey was originally planned to occur from Delaware to northern Florida (see Figure 1 of Spectrum's application), consisting of ~21,635 km of survey line. This plan has been modified and now consists of ~13,766 km of operations. Please see ''Spectrum Survey Plan Modification'' for further information). The acoustic source planned for deployment is a 32-airgun array with a total volume of 4,920 in^3. The array would consist of airguns ranging in volume from 50 in^3 to 250 in^3. The airguns would be configured as four subarrays, each with eight to ten airguns (see Figure 2 in Appendix A of Spectrum's application). The four airgun strings would be towed at 6 to 10-m depth, and would fire every 25 m or 10 s, depending on exact vessel speed. Spectrum provided modeling results for their array, including notional source signatures, 1/3-octave band source levels as a function of azimuth angle, and received sound levels as a function of distance and direction at 16 representative sites in the survey area. For more detail, please see Appendix A of Spectrum's application.

As stated above, Spectrum notified NMFS on June 26, 2018, of a modification to their survey plan. Please see ''Spectrum Survey Plan Modification'' for further information.

TGS—TGS's survey is planned to occur from Delaware to northern Florida (see Figure 1–1 of TGS's application), and consists of ~58,300 km of survey line. The survey plan consists of two contiguous survey grids with differently spaced lines (see Figures 1–1 to 1–4 of TGS's application), and would involve use of two source vessels operating independently of one another at a minimum of 100 km separation distance. The acoustic sources planned for deployment are 40-airgun arrays with a total volume of 4,808 in^3. The array would consist of airguns ranging in volume from 22 in^3 to 250 in^3. The airguns would be configured as four identical strings (see Figure 3 in Appendix B of TGS's application). The four airgun strings would be towed at 7-m depth, and would fire every 25 m or 10 s, depending on exact vessel speed. More detail regarding TGS's acoustic source and modeling related to TGS's application is provided in Appendix B of TGS's application.

Western—Western's survey is planned to occur from Maryland to northern Florida (see Figure 1–1 of Western's application), and consists of ~27,330 km of survey line. The survey plan consists of a survey grid with differently spaced lines (see Figures 1–1 to 1–4 of Western's application). The acoustic source planned for deployment is a 24-airgun array with a total volume of 5,085 in^3. The airguns would be configured as three identical strings. The three airgun strings would be towed at 10-m depth, and would fire every 37.5 m (approximately every 16 s, depending on vessel speed). More detail regarding Western's acoustic source and modeling related to Western's application is provided in Appendix B of Western's application.

CGG—CGG's survey is planned to occur from Virginia to Georgia (see Figure 3 of CGG's application), and consists of ~28,670 km of survey line. The acoustic source planned for deployment is a 36-airgun array with a total volume of 5,400 in^3. The array would consist of airguns ranging in volume from 40 in^3 to 380 in^3. The airguns would be configured as four identical strings (see Figure 2 of CGG's application). The four airgun strings would be towed at 7-m depth, and would fire every 25 m or 10 s, depending on exact vessel speed. More detail regarding CGG's acoustic source and modeling related to CGG's application is provided in CGG's application.

TABLE 1—SURVEY AND AIRGUN ARRAY CHARACTERISTICS

Company	Total planned survey km	Total volume (in^3)	Number of guns	Number of strings	Nominal source output (downward) [1]			Shot interval (m)	Tow depth (m)
					0–pk	pk–pk	rms		
ION	13,062	6,420	36	4	257	263	[4] 247	50	10
Spectrum	13,766	4,920	32	4	266	272	243	25	6–10
TGS	58,300	4,808	40	4	255	([3])	240	25	7
Western	27,330	5,085	24	3	([3])	262	235	37.5	10
CGG	28,670	5,400	36	4	([3])	259	[3 4] 243	25	7
BOEM [2]	n/a	5,400	18	3	247	([3])	233	n/a	6.5

[1] See ''Description of Active Acoustic Sound Sources,'' later in this document, for discussion of these concepts.
[2] Notional array characteristics modeled and source characterization outputs from BOEM's PEIS (2014a) provided for comparison.
[3] Values not given; however, SPL (pk–pk) is usually considered to be approximately 6 dB higher than SPL (0–pk) (Greene, 1997).
[4] Value decreased from modeled 0–pk value by minimum 10 dB (Greene, 1997).

Comments and Responses

We published a Notice of Proposed IHAs in the **Federal Register** on June 6, 2017 (82 FR 26244), beginning a 30-day comment period. In that notice, we requested public input on the requests for authorization described therein, our analyses, the proposed authorizations, and any other aspect of the Notice of Proposed IHAs for the five separate specified geophysical survey activities, and requested that interested persons submit relevant information, suggestions, and comments. We further specified that, in accordance with the requirements of the MMPA, we would only consider comments that were relevant to marine mammal species that occur in U.S. waters of the Mid- and South Atlantic and the potential effects of the specified geophysical survey activities on those species and their habitat. We also noted that comments

indicating general support for or opposition to hydrocarbon exploration or any comments relating to hydrocarbon development (*e.g.,* leasing, drilling) were not relevant to the proposed actions and would not be considered. We requested that comments indicate whether they were general to all of the proposed authorizations or specific to one or more of the five separate proposed authorizations, and that comments should be supported by data or literature citations as appropriate. Following requests to extend the public comment period, we determined it appropriate to do so by an additional 15 days (82 FR 31048; July 5, 2017). Including the 15-day extension, the public comment period concluded on July 21, 2017. Comments received after the close of the comment period were not considered.

During the 45-day comment period, we received 117,294 total comment letters. Of this total, we determined that approximately 3,196 comment letters represented unique submissions, including 73 letters from various organizations or individuals acting in an official capacity (*e.g.,* non-governmental organizations, representatives and members of the oil and gas industry, state and local government, members of Congress, members of academia) and 3,103 unique submissions from private citizens. We note that the 73 letters represent approximately 330 organizations or individuals, as many letters included multiple co-signers. The remaining approximately 114,118 comment letters followed one of 20 different generic template formats, in which respondents provided comments that were identical or substantively the same. We consider each of the 20 different templates to represent a single unique submission that is included in the value cited above (3,196). Separately, we received 15 petitions, with a total of 99,423 signatures. Of these, one petition (595 signatures) expressed support for issuance of the proposed IHAs, while the remainder expressed opposition to issuance of the proposed IHAs or, more generally, to oil and gas exploration and/or development in the U.S. Atlantic Ocean.

NMFS has reviewed all public comments received on the proposed issuance of the five IHAs. All relevant comments and our responses are described below. Comments indicating general support for or opposition to hydrocarbon exploration but not containing relevant recommendations or information are not addressed here. Similarly, any comments relating to hydrocarbon development (*e.g.,* leasing, drilling)—including numerous comments received that expressed concern regarding the risks of oil spills or of potential future industrialization on the U.S. Atlantic coast—are not relevant to the proposed actions and therefore were not considered and are not addressed here. We also provide no response to specific comments that addressed species or statutes not relevant to our proposed actions under section 101(a)(5)(D) of the MMPA (*e.g.,* comments related to sea turtles), nor do we respond to comments more appropriately directed at BOEM pursuant to their authority under the Outer Continental Shelf Lands Act (OCSLA) to permit the planned activities. For those comments germane to the proposed IHAs, we outline our comment responses by major categories. Recurring comments are noted below as having been submitted by ''several'' or ''many'' commenters to avoid repetition. The 73 letters from various organizations or individuals acting in an official capacity, and representatives of each of the 20 form letter templates, are available online at: *www.fisheries.noaa.gov/action/incidental-take-authorization-oil-and-gas-industry-geophysical-survey-activity-atlantic.* Remaining comments are part of our administrative record for these actions but are not available online.

General Comments

A large majority of commenters, including all of those following one of the 20 templates, expressed general opposition towards geophysical airgun surveys in the U.S. Atlantic Ocean. We reiterate here that NMFS's proposed actions concern only the authorization of marine mammal take incidental to the planned surveys—jurisdiction concerning decisions to allow the surveys rests solely with BOEM, pursuant to their authority under the OCSLA. Further, NMFS does not have discretion regarding issuance of requested incidental take authorizations pursuant to the MMPA, assuming (1) the total taking associated with a specified activity will have a negligible impact on the affected species or stock(s); (2) the total taking associated with a specified activity will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (not relevant here); (3) the total taking associated with a specified activity is small numbers of marine mammals of any species or stock; and (4) appropriate mitigation, monitoring, and reporting of such takings are set forth, including mitigation measures sufficient to meet the standard of least practicable adverse impact on the affected species or stocks. A large volume of the comments received request that NMFS not issue any of the IHAs and/or express disdain for NMFS's proposal to issue the requested IHAs, but without providing information relevant to NMFS's decisions. These comments appear to indicate a lack of understanding of the MMPA's requirement that NMFS shall issue requested authorizations when the above listed conditions are met; therefore, these comments were not considered.

In general, commenters described the close linkages between their local and state economies to a healthy ocean, contending that the planned surveys could have substantial impacts on, for example, commercial and recreational fishing, wildlife viewing, outdoor recreation, and businesses dependent on these activities. Commenters suggested that NMFS should undertake analyses unrelated to the proposed actions (*i.e.,* issuance of requested IHAs), such as a cost-benefit analysis of hydrocarbon exploration and development compared to the economic benefits of coastal tourism and healthy fisheries. Many commenters also noted that over 120 municipalities and cities and 1,200 elected officials on the Atlantic coast have passed resolutions or otherwise formally opposed hydrocarbon exploration and/or development in the region. We also received comments expressing general opposition to oil and gas exploration activity from the Business Alliance for Protecting the Atlantic Coast, which stated that the comments were submitted on behalf of 41,000 businesses and 500,000 commercial fishing families. While NMFS recognizes the overwhelming opposition expressed by the public to oil and gas exploration and/or development in the U.S. Atlantic Ocean that it has received, we remain appropriately focused on consideration of the best available scientific information in support of our analyses pursuant to the MMPA, specific to the five IHAs considered herein.

Multiple commenters focused on specific, rather than general, issues that are not germane to our consideration of requested action under the MMPA. For example, the Northwest Atlantic Marine Alliance (NAMA) and other groups provided comments related to potential impacts on commercial fisheries, and the New Jersey Council of Diving Clubs expressed concern regarding potential impacts of the planned surveys on recreational divers. Recommendations were provided concerning mitigating potential impacts. We reiterate that NMFS's proposed action—the issuance

of IHAs authorizing incidental take of marine mammals—necessarily results in impacts only to marine mammals and marine mammal habitat. Effects of the surveys more broadly are the purview of BOEM, which has jurisdiction under OCSLA for permitting the actual surveys, as opposed to authorizing take of marine mammals incidental to a permitted survey. Therefore, we do not address comments such as these.

Multiple groups stated that NMFS should consider impacts and protection for other species in the action area, such as Atlantic sturgeon, other fish species, invertebrates, plankton, and sea turtles. Some of these comments specifically referenced the importance of the area offshore Cape Hatteras as home to a diverse assemblage of non-marine mammal species, including sharks, turtles, seabirds, and other fish species. The NAMA provided comments relating to Essential Fish Habitat (EFH) (as designated pursuant to the Magnuson Stevens Fishery Conservation and Management Act (MSA), as amended by the Sustainable Fisheries Act of 1996 (Pub. L. 104–267)), including concerns regarding effects to EFH resulting from the planned surveys. Because NMFS's proposed action is limited to the authorization of marine mammal take incidental to the planned surveys, effects of the surveys on aspects of the marine environment other than marine mammals and their habitat are not relevant to NMFS's analyses under the MMPA. Pursuant to guidance from NMFS's Office of Habitat Conservation concerning EFH and MMPA incidental take authorizations, we have determined that the issuance of these IHAs will not result in adverse impacts to EFH, and further, that issuance of these IHAs does not require separate consultation per section 305(B)(2) of the MSA. We do not further address potential impacts to EFH.

The MMPA does require that we evaluate potential effects to marine mammal habitat, which includes prey species (*e.g.,* zooplankton, fish, squid). However, consideration of potential effects to taxa other than marine mammals and their prey, or consideration of effects to potential prey species in a context other than the import of such effects on marine mammals, is not relevant to our action under the MMPA. We have appropriately considered effects to marine mammal habitat. Separately, BOEM evaluated effects to all relevant aspects of the human environment (including marine mammals and other taxa) through the analysis presented in their PEIS (available online at: *www.boem.gov/Atlantic-G-G-PEIS/*), and effects to all potentially affected species that are listed under the Endangered Species Act (ESA) and any critical habitat designated for those species were addressed through consultation between BOEM and NMFS pursuant to section 7 of the ESA. That Biological Opinion, which evaluated both BOEM's (issuing permits for the five surveys) and NMFS's (issuing IHAs associated with the five permitted surveys) proposed actions, is available online at: *www.fisheries.noaa.gov/action/incidental-take-authorization-oil-and-gas-industry-geophysical-survey-activity-atlantic.* We do not further address taxa other than marine mammals and marine mammal prey.

Marine Mammal Impacts

Comment: Many commenters expressed concern regarding the perceived lack of information regarding the affected marine mammal stocks and the impacts of the surveys on marine mammal individuals and populations and their habitat (direct and indirect; short- and long-term).

Response: NMFS acknowledges that, while there is a growing body of literature on the affected marine mammal stocks and regarding the impacts of noise on individual marine mammals, data gaps do remain, particularly with regard to potential population-level impacts and cumulative impacts. However, NMFS must use the best available scientific information in analyses supporting its determinations pursuant to the MMPA, and has done so here. While NMFS does not take lightly the potential effects of surveys on marine mammal populations, these surveys, with the robust suite of required mitigation and monitoring, are expected to have a negligible impact on the affected species and stocks.

Comment: Many commenters expressed general concern regarding impacts to both individual marine mammals and potential population-level harm, including impacts to important behaviors and chronic stress stemming from acoustic disturbance. More specifically, this included: Potential displacement from preferred feeding, breeding, and migratory habitats, which could lead to long-term and large-scale habitat avoidance or abandonment; impacts to mating, vocalizing, and other key marine mammal behaviors; communication interference between cow-calf pairs, which could lead to stranding increases and juvenile deaths; hearing loss hindering recruitment and marine mammals' ability to locate mates and find food.

Response: NMFS has carefully reviewed the best available scientific information in assessing impacts to marine mammals, and recognizes that the surveys have the potential to impact marine mammals through threshold shifts, behavioral effects, stress responses, and auditory masking. However, NMFS has determined that the nature of such potentially transitory exposure—any given location will be exposed to survey noise only relatively briefly and infrequently—means that the potential significance of the authorized taking, including potential long-term avoidance, is limited. NMFS has also prescribed a robust suite of mitigation measures, such as time-area restrictions and extended distance shutdowns for certain species, that are expected to further reduce the duration and intensity of acoustic exposure, while limiting the potential severity of any possible behavioral disruption.

Comment: Many commenters described impacts to ''millions of marine mammals,'' expressing concern that NMFS would allow such a level of impacts, or stating concern that NMFS would allow killing of marine mammals. Similarly, many commenters refer to taking or killing ''138,000 marine mammals.''

Response: Many of these comments were written with reference to the acoustic exposure analysis provided in BOEM's PEIS, which is not directly related to the specific surveys that are the subject of NMFS's analysis. In fact, the more specific figure commonly cited (*i.e.,* 138,000) represents the number of incidents of Level A harassment estimated by BOEM in their analysis using now-outdated guidance (*i.e.,* 180-dB root mean square (rms) with no consideration of frequency sensitivity) that the best available science indicates does not reflect when Level A harassment should be expected to occur. Certain non-governmental organizations have incorrectly suggested the information represents animals killed. In addition, BOEM's programmatic analysis was based on a vastly greater amount of survey activity occurring per year over a period of nine years, versus the five surveys considered herein. Regardless, NMFS cannot issue the authorizations unless the total taking expected to occur as a result of each specified activity is determined to result in a negligible impact to the affected species or stocks. The best available science indicates that Level B harassment, or disruption of behavioral patterns, is likely to occur, and that a limited amount of auditory injury, or permanent threshold shift (PTS) (Level A harassment) may occur for a few

species. No mortality is expected to occur as a result of the planned surveys, and there is no scientific evidence indicating that any marine mammal could experience mortality as a direct result of noise from geophysical survey activity. Authorization of mortality may not occur via IHAs, and such authorization was neither requested nor proposed. Finally, we emphasize that an estimate of take numbers alone is not sufficient to assess impacts to a marine mammal population. Take numbers must be viewed contextually with other factors, as explained in the ''Negligible Impact Analyses and Determinations'' section of this Notice.

Comment: Several commenters referenced studies showing that noise from airgun surveys can travel great distances underwater, leading to concern that the surveys would impact marine mammals throughout the specific geographic region at all times. Some commenters then suggested that this would result in there being no available habitat for displaced animals to escape to.

Response: NMFS acknowledges that relatively loud, low-frequency noise (as is produced by airgun arrays) has the potential to propagate across large distances. However, propagation and received sound levels are highly variable based on many biological and environmental factors. For example, while one commonly cited study (Nieukirk *et al.,* 2012) described detection of airgun sounds almost 4,000 km from the acoustic source, the sensors were located within the deep sound channel (SOFAR), where low-frequency signals may travel great distances due to the advantageous propagation environment. While sounds within this channel are unlikely to be heard by most marine mammals due to the depth of the SOFAR channel—which is dependent primarily on temperature and water pressure and therefore variable with latitude—it is arguable whether sounds that travel such distances may be heard by whales as a result of refraction to shallower depths (Nieukirk *et al.,* 2012; McDonald *et al.,* 1995). Regardless, while the extreme propagation distances cited in some comments may not be realistic in terms of effects on mysticetes, we acknowledge that contraction of effective communication space for whales that vocalize and hear at frequencies overlapping those emitted by airgun arrays can occur at distances on the order of tens to hundreds of kilometers. However, attenuation to levels below the behavioral harassment criterion (*i.e.,* 160 dB rms) will likely always occur over much shorter distances and, therefore, we do not agree with the contention that essentially the entire specific geographic region would be ensonified to a degree that marine mammals would find it unsuitable habitat. Rather, it is likely that displacement would occur within a much smaller region in the vicinity of the acoustic source (*e.g.,* within 5–10 km of the source, depending on season and location). Overall, the specific geographic region and marine mammal use of the area is sufficiently large that, although displacement may occur, the region offers enough habitat for marine mammals to seek temporary viable habitat elsewhere, if necessary. Many of the affected species occupy a wide portion of the region, and it is expected that individuals of these species can reasonably find temporary foraging grounds or other suitable habitat areas consistent with their natural use of the region. Further, although the planned surveys would cover large portions of the U.S. Mid- and South Atlantic, they will only be transitory in any given area. Therefore, NMFS does not expect displacement to occur frequently or for long durations. Importantly, for species that show high site fidelity to a particular area (*e.g.,* pilot whales around Cape Hatteras) or to bathymetric features (*e.g.,* sperm whales and beaked whales), NMFS has required additional time-area restrictions to reasonably minimize these impacts.

Comment: The Bald Head Island Association commented that many bottlenose dolphin populations are depleted, and risks from the surveys are too great.

Response: NMFS acknowledges that coastal bottlenose dolphin stocks are depleted under the MMPA, and we described the 2013–2015 Unusual Mortality Event affecting these stocks in our Notice of Proposed IHAs. NMFS is requiring a year-round closure to all survey activity out to 30 km offshore, including a 20-km distance beyond which encountered dolphins would generally be expected to be of the offshore stock and a 10-km buffer distance that is expected to encompass all received sound levels exceeding the 160-dB rms Level B harassment criterion. In consideration of this mitigation requirement, NMFS believes that impacts to coastal bottlenose dolphins will be minimal.

Comment: The New York State Department of Environmental Conservation expressed concern about impacts from the surveys to animals in the New York Bight, noting that even though the surveys would not be occurring in the vicinity of New York Bight many of the same animals that use the New York Bight for certain life history strategies would also be found in certain times of year in the specific geographic region.

Response: Although unrelated to our analyses and necessary findings pursuant to the MMPA, we note that in requesting the opportunity to conduct review of the proposed surveys pursuant to the Coastal Zone Management Act, New York did not demonstrate that the surveys would have reasonably foreseeable effects on New York's coastal uses or resources. Therefore, New York's request was denied. However, we acknowledge that some of the same animals that may occur in the New York Bight could also occur at other times of year within the survey region and, therefore, be affected by the specified activities. However, as detailed elsewhere in this document, we have found for each specified activity and each potentially affected species or stock that the taking would have a negligible impact.

Comment: The Natural Resources Defense Council (NRDC) submitted comments on behalf of itself and over thirty other organizations, including the Center for Biological Diversity, Defenders of Wildlife, Earthjustice, The Humane Society of the United States, Sierra Club, *et al.* Hereafter, we refer to this collective letter as ''NRDC.'' NRDC and other commenters assert that the surveys will drive marine mammals into shipping lanes, thereby increasing their risk of ship strike.

Response: As an initial matter, we address overall themes in NRDC's 85-page comment letter. In addition to mischaracterizing the literature, likely impacts to marine mammals, and NMFS's analyses in multiple places—which we attempt to correct throughout our responses—the letter repeatedly makes use of undefended or off-point assertions (*e.g.,* that NMFS's findings are ''arbitrary and capricious'' and ''non-conservative''). While we have attempted to clarify and correct individual mischaracterizations in our specific responses to comments, we broadly address the issue here. NRDC's 16 assertions that NMFS's analyses and/or conclusions are ''arbitrary and capricious'' or just ''arbitrary'' are unfounded. Similarly, NRDC claims that NMFS's approaches or decisions are ''non-conservative,'' or should be more ''conservative,'' at least 15 times, with no indication of what standard they are seeking to attain. While NRDC may disagree with the issuance of the IHAs or the underlying activities themselves, we believe the administrative record for these IHAs amply demonstrates that NMFS used the best available science

during our administrative process to inform our analyses and satisfy the standards under section 101(a)(5)(D).

With regard to this specific comment, the surveys are largely not occurring in or near any shipping lanes, as they will occur a minimum of 30 km offshore. NMFS is not aware of any scientific information suggesting that the surveys would drive marine mammals into shipping lanes, and disagrees that this would be a reasonably anticipated effect of the specified activities.

Comment: Comments submitted jointly by Oceana and the International Fund for Animal Welfare (hereafter, ''Oceana'') and, separately, by Sea Shepherd Legal discuss particular concerns regarding potential impacts to large whales. The comments cite studies showing modified singing behavior and habitat avoidance among fin whales in response to airguns; that sperm whales in the Gulf of Mexico have shown decreased buzz rates around airguns; that singing among humpback whales declined in response to airgun noise; etc.

Response: NMFS reviewed all cited studies in making its determinations for both the proposed and final IHAs, and agrees that there are multiple studies documenting changes in behavior and/or communication amongst large whales in response to airgun noise, sometimes at significant distance. Changes in vocalization associated with exposure to airgun surveys within migratory and non-migratory contexts have been observed (*e.g.,* Castellote *et al.,* 2012; Blackwell *et al.,* 2013; Cerchio *et al.,* 2014). The potential for anthropogenic sound to have impacts over large spatial scales is not surprising for species with large communication spaces, like mysticetes (*e.g.,* Clark *et al.,* 2009); however, not every change in a vocalization would necessarily rise to the level of a take, much less have meaningful consequences to the individual or for the affected population. As noted previously, the planned surveys are expected to be transient and would not result in any sustained impacts to such behaviors for baleen whales. We also acknowledge that exposure to noise from airguns may impact sperm whale foraging behavior (Miller *et al.,* 2009). However, our required mitigation—including time-area restrictions designed to protect certain habitat expected to be of importance for foraging sperm whales, in addition to standard shutdown requirements expected to minimize the severity and duration of any disturbance—when considered in context of the transient nature of the impacts possible for these surveys lead us to conclude that effects to large whales will be no greater than a negligible impact and will be mitigated to the level of least practicable adverse impact.

Comment: Several industry commenters stated, in summary, that there is no scientific evidence that geophysical survey activities have caused adverse consequences to marine mammal stocks or populations, and that there are no known instances of injury to individual marine mammals as a result of such surveys, stating that similar surveys have been occurring for years without significant impacts. One stated that surveys have been ongoing in the Gulf of Mexico for years and have not resulted in any negative impacts to marine mammals, including reducing fitness in individuals or populations. Referring to other regions, the commenters stated that bowhead whale numbers have increased in the Arctic despite survey activity. CGG noted that there is no ''empirical evidence'' of surveys causing injury or mortality to marine mammals, and that previous surveys resulted in less take than authorized. Another group added that BOEM has spent $50 million on protected species and noise research over four decades with no evidence of adverse effects.

Response: Disruption of behavioral patterns (*i.e.,* Level B harassment) has been documented numerous times for marine mammals in the presence of airguns (in the form of avoidance of areas, notable changes in vocalization or movement patterns, or other shifts in important behaviors; see ''Potential Effects of the Specified Activity on Marine Mammals and Their Habitat''). Further, lack of evidence for a proposition does not prove it is false. In this case, there is growing scientific evidence demonstrating the connections between sub-lethal effects, such as behavioral disturbance, and population-level effects on marine mammals (*e.g.,* Lusseau and Bedjer, 2007; New *et al.,* 2014). Disruptions of important behaviors, in certain contexts and scales, have been shown to have energetic effects that can translate to reduced survivorship or reproductive rates of individuals (*e.g.,* feeding is interrupted, so growth, survivorship, or ability to bring young to term is compromised), which in turn can adversely affect populations depending on their health, abundance, and growth trends.

Based on the available evidence, a responsible analysis of potential impacts of airgun noise on marine mammal individuals and populations cannot assume that such effects cannot occur. In reality, conclusive statements regarding population-level consequences of acoustic stressors cannot be made due to insufficient investigation, as such studies are exceedingly difficult to carry out and no appropriate study and reference populations have yet been established. For example, a recent report from the National Academy of Sciences noted that, while a commonly-cited statement from the National Research Council (''[n]o scientific studies have conclusively demonstrated a link between exposure to sound and adverse effects on a marine mammal population'') remains true, it is largely because such impacts are very difficult to demonstrate (NRC, 2005; NAS, 2017). Population-level effects are inherently difficult to assess because of high variability, migrations, and multiple factors affecting the populations. However, NMFS has carefully considered the available evidence in determining the most appropriate suite of mitigation measures and in making the necessary determinations (see ''Negligible Impact Analyses and Determinations'').

Comment: NRDC states that NMFS must consider that behavioral disturbance can amount to Level A harassment, or to serious injury or mortality, if it interferes with essential life functions through secondary effects, stating that displacement from migration paths can result in heightened risk of ship strike or predation, especially for right whales. In a similar vein, Oceana expressed concern about the presence of additional ships in the Atlantic, risking serious injury to marine mammals from ship strike or entanglement. Relatedly, NRDC noted that NMFS's conclusion that ship strikes will not occur indicates an assumption that required ship-strike avoidance procedures will be effective. NRDC disagrees that the ship-strike avoidance measures will be effective.

Response: NMFS acknowledges that sufficient disruption of behavioral patterns could theoretically, likely in connection with other stressors, result in a reduction in fitness and ultimately injury or mortality. However, such an outcome could likely result only from repeated disruption of important behaviors at critical junctures, or sustained displacement from important habitat with no associated compensatory ability. No such outcome is expected as a result of these surveys, which will be transient in any given area within the large overall region, and which avoid some of the most important habitat. Effects such as those suggested by NRDC would not be expected for

right whales, as the surveys are required to avoid migratory pathways (80 km from coast), or achieve comparable protection provided through implementation of a NMFS-approved mitigation and monitoring plan at distances between 47–80 km offshore (see ''Mitigation'' for more information).

Although the primary stressor to marine mammals from the specified activities is acoustic exposure to the sound source, NMFS takes seriously the risk of vessel strike and has prescribed measures sufficient to avoid the potential for ship strike to the extent practicable. NMFS has required these measures despite a very low likelihood of vessel strike; vessels associated with the surveys will add a discountable amount of vessel traffic to the specific geographic region (*i.e.,* each survey will operate with roughly 2–3 vessels) and, furthermore, vessels towing survey gear travel at very slow speeds (*i.e.,* roughly 4–5 kn).

NMFS's required vessel strike avoidance protocol is expected to further minimize any potential interactions between marine mammals and survey vessels. Please see ''Vessel Strike Avoidance'' for a full description of requirements, which include: Vessels must maintain a 10 kn speed restriction when in North Atlantic right whale critical habitat, Seasonal Management Areas, or Dynamic Management Areas; vessel operators and crews must maintain a vigilant watch for all marine mammals and must take necessary actions to avoid striking a marine mammal; vessels must reduce speeds to 10 kn or less when mother/calf pairs, pods, or large assemblages of cetaceans are observed near a vessel; and vessels must maintain minimum separation distances.

Comment: NRDC stated that NMFS did not properly consider potential impacts of masking to marine mammals. For example, NRDC notes that NMFS addresses masking in the general consequences discussion of its negligible impact analysis, but disagrees with NMFS's conclusion that consequences are appropriately categorized as ''medium'' rather than ''high'' for mysticetes, citing the distances at which vocal modifications to distant sounds have been detected in low-frequency cetaceans and newly-described low-level communication calls between humpback whales and their calves, which they suggest have dire implications for right whales. NRDC also states that NMFS incorrectly thinks masking is co-extensive with the modeled 160-dB rms behavioral harassment zones, and suggests that NMFS should take a modeling approach to better assess potential masking. Relatedly, another commenter stated a belief that NMFS assumes that there is no potential for masking during the interpulse interval, when in fact there is noise during that period due to multipath arrivals.

Response: NMFS disagrees that the potential impacts of masking were not properly considered. NMFS acknowledges our understanding of the literature NRDC cites regarding the greater sensitivity of low-frequency cetaceans to airgun survey noise via the designation of these effects as ''medium,'' but fundamentally, the masking effects to any one individual whale from one survey operating far offshore are expected to be minimal. Masking is referred to as a chronic effect because one of the key harmful components of masking is its duration—the fact that an animal would have reduced ability to hear or interpret critical cues becomes much more likely to cause a problem the longer it is occurring. Also, inherent in the concept of masking is the fact that the potential for the effect is only present during the times that the animal and the source are in close enough proximity for the effect to occur (and further this time period would need to coincide with a time that the animal was utilizing sounds at the masked frequency) and, as our analysis (both quantitative and qualitative components) indicates, because of the relative movement of whales and vessels, we do not expect these exposures with the potential for masking to be of a long duration within a given day. Further, because of the relatively low density of mysticetes, the time-area restrictions, and large area over which the vessels travel, we do not expect any individual whales to be exposed to potentially masking levels from these surveys more than a few days in a year.

NMFS recognizes that masking may occur beyond the 160-dB zone and, further, that the primary concern is when numerous sources, many of which may be at distances beyond their 160-dB isopleth, contribute to higher background noise levels over extended time periods and significant portions of an individual's acoustic habitat. However, as noted above, any masking effects of these single surveys operating far offshore (with no expectation that any of the five would be in close enough proximity to one another to contemporaneously expose animals to noise from multiple source vessels) are expected to be limited and brief, if present. Further, we recognize the presence of multipath arrivals, especially the farther the receiver is from the ship, but given the reduced received levels at distance, combined with the short duration of potential masking and the lower likelihood of extensive additional contributors to background noise this far offshore and within these short exposure periods, we believe that the incremental addition of the seismic vessel is unlikely to result in more than minor and short-term masking effects, likely occurring to some small number of the same individuals captured in the estimate of behavioral harassment.

In regard to some of the specific examples NRDC raised, we acknowledge that vocal modifications of low-frequency cetaceans in response to distant sound sources have been detected. However, as discussed elsewhere in this Notice, not every behavioral change or minor vocal modification rises to the level of a take or has any potential to adversely impact marine mammal fitness, and NRDC has not demonstrated why it believes the short duration exposures that low-frequency cetaceans might be exposed to a few times a year from a survey should constitute a ''high'' versus ''medium'' consequence in NMFS's assessment framework.

Similarly, NMFS is also aware of the Videsen *et al.* (2017) paper reporting the lower-level communication calls between humpback mother-calf pairs and noting the increased risk of cow-calf separation with increases in background noise. We first note that only neonates were tagged and measured in this study (*i.e.,* circumstances could change with older calves). Further, while vocalizations between these pairs are comparatively lower level than between adults, the cow and neonate calf are in regular close proximity (as evidenced by the extent of measured sound generated by rubbing in this study), which means that the received levels for cow-calf communication are higher than they would be if the animals were separated by the distance typical between adults—in other words, it is unclear whether these lower-level, but close proximity, communications are comparatively more susceptible to masking. Assuming that right whale cow-calf pairs use the same lower-level communication calls, we first note that across all five surveys, modeled results estimate that 19 right whales may intercept with the tracklines of the surveys such that they are potentially taken and, further, as described in the ''Negligible Impact Analyses and Determinations'' section and based on available demographic information, it should be expected that no more than four exposures could be of adult females with calves (not

specifically neonates). Again, when this very low likelihood of encountering cow-calf pairs is combined with the fact that any individuals (or cow-calf pairs) would not be expected to be exposed on more than a couple/few days in a year, NRDC has not demonstrated how the consequences of these activities would be ''catastrophic,'' for right whales, and we believe our analysis supports a ''medium'' consequence rating.

Last, in response to the suggestion that we utilize a model, such as the model NMFS used for assessing similar potential impacts in the Gulf of Mexico, to assess impacts to communication space from the surveys evaluated here—it is neither necessary nor an appropriate use of those tools. As noted above, the combination of the modeled take estimates, along with a qualitative evaluation of the temporal and spatial footprint of the activities within the large action area and dispersed marine mammal distributions, makes it clear that masking effects, if any, would be highly limited for these activities. In the Gulf of Mexico, NMFS used the referenced model in the context of a five-year rule to programmatically assess the chronic impacts of an entire seismic program in a mature and active hydrocarbon-producing region, with a significantly greater amount of effort than is contemplated in these five surveys, overlaid in an area with already otherwise high ambient noise. Use of the model is comparatively expensive and time-consuming, and produces a relatively gross-scale comparison of predicted annual averages (or other duration) of accumulated sound energy (which can also be interpreted in the context of the communication space of any species). This sort of analysis can be helpful in understanding relative chronic effects when higher and longer-term overall levels of activity and impacts are being evaluated across areas with notably variable levels of activities and/or ambient noise, and can potentially inform decisions regarding time-area mitigation. Here, however, any impacts to communication space from any individual survey are expected to be minimal; in addition to being unnecessary, the lack of granularity in the suggested model (which is appropriate at larger and denser scales of impacts, and which can be improved with improvement of the available input data) is such that its application to these activities would not produce useful information.

Comment: The South Carolina Environmental Law Project, on behalf of the Business Alliance for Protecting the Atlantic Coast, commented that chronic stress is possible from the specified activities and that likely stress effects would be exacerbated due to their contention that avoidance is impossible.

Response: As described in our Notice of Proposed IHAs, NMFS recognizes that stress from acoustic exposure is one potential impact of these surveys, and that chronic stress can have fitness, reproductive, etc. impacts at the population-level scale. However, we believe the possibility for chronic stress is low given the transitory and intermittent nature of the sound source (*i.e.,* acoustic exposure in specific areas will not be long lasting). The potential for chronic stress was evaluated in making the determinations presented in NMFS's negligible impact analyses.

Comment: An individual stated that NMFS did not account for long-term impacts to species, writing that it is impossible to accurately account for impacts without looking at the effects of sound disturbance on energy balance (*e.g.,* when disturbance results in additional time spent traveling and/or foraging in less optimal habitats, the result may be a negative energy balance). The commenter stated further that this negative energy balance could have effects both individually and cumulatively for a population, and that the cumulative effect of behavioral disturbance could be equivalent to a certain amount of lethal takes.

Response: NMFS acknowledges that the concerns raised are theoretically possible, but in this case, with limited duration of individual surveys or of overlap of multiple surveys, and modeled take estimates suggesting that individuals would rarely be impacted by any given survey more than a few days in a year, frequent and long-term displacement is not expected. Therefore, NMFS does not anticipate behavioral disruptions sufficient to negatively impact individual energy balances, much less to a degree where long-term effects resulting in impacts to recruitment or survival would occur. For example, while the available evidence indicates sensitivity to disruption of foraging efficiency for sperm whales exposed to airgun noise (Miller *et al.,* 2009), a recent bioenergetic modeling exercise showed that infrequent, minor disruptions in foraging—as are expected in this case—are unlikely to be fatal (Farmer *et al.,* 2018). The authors conclude that foraging disruptions would have to be relatively frequent to lead to terminal starvation, but continual minor disruptions can cause substantial reductions in available reserves. Given the temporary, infrequent nature of exposure likely to result from the planned surveys, in conjunction with the planned mitigation, which includes effort restrictions in areas expected to be of importance for sperm whale foraging, it is unlikely that either continual minor disruptions or less frequent, but more severe disruptions would occur.

Comment: One individual cited Schnitzler *et al.* (2017) in stating that the varied anatomy of individual sperm whale ears indicates that ''tolerable'' sound levels may not be the same for different animals.

Response: NMFS acknowledges that actual individual responses to noise exposure will vary based on a variety of factors, including individual anatomy but more likely because of individual context and experience. However, sufficient scientific information does not exist to assess differential impacts to specific individuals. Therefore, NMFS uses generic acoustic thresholds in order to predict potential responses to noise exposure. However, NMFS has required a sufficiently robust suite of mitigation measures to provide reasonable certainty of general reduction of takes and of intensity and/or duration of acoustic exposures for individual sperm whales.

Comment: The Bald Head Island Association noted that many marine mammals have washed up on their beaches in recent years, including a beaked whale and juvenile dolphin after offshore airgun surveys. Sea Shepherd Legal claimed that NMFS did not adequately address the potential for stranding events, noting several studies that they claim link strandings with airgun surveys. They also noted that NMFS did not acknowledge a January 2017 mass stranding of false killer whales when considering impacts to species.

Response: Marine mammals are known to strand for a variety of reasons, such as infectious agents, biotoxicosis, starvation, fishery interaction, ship strike, unusual oceanographic or weather events, sound exposure, or combinations of these stressors sustained concurrently or in series (*e.g.,* Geraci *et al.,* 1999). However, the cause or causes of most strandings are unknown (*e.g.,* Best, 1982). Stranding events are known to occasionally happen as a result of sound exposure, *e.g.,* Southall *et al.,* 2006, 2013; Jepson *et al.,* 2013; Wright *et al.,* 2013, with stranding thought to occur subsequent to the exposure, as a result of non-auditory physiological effects or injuries, which theoretically might occur as a secondary effect of extreme behavioral reactions (*e.g.,* change in dive profile as a result of an avoidance reaction). However, such events are typically associated with use of military

tactical sonar, which has very different characteristics than airgun noise.

NMFS is unaware of any information linking possible strandings on Bald Head Island, or in any other location on the East Coast, with offshore airgun survey activity, and does not expect the planned surveys to have any potential to result in stranding events or the type of injuries or effects that could lead to stranding events, given the required mitigation and operational protocols. In support of its position, Sea Shepherd Legal cites two review articles (Gordon *et al.,* 2003; Compton *et al.,* 2008) that make general statements regarding the potential effects of airgun noise and/or review best practices in mitigation—NMFS reviewed these papers and discussed them in our Notice of Proposed IHAs. Sea Shepherd also cites a third document (Engel *et al.,* 2004) questioning whether such surveys may be responsible for coincident strandings of humpback whales in Brazil in 2002, and notes NMFS's discussion of a 2002 beaked whale stranding event that was contemporaneous with and reasonably associated spatially with an airgun survey in the Gulf of California. However, unlike for strandings associated with use of military sonar, no conclusive causal link was made, and these observations remain based on spatial and/or temporal coincidence. NMFS here acknowledges the 2017 stranding of false killer whales in Florida referenced by Sea Shepherd Legal, for which no cause was found.

However, as a precaution NMFS has modified its reporting requirements to include protocols relating to minimization of additional harm to live-stranded (or milling) marine mammals. Addition of these protocols does not imply any change to our determination that stranding events are unlikely, nor does it imply that a stranding event that does occur is necessarily the result of the specified activities. However, we recognize that regardless of the cause of a stranding event, it is appropriate to take action in certain circumstances to avoid additional harm. Please see ''Monitoring and Reporting'' for more information.

Marine Mammal Impacts—Habitat

Comment: Many commenters expressed concern regarding potential impacts to marine mammal prey and/or food webs from the planned surveys. NRDC specifically provided numerous citations in claiming that the surveys could impact marine mammal prey through the following: (1) Cause severe physical injury and mortality; (2) damage hearing and sensory abilities of fish and marine invertebrates; (3) impede development of early life history stages; (4) induce stress that physically damages marine invertebrates and compromises fish health; (5) cause startle and alarm responses that interrupt vital behaviors; (6) alter predator avoidance behavior that may reduce probability of survival; (7) affect catchability of prey species; (8) mask important biological sounds essential to survival; (9) reduce reproductive success, potentially jeopardizing long-term sustainability of fish populations; (10) interrupt feeding behaviors and induce other species-specific effects that may increase risk of starvation, reduce reproduction, and alter community structure; and (11) compromise orientation of fish larvae with potential ecosystem-level effects. Additionally, many commenters cited a recent publication by McCauley *et al.* (2017) as evidence that the surveys could potentially impact zooplankton and consequently marine mammal food webs.

In contrast, the International Association of Geophysical Contractors, American Petroleum Institute, and National Ocean Industries Association (hereafter, ''the Associations'') stated that McCauley *et al.* (2017) ''purports to demonstrate, but fails to prove, that seismic survey air sources negatively impact zooplankton.'' The Associations cite small sample size, variability in the baseline and experimental data, and the ''large number of speculative conclusions that appear to be inconsistent with the data collected over a two-day period'' in stating that the research ''creates no reasonable implication regarding the potential effects of seismic surveys on marine mammals.''

Response: NMFS strongly disagrees with NRDC's contention that we ignored effects to prey species; in fact, we considered relevant literature (including that cited by NRDC) in finding that the most likely impact of survey activity to prey species such as fish and invertebrates would be temporary avoidance of an area, with a rapid return to recruitment, distribution, and behavior anticipated. While there is a lack of specific scientific information to allow an assessment of the duration, intensity, or distribution of effects to prey in specific locations at specific times and in response to specific surveys, NMFS's review of the available information does not indicate that such effects could be significant enough to impact marine mammal prey to the extent that marine mammal fitness would be affected. A more detailed discussion is provided in ''Potential Effects of the Specified Activities on Marine Mammals and Their Habitat.''

In summary, fish react to sounds which are especially strong and/or intermittent low-frequency sounds, and behavioral responses such as flight or avoidance are the most likely effects. However, the reaction of fish to airguns depends on the physiological state of the fish, past exposures, motivation (*e.g.,* feeding, spawning, migration), and other environmental factors. While we agree that some studies have demonstrated that airgun sounds might affect the distribution and behavior of some fishes, potentially impacting foraging opportunities or increasing energetic costs (*e.g.,* Fewtrell and McCauley, 2012; Pearson *et al.,* 1992; Skalski *et al.,* 1992; Santulli *et al.,* 1999; Paxton *et al.,* 2017), other studies have shown no or slight reaction to airgun sounds (*e.g.,* Pena *et al.,* 2013; Wardle *et al.,* 2001; Jorgenson and Gyselman, 2009; Cott *et al.,* 2012). Most commonly, though, the impacts of noise on fish are temporary. Investigators reported significant, short-term declines in commercial fishing catch rate of gadid fishes during and for up to five days after survey operations, but the catch rate subsequently returned to normal (Engas *et al.,* 1996; Engas and Lokkeborg, 2002); other studies have reported similar findings (Hassel *et al.,* 2004).

As discussed by NRDC, however, even temporary effects to fish distribution patterns can impact their ability to carry out important life-history functions. SPLs of sufficient strength have been known to cause injury to fish and fish mortality and, in some studies, fish auditory systems have been damaged by airgun noise (McCauley *et al.,* 2003; Popper *et al.,* 2005; Song *et al.,* 2008). However, in most fish species, hair cells in the ear continuously regenerate and loss of auditory function likely is restored when damaged cells are replaced with new cells. Halvorsen *et al.* (2012b) showed that a TTS of 4–6 dB was recoverable within 24 hours for one species. Impacts would be most severe when the individual fish is close to the source and when the duration of exposure is long—both of which are conditions unlikely to occur during these surveys, which will be transient in any given location and likely result in brief, infrequent noise exposure to prey species in any given area. For these surveys, the sound source is constantly moving, and most fish would likely avoid the sound source prior to receiving sound of sufficient intensity to cause physiological or anatomical damage. In addition, ramp-up may

allow certain fish species the opportunity to move further away from the sound source.

Available data suggest that cephalopods are capable of sensing the particle motion of sounds and detect low frequencies up to 1–1.5 kHz, depending on the species, and so are likely to detect airgun noise (Kaifu *et al.,* 2008; Hu *et al.,* 2009; Mooney *et al.,* 2010; Samson *et al.,* 2014). Auditory injuries (lesions occurring on the statocyst sensory hair cells) have been reported upon controlled exposure to low-frequency sounds, suggesting that cephalopods are particularly sensitive to low-frequency sound (Andre *et al.,* 2011; Sole *et al.,* 2013). Behavioral responses, such as inking and jetting, have also been reported upon exposure to low-frequency sound (McCauley *et al.,* 2000b; Samson *et al.,* 2014). Similar to fish, however, the transient nature of the surveys leads to an expectation that effects will be largely limited to behavioral reactions and would occur as a result of brief, infrequent exposures.

With regard to potential impacts on zooplankton, McCauley *et al.* (2017) found that exposure to airgun noise resulted in significant depletion for more than half the taxa present and that there were two to three times more dead zooplankton after airgun exposure compared with controls for all taxa, within 1 km of the airguns. However, the authors also stated that in order to have significant impacts on *r*-selected species such as plankton, the spatial or temporal scale of impact must be large in comparison with the ecosystem concerned, and it is possible that the findings reflect avoidance by zooplankton rather than mortality (McCauley *et al.,* 2017). In addition, the results of this study are inconsistent with a large body of research that generally finds limited spatial and temporal impacts to zooplankton as a result of exposure to airgun noise (*e.g.,* Dalen and Knutsen, 1987; Payne, 2004; Stanley *et al.,* 2011).

A modeling exercise was conducted as a follow-up to the McCauley *et al.* (2017) study (as recommended by McCauley *et al.* (2017)), in order to assess the potential for impacts on ocean ecosystem dynamics and zooplankton population dynamics (Richardson *et al.,* 2017). Richardson *et al.* (2017) found that for copepods with a short life cycle in a high-energy environment, a full-scale airgun survey would impact copepod abundance up to three days following the end of the survey, suggesting that effects such as those found by McCauley *et al.* (2017) would not be expected to be detectable downstream of the survey areas, either spatially or temporally. However, these findings are relevant for zooplankton with rapid reproductive cycles in areas where there is a high natural replenishment rate resulting from new water masses moving in, and the findings may not apply in lower-energy environments or for zooplankton with longer life-cycles. In fact, the study found that by turning off the current, as may reflect lower-energy environments, the time to recovery for the modelled population extended from several days to several weeks.

However, while potential impacts to zooplankton are of obvious concern with regard to their follow-on effects for higher-order predators, the survey area is not an important area for feeding for taxa that feed directly on zooplankton, *i.e.,* mysticetes. In the absence of further validation of the McCauley *et al.* (2017) findings, if we assume a worst-case likelihood of severe impacts to zooplankton within approximately 1 km of the acoustic source, the large spatial scale and expected wide dispersal of survey vessels does not lead us to expect any meaningful follow-on effects to the prey base for odontocete predators. While the large scale of effect observed by McCauley *et al.* (2017) may be of concern, especially in a more temperate environment, NMFS concludes that these findings indicate a need for more study, particularly where repeated noise exposure is expected—a condition unlikely to occur in relation to these planned surveys. We do not offer further comment with regard to the specific criticisms of the Associations, other than to say that their dismissal of the study seems to reflect an unsubstantiated opinion.

Overall, prey species exposed to sound might move away from the sound source, experience TTS, experience masking of biologically relevant sounds, or show no obvious direct effects. Mortality from decompression injuries is possible in close proximity to a sound, but only limited data on mortality in response to airgun noise exposure are available (Hawkins *et al.,* 2014). The most likely impacts for most prey species in a given area would be temporary avoidance of the area. The surveys are expected to move through an area relatively quickly, limiting exposure to multiple impulsive sounds. In all cases, sound levels would return to ambient once a survey ends and the noise source is shut down and, when exposure to sound ends, behavioral and/or physiological responses are expected to end relatively quickly (McCauley *et al.,* 2000b). The duration of fish avoidance of a given area after survey effort stops is unknown, but a rapid return to normal recruitment, distribution, and behavior is anticipated. While the potential for disruption of spawning aggregations or schools of important prey species can be meaningful on a local scale, the mobile and temporary nature of the surveys and the likelihood of temporary avoidance behavior suggest that impacts would be minor.

Comment: A group of scientists (C.W. Clark, S.D. Kraus, D.P. Nowacek, A.J. Read, M. Rekdahl, A.N. Rice, H. Rosenbaum, and R.S. Schick) submitted a collective comment letter. Hereafter, we refer to this letter as ''Nowacek *et al.*'' Nowacek *et al.* and NRDC stated that it is inappropriate to conclude that these surveys will not impact marine mammal acoustic habitat, since the production of airgun noise is known to increase ambient noise, thereby negatively impacting habitat. NRDC further states that NMFS has failed to adequately account for impacts to acoustic habitat. In support of their statements, Nowacek *et al.* submitted the results of a sound field modeling exercise in which they considered energy produced from seven shots of a 40-element array at 6 m depth (other important source details were not provided) across one-third-octave bands spanning the 71–224 Hz frequency range. Resulting sound fields were concatenated at 1-s resolution for two different water depths (50 and 200 m) (commenters submitted animations associated with this exercise; these are available upon request and are part of our administrative record for these actions). They wrote that these animations highlight the dynamic nature of the marine environment, especially the low-frequency sound field, and the large area over which sound levels are increased above ambient levels but below current regulatory harassment thresholds. The commenters then correctly note that consideration of likely takes is limited to just a portion of the area over which airgun noise extends into the marine environment. Nowacek *et al.* also recommended that NMFS produce a quantitative methodology for assessing the region's acoustic environment, the proportional contributions from each of the natural and anthropogenic noise inputs, and create mechanisms to mitigate these lower-level noise exposures.

Response: The commenters' claims that NMFS concluded that there ''would be no impact to the quality of the acoustic habitat'' or suggested that ''there is no basis for acoustic habitat impacts'' are erroneous. NMFS made no such statements, but rather

acknowledged in our Notice of Proposed IHAs that it was likely that there would be impacts to acoustic habitat, particularly for low-frequency cetaceans. In fact, we explicitly considered this likelihood in our preliminary negligible impact analyses, finding that ''consequence'' of the surveys should be considered as higher for mysticete whales than for other species for this reason.

NMFS addressed potential effects to habitat, including acoustic habitat, and acknowledges that the surveys will increase noise levels in the vicinity of operating source vessels. However, following consideration of the available information, NMFS concludes that these impacts will not significantly affect ambient noise levels or acoustic communication space over long time periods, especially in the context of any given exposed individual. As described previously, exploratory surveys such as these cover a large area but would be transient rather than focused in a given location over time and therefore would not be considered as contributing meaningfully to chronic effects in any given location. Given these conclusions, a separate quantitative analysis of potential impacts to acoustic habitat, as is suggested by Nowacek *et al.,* is not warranted. In contrast, we did develop and perform such analysis for a different assessment of much more extensive geophysical survey activity (see Appendix K in BOEM, 2017) to be conducted over a period of ten years, versus the limited amount of survey activity to be conducted over a period of one year here.

We acknowledge and appreciate the commenters' scientific expertise, but there are relevant statutory and regulatory requirements that inform NMFS in the scope of analysis relevant to a finding of negligible impact. Please see also our response to a previous comment above, in which NRDC makes similar charges regarding the impacts of masking. Finally, regarding terminology used in the comments (*i.e.,* ''primary constituent elements''), the discussion in this document pertains specifically to the MMPA and not components related to critical habitat designated under the ESA.

Comment: The Sierra Club Marine Group noted that Cape Hatteras has a very unique morphology, and that these features support upwelling that supports significant biodiversity, including beaked whales. The commenters stated that impacts to this habitat provide a compelling reason to deny the IHAs.

Response: As described in our Notice of Proposed IHAs, NMFS concurs that Cape Hatteras provides important habitat for a diverse assemblage of species, particularly for species such as sperm whales, beaked whales, pilot whales, and other species that show high site fidelity to the area. Accordingly, NMFS has designed a time-area restriction encompassing the area referenced in the comment that precludes survey effort within the area for a three-month period (January to March; Stanistreet *et al.,* 2018); the restriction is defined specifically to benefit beaked whales, sperm whales, and pilot whales, with the specific timing intended as the most appropriate for sperm whales. We also require mitigation to reduce the intensity and duration of exposure for these species—particularly for acoustically sensitive species, such as beaked whales, for which shutdown is required at an extended distance of 1.5 km. Separately, NMFS has required year-round closures of similar high-relief habitats further offshore that are predicted to host relatively high densities of beaked whales. In addition, the North Atlantic right whale closure will protect portions of the area referenced by the commenters, as it extends out to 90 km from the coastline (*i.e.,* 80 km plus a 10 km buffer, see ''Mitigation'') and is in effect from November through April (or comparable protection provided through implementation of a NMFS-approved mitigation and monitoring plan at distances between 47–80 km offshore), whereas the seasonal restriction off of Cape Hatteras is in effect from January through March. NMFS believes these restrictions provide a high degree of protection to these species and the habitat they utilize around Cape Hatteras, while meeting the MMPA's least practicable adverse impact standard. When the contextual factor addressing required mitigation is considered, the outcome is a negligible impact to affected species.

Comment: An individual states that the surveys have the potential to impair the Chesapeake Bay, and that such impairment would have wider ecological and economic repercussions beyond the scope of impacting marine mammals. Similarly, one group mentioned that impacts from the surveys could ripple into smaller bays and inlets elsewhere along the East Coast, and impact species long after surveys are complete.

Response: NMFS's action is authorizing the taking of marine mammals pursuant to section 101(a)(5)(D); therefore, impacts of the survey on aspects of the environment other than marine mammals and their habitat are not relevant to NMFS's analysis conducted pursuant to the MMPA. However, the authorization of marine mammal take incidental to the planned surveys would not impact marine mammals of the Chesapeake Bay or of other coastal bays and estuaries. Surveys may not operate closer than 30 km to shore at any time.

North Atlantic Right Whale

Comment: Many commenters expressed concern regarding the North Atlantic right whale and potential impacts of the specified activities, given their declining population size, an ongoing Unusual Mortality Event (UME), declining calf production, and annual exceedances of the calculated potential biological removal value (see ''Description of Marine Mammals in the Area of the Specified Activities—North Atlantic Right Whale'' for further discussion of these issues). Some commenters noted additional concern regarding potential survey overlap with biologically important areas. Others highlighted concerns regarding increased risk of ship strike and/or entanglement with survey vessels, in addition to the potential for acoustic and behavioral effects.

Response: NMFS appreciates the concerns expressed by commenters regarding right whales. As an agency, NMFS is working to address the numerous issues facing right whales, including continued work to reduce deaths due to ship strike and entanglement in fishing gear and ongoing investigation of the UME, as well as other measures to investigate and address the status of the species. The best available scientific information shows that the majority of right whale sightings in the southeast occur in right whale calving areas from roughly November through April, with individual right whales migrating to and from these areas through mid-Atlantic shelf waters. Because of these concerns regarding right whales, NMFS is requiring closure of these areas (out to 90 km from shore) to survey activity from November 1 to April 30 (or that comparable protection is achieved through implementation of a NMFS-approved mitigation and monitoring plan at distances between 47–80 km offshore). This measure is expected to largely avoid disruption of behavioral patterns for right whales and to minimize overall acoustic exposures. Therefore, NMFS believes that this restriction provides for migratory passage to and from calving grounds as well as avoiding impacts to the whales while on the grounds. In addition, NMFS re-evaluated potential right whale takes using the best available

scientific information (*i.e.,* Roberts *et al.,* 2017) and in consideration of the revised time-area restriction. The result of this analysis shows that takes of right whales will be minimal.

Comment: NRDC and, separately, Nowacek *et al.* state that airgun surveys have been linked to significant reductions in the probability of calf survival in western Pacific gray whales (another endangered baleen whale population), claiming that these findings indicate that similar surveys off the southeastern U.S will have significant negative effects on the whales that occur anywhere in the region.

Response: Commenters cite a preliminary report (Cooke *et al.,* 2015) that documented a reduction in calf survival that they suggested may be related to disruption of foraging from airgun survey activity and pile driving in Russia due to presumed avoidance of foraging areas. However, a more recent analysis (Cooke *et al.,* 2017) invalidated these findings, showing that this was a sampling effect, as those calves that were assumed dead in the 2015 study have since been observed alive elsewhere. The new study found no significant annual variation in calf survival. Johnson *et al.* (2007) had previously reported that foraging gray whales exposed to airgun sounds during surveys in Russia did not experience any biologically significant or population-level effects.

Comment: J.J. Roberts and P.N. Halpin of the Duke University Marine Geospatial Ecology Lab (hereafter, ''MGEL'') provided two comments related to right whales. First, the commenters stated, in summary, that the time-area restriction included in our Notice of Proposed IHAs for the specific purpose of avoiding impacts to the North Atlantic right whale would not be sufficient to achieve its stated purpose. The commenters noted multiple lines of scientific evidence that right whales occur beyond the area defined in the Notice of Proposed IHAs (*i.e.,* a 20-nmi coastal strip, superseded by either critical habitat or seasonal management areas, and buffered by a distance of 10 km; this equates roughly to a 47-km coastal strip). The commenters also reiterated concern regarding an error associated with the right whale take estimates for two applicants (TGS and Western). Finally, the commenters noted that they were developing updated density models for the right whale; these revised models more than double the survey effort utilized by the models in the region south of Cape Hatteras, while additional new data boost coverage in non-summer seasons. As stated by the commenters, collectively these data allow for a notable upgrade in right whale density model performance in the regions and seasons addressed here. The commenters noted that, while the revised models have not been through formal peer review, they utilize the same methodology as the Roberts *et al.* (2016) publication, which has been peer reviewed.

Response: We agree with these comments, and addressed them through use of the revised North Atlantic right whale models (Roberts *et al.,* 2017) in developing new exposure estimates for all five applicant companies. Importantly, in agreement with the statements of the commenters and with the outputs of the revised models, we revised the time-area restriction by increasing the standoff distance from shore to 90 km (*i.e.,* 80 km plus a 10 km buffer) (or requiring that comparable protection is achieved through implementation of a NMFS-approved mitigation and monitoring plan at distances between 47–80 km offshore). As stated by MGEL and other commenters, Norris *et al.* (2014) reported acoustic detections of right whales in the southeast beyond the previous 47 km limit, while Foley *et al.* (2011) documented a right whale birth beyond the previous limit. The right whale model produced by Roberts *et al.* (2016) explicitly included distance from shore as a predictor in the model; right whale densities significantly above zero were predicted beyond the proposed 47 km limit. The revised model retains distance from shore as a predictor and, in the region north of Cape Fear, indicates that right whale density peaks at about 50 km offshore during the winter and is moderate to about 80 km from shore, beyond which limit density is predicted as dropping off rapidly. Please see ''Estimated Take—North Atlantic Right Whale'' and ''Mitigation'' for additional discussion.

Comment: Nowacek *et al.* commented that NMFS should perform a quantitative evaluation of right whale health and reproductive rates, including mortality and sublethal effects of entanglement. They noted that tools such as the Population Consequences of Disturbance (PCOD) model could be used to perform such an analysis. However, Nowacek *et al.* provided their own modeling example, including a health assessment of five North Atlantic right whales, which they described in their comment letter. Nowacek *et al.'*s analysis showed that a small decrement in health that could be linked to stress caused by chronic noise exposure can result in negative consequences for individual right whales.

Response: NMFS appreciates the attention given to this issue by the commenters, and finds the analysis provided in their letter useful. As noted by many commenters, the primary threats to the right whale remain ship strike and entanglement in fishing gear. However, NMFS considered this analysis and its conclusions in its determination to revisit the acoustic exposure analysis conducted for right whales and in reconsidering the most appropriate habitat-based mitigation requirements related to right whales. Following these new analyses, NMFS finds that predicted takes of right whales have been substantially reduced and that potential impacts to the right whale have been reduced to the level of least practicable adverse impact. While it is likely not possible to completely avoid acoustic exposures of North Atlantic right whales, NMFS finds that such exposures will be minimized and that, importantly, the impact of acoustic exposures will be minimized by avoiding entirely the habitat expected to be important for right whales for calving and migratory behavior (or that comparable protection is achieved through implementation of a NMFS-approved mitigation and monitoring plan at distances between 47–80 km offshore). In the event that right whales are encountered outside these areas, the expanded shutdown requirement will minimize the severity and/or duration of acoustic exposures. Finally, while exposures of right whales at levels below those expected to result in disruption of behavioral patterns but above the level of ambient noise may occur, NMFS does not consider such potential exposures as likely to constitute ''chronic noise exposure,'' as a result of the relatively brief duration of any given survey in any particular location; therefore, it is unlikely that the specified activities could result in impacts such as those assessed through the analysis of Nowacek *et al.*

Comment: One commenter described the relationship between noise and stress shown by Rolland *et al.* (2012) for right whales, stating that the planned surveys could increase stress in right whales.

Response: While NMFS concurs that the findings of Rolland *et al.* (2012) indicate a connection between noise exposure and stress in right whales, the number of vessels associated with the surveys is unlikely to contribute to significant additive vessel traffic and associated vessel noise as compared with vessel activity already occurring in the region. Rolland *et al.* (2012)

measured vessel density in an area with much more concentrated activity (*i.e.,* shipping lanes in the Bay of Fundy) than what would occur in the activity area. While noise from the surveys, whether due to use of the airgun arrays or from the vessels themselves, may cause stress responses in exposed animals, NMFS finds it unlikely that such responses will significantly impact individual whales as chronic noise exposure is not expected.

Comment: Several groups commented on additional data NMFS should have considered in assessing impacts to North Atlantic right whales. For example, the Marine Mammal Commission (MMC) recommended that we consult with NMFS's Northeast Fisheries Science Center regarding results of their most recent acoustic analysis, which they contend may provide insight on occurrence of right whales at different distances from shore. Similarly, Nowacek *et al.* recommended that NMFS should consider more recent data from the Atlantic Marine Assessment Program for Protected Species (AMAPPS) surveys or right whale surveys in the southeast curated by the North Atlantic Right Whale Consortium. NRDC stated that NMFS must use additional data sources in calculating right whale densities, noting that recent passive acoustic studies have detected whales further offshore and with broader seasonality than previously expected.

Response: NMFS agrees with these comments, and has considered these various sources of newer data, including by revising acoustic exposure estimates for right whales by using the latest density models for right whales (Roberts *et al.,* 2017). These revised models incorporate the southeast U.S. right whale survey data as well as the AMAPPS data. While the revised model does not directly incorporate acoustic data—we note that NRDC offers no suggestions as to how this might be accomplished—it was validated through comparison with passive acoustic monitoring data (Davis *et al.,* 2017). While this validation work does suggest that the revised model may underestimate right whale presence in certain locations or seasons—for example, acoustic data indicate that the model may underestimate the presence of whales relatively far from shore during the winter in the region north of Cape Hatteras—we developed an extended right whale closure (out to 90 km from shore) (or we require that comparable protection is achieved through implementation of a NMFS-approved mitigation and monitoring plan at distances between 47–80 km offshore) in an effort to reasonably encompass the likelihood of increased whale presence at greater distances from shore than have previously been expected.

Comment: Sea Shepherd Legal stated that NMFS ignored the ''Cetacean & Sound Mapping platform (''CetSound'')'' when discussing biologically important areas for North Atlantic right whales.

Response: Though NMFS did not give specific reference to ''CetSound'' in our Notice of Proposed IHAs, we did in fact incorporate and consider information available through NOAA's CetSound website (*cetsound.noaa.gov*), including information relating to BIAs, as discussed by LaBrecque *et al.* (2015).

Cumulative Impacts and Related Issues

Comment: Many commenters expressed concern regarding ''cumulative,'' ''aggregate'' and ''synergistic'' impacts. Commenters stated that NMFS did not adequately address cumulative or aggregate impacts from the five surveys, which are planned to occur within the same broad geographic region and which could overlap temporally. Some commenters referenced the large amount of survey effort described in BOEM's PEIS, erroneously ascribing the potential cumulative impacts associated with that level of effort—associated with nine years of surveys in support of an active oil and gas program in the Atlantic—to the significantly smaller amount of activity contemplated in our five separate proposed IHAs. Commenters urged the agency to review cumulative impacts using a risk-averse approach, considering such impacts in the context of effects to both species and ecosystems, as well as across time and geographic extent. As discussed in a previous comment response, some commenters cited studies demonstrating potential long-range propagation of airgun signals as reason for additional consideration of cumulative impacts. Similarly, some commenters claimed a need to consider takes in the aggregate and to consider potential takes from other sources. Nowacek *et al.* specified that NMFS should assess aggregate impacts in addition to cumulative impacts, highlighting available tools to do so. One commenter suggested that a cumulative noise management plan should be developed. Commenters such as Nowacek *et al.* decry our independent consideration of the effects of each individual specified activity under the MMPA as ''completely without basis in science or logic.'' Similarly, NRDC claims that failing to consider the total impact of all five surveys in the negligible impact assessment does not satisfy NMFS's legal obligations and is ''contrary to common sense and principles of sound science.'' NRDC also states that NMFS's negligible impact determination underestimates impacts to marine mammal species and populations because it fails to consider the effects of other anticipated activities on the same marine mammal populations. Finally, some commenters acknowledged that the MMPA does not require consideration of cumulative impacts but stated that NMFS must do so in this case given the unprecedented scale of these surveys in the Atlantic.

Response: Cumulative impacts (also referred to as cumulative effects) is a term that appears in the context of NEPA and the ESA, but it is defined differently in those different contexts. Neither the MMPA nor NMFS's codified implementing regulations address consideration of other unrelated activities and their impacts on populations. However, the preamble for NMFS's implementing regulations (54 FR 40338; September 29, 1989) states in response to comments that the impacts from other past and ongoing anthropogenic activities are to be incorporated into the negligible impact analysis via their impacts on the environmental baseline. Consistent with that direction, NMFS here has factored into its negligible impact analyses the impacts of other past and ongoing anthropogenic activities via their impacts on the baseline (*e.g.,* as reflected in the density/distribution and status of the species, population size and growth rate, and other relevant stressors (such as incidental mortality in commercial fisheries)). In addition, the context aspect of our assessment framework also considers these factors. See the ''Negligible Impact Analyses and Determinations'' section of this notice.

Our 1989 final rule for the MMPA implementing regulations also addressed public comments regarding cumulative effects from future, unrelated activities. There we stated that such effects are not considered in making findings under section 101(a)(5) concerning negligible impact. We indicated that NMFS would consider cumulative effects that are reasonably foreseeable when preparing a NEPA analysis; and also that reasonably foreseeable cumulative effects would be considered under section 7 of the ESA for ESA-listed species.

In this case, we deem each of these IHAs a future, unrelated activity relative to the others. Although these IHAs are all for surveys that will be conducted for

a similar purpose, they are unrelated in the sense that they are discrete actions under section 101(a)(5)(D), issued to discrete applicants.

Here, we recognize the potential for cumulative impacts, and that the aggregate impacts of the five surveys will be greater than the impacts of any given survey. The direct aggregate impacts of multiple surveys were addressed through the associated NEPA analyses: In BOEM's PEIS, which addressed the impacts of a significantly greater amount of survey activity that may be permitted by BOEM, and which NMFS adopted as the basis for its Record of Decision; as well as in NMFS's tiered Environmental Assessment, which supported a Finding of No Significant Impact (FONSI) for the issuance of the five IHAs here.

In our FONSI, NMFS's assessment was focused on whether the predicted level of take from the five surveys, when considered in context, would have a meaningful biological consequence at a species or population level. NMFS, therefore, assessed and integrated other contextual factors (*e.g.,* species' life history and biology, distribution, abundance, and status of the stock; mitigation and monitoring; characteristics of the surveys and sound sources) in determining the overall impact of issuance of the five IHAs on the human environment. Key considerations included the nature of the surveys and the required mitigation. In all cases, it is expected that sound levels will return to previous ambient levels once the acoustic source moves a certain distance from the area, or the surveys cease, and it is unlikely that the surveys will all occur at the same time in the same places, as the area within which the surveys will occur is very large and some will occur for less than six months. In other words, we would not expect the duration of a sound source to be greater than moderate and intermittent in any given area. Surveys have been excluded from portions of the total area deemed to result in the greatest benefit to marine mammals. These restrictions will not only reduce the overall numbers of take but, more importantly, will eliminate or minimize impacts to marine mammals in the areas most important to them for feeding, breeding, and other important functions. Therefore, these measures are expected to meaningfully reduce the severity of the takes that do occur by limiting impacts that could reduce reproductive success or survivorship.

In summary, NMFS finds that when the required mitigation and monitoring is considered in combination with the large spatial extent over which the activities are spread across for comparatively short durations (less than one year), the potential impacts are both temporary and relatively minor. Therefore, NMFS does not expect aggregate impacts from the five surveys to marine mammals to affect rates of recruitment or survival, either alone or in combination with other past, present, or ongoing activities. The cumulative impacts of these surveys (*i.e.,* the incremental impact of the action when added to other past, present, and reasonably foreseeable future actions) were addressed as required through the NEPA documents cited above and, as noted, supported a FONSI for the five IHAs. These documents, as well as the relevant Stock Assessment Reports, are part of NMFS's Administrative Record for this action, and provided the decision-maker with information regarding other activities in the action area that affect marine mammals, an analysis of cumulative impacts, and other information relevant to the determinations made under the MMPA.

Separately, cumulative effects were analyzed as required through NMFS's required intra-agency consultation under section 7 of the ESA, which concluded that NMFS's action of issuing the five IHAs was not likely to jeopardize the continued existence of listed marine mammals and was not likely to adversely affect any designated critical habitat.

We note that section 101(a)(5)(D) of the MMPA requires NMFS to make a determination that the take incidental to a ''specified activity'' will have a negligible impact on the affected species or stocks of marine mammals, and will not result in an unmitigable adverse impact on the availability of marine mammals for taking for subsistence uses. We believe the ''specified activity'' for which incidental take coverage is being sought under section 101(a)(5)(D) is appropriately defined and described by the IHA applicant, just as with applications submitted for section 101(a)(5)(A) incidental take regulations. Here there are five specified activities, with a separate applicant for each. NMFS must make the necessary findings for each specified activity.

Comment: Several commenters discussed a recent report from the National Academy of Sciences concerning cumulative impacts to marine mammals (''Approaches to Understanding the Cumulative Effects of Stressors on Marine Mammals''; NAS, 2017), suggesting that NMFS should have reviewed this report in addressing cumulative impacts.

Response: NMFS acknowledges the importance of this new report, which was not available at the time of writing for our Notice of Proposed IHAs. We reviewed this report and considered its findings in relation to our considerations pursuant to NEPA as well as with regard to its general findings for marine mammals. Behavioral disturbance or stress may reduce fitness for individual animals and/or may exacerbate existing declines in reproductive health and survivorship. For example, stressors such as noise and pollutants can induce responses involving the neuroendocrine system, which controls reactions to stress and regulates many body processes (NAS, 2017). As an example, Romano *et al.* (2004) found that upon exposure to noise from a seismic watergun, bottlenose dolphins had elevated levels of a stress-related hormone and, correspondingly, a decrease in immune cells. Population-level impacts related to energetic effects or other impacts of noise are difficult to determine, but the addition of other stressors can add considerable complexity due to the potential for interaction between the stressors or their effects (NAS, 2017). When a population is at risk NAS (2017) recommends identifying those stressors that may feasibly be mitigated. In this case, we have done so by prescribing a comprehensive suite of mitigation measures that both specifically tailors real-time detection and mitigation requirements to the species most sensitive to noise from airguns or to additional stressors in general (due to overall vulnerability of the stock), and includes habitat-based mitigation that restricts survey effort in the areas and times expected to be most important for the species at greatest risk of more severe impacts from the specified activities (or requires comparable protection via other methods).

Acoustic Thresholds

Comment: NRDC and several other commenters criticized NMFS's use of the 160-dB rms Level B harassment threshold, stating that the threshold is based on outdated information and that current research shows that behavioral impacts can occur at levels below the threshold. Criticism of our use of this threshold also focused on its nature as a step function, *i.e.,* it assumes animals don't respond to received noise levels below the threshold but always do respond at higher received levels. Several organizations also suggest that reliance on this threshold results in consistent underestimation of impacts. Commenters urged the agency to provide additional technical acoustic guidance regarding thresholds for behavioral harassment and stated that

no determinations regarding the proposed IHAs can be made until such new guidance has been developed. NRDC specifically stated that NMFS should employ specific thresholds for which species-specific data are available, and then create generalized thresholds for other species, and that the thresholds should be expressed as linear risk functions where appropriate to account for intraspecific and contextual variability. NRDC and others suggested that NMFS must revise the threshold as suggested in Nowacek *et al.* (2015), which recommended a dose function centered on 140 dB rms. TGS suggested that NMFS should re-evaluate take estimates using the approach described in Wood *et al.* (2012).

Response: NMFS acknowledges that the 160-dB rms step-function approach is simplistic, and that an approach reflecting a more complex probabilistic function may more effectively represent the known variation in responses at different levels due to differences in the receivers, the context of the exposure, and other factors. Certain commenters suggested that our use of the 160-dB threshold implies that we do not recognize the science indicating that animals may react in ways constituting behavioral harassment when exposed to lower received levels. However, we do recognize the potential for Level B harassment at exposures to received levels below 160 dB rms, in addition to the potential that animals exposed to received levels above 160 dB rms will not respond in ways constituting behavioral harassment. These comments appear to evidence a misconception regarding the concept of the 160-dB threshold. While it is correct that in practice it works as a step-function, *i.e.,* animals exposed to received levels above the threshold are considered to be ''taken'' and those exposed to levels below the threshold are not, it is in fact intended as a sort of mid-point of likely behavioral responses (which are extremely complex depending on many factors including species, noise source, individual experience, and behavioral context). What this means is that, conceptually, the function recognizes that some animals exposed to levels below the threshold will in fact react in ways that are appropriately considered take, while others that are exposed to levels above the threshold will not. Use of the 160-dB threshold allows for a simplistic quantitative estimate of take, while we can qualitatively address the variation in responses across different received levels in our discussion and analysis.

NRDC consistently cites reports of changes in vocalization, typically for baleen whales, as evidence in support of a lower threshold than the 160-dB threshold currently in use. A mere reaction to noise exposure does not, however, mean that a take by Level B harassment, as defined by the MMPA, has occurred. For a take to occur requires that an act have ''the potential to disturb by causing disruption of behavioral patterns,'' not simply result in a detectable change in motion or vocalization. Even a moderate cessation or modification of vocalization might not appropriately be considered as being of sufficient severity to result in take (Ellison *et al.,* 2012). NRDC claims these reactions result in biological consequences indicating that the reaction was indeed a take but does not provide a well-supported link between the reported reactions at lower received levels and the claimed consequences. In addition, NRDC fails to discuss documented instances of marine mammal exposure to received levels greater than 160 dB that did not elicit any response. Just a few examples are presented here:

- Malme *et al.* (1985) conducted a study consisting of playback using a stationary or moving single airgun and humpback whales. No clear overall signs of avoidance of the area were recorded for feeding/resting humpback whales exposed to received levels up to 172 dB. Although startle responses were observed when the airgun was first turned on, likely due to the novelty of the sound, increasing received levels did not result in increasing probability of avoidance. In three instances, whales actually approached the airgun.
- Malme *et al.* (1988) conducted a controlled exposure experiment involving a moving single airgun and gray whales. From this study, the authors predicted a 0.5 probability that whales would stop feeding and move away from the area when received levels reached 173 dB and a 0.1 probability of feeding interruption at a received level of 163 dB. However, whale responses were highly variable, with some whales remaining feeding with received levels as high as 176 dB.
- McCauley *et al.* (1998, 2000a, 2000b) report observations associated with an actual seismic survey (array volume 2,678 in ^{3}) and controlled approaches of humpback whales with a single airgun. When exposed to the actual seismic survey, avoidance maneuvers for some whales began at a range of 5–8 km from the vessel; however, in three trials whales at a range beyond 5 km showed no discernible effects on movement patterns. In addition, some male humpback whales were attracted to the single airgun (maximum received level of 179 dB). Overall, McCauley *et al.* (2000a) found no gross disruption of humpback whale movements in the region of the source vessel, based on encounter rates.
- Malme *et al.* (1983, 1984) conducted playback experiments with gray whales involving a single airgun and a full array (2,000–4,000 in ^{3}). For playback of the array, it was estimated that probability of avoidance during migration (including moving inshore and offshore to avoid the area or to pass the noise source at a greater distance then would normally occur) was 0.1 at 164 dB; 0.5 at 170 dB; and 0.9 at levels greater than 180 dB.

These examples are related only to baleen whales, for which NRDC provides examples of vocalization changes in response to noise exposure. Although associated received levels are not available, a substantial body of evidence indicates that delphinids are significantly more tolerant of exposure to airgun noise. Based on review of monitoring reports from many years of airgun surveys, many delphinids approach acoustic source vessels with no apparent discomfort or obvious behavioral change (Barkaszi *et al.,* 2012; Stone, 2015a). Behavioral observations of gray whales during an airgun survey monitored whale movements and respirations pre-, during-, and post-seismic survey (Gailey *et al.,* 2016). Behavioral state and water depth were the best 'natural' predictors of whale movements and respiration and, after considering natural variation, none of the response variables were significantly associated with survey or vessel sounds.

Overall, we reiterate the lack of scientific consensus regarding what criteria might be more appropriate. Defining sound levels that disrupt behavioral patterns is difficult because responses depend on the context in which the animal receives the sound, including an animal's behavioral mode when it hears sounds (*e.g.,* feeding, resting, or migrating), prior experience, and biological factors (*e.g.,* age and sex). Other contextual factors, such as signal characteristics, distance from the source, and signal to noise ratio, may also help determine response to a given received level of sound. Therefore, levels at which responses occur are not necessarily consistent and can be difficult to predict (Southall *et al.,* 2007; Ellison *et al.,* 2012; Bain and Williams, 2006).

There is currently no agreement on these complex issues, and NMFS followed the practice at the time of submission and review of these applications in assessing the likelihood

of disruption of behavioral patterns by using the 160-dB threshold. This threshold has remained in use in part because of the practical need to use a relatively simple threshold based on available information that is both predictable and measurable for most activities. We note that the seminal review presented by Southall *et al.* (2007) did not suggest any specific new criteria due to lack of convergence in the data. NMFS is currently evaluating available information towards development of guidance for assessing the effects of anthropogenic sound on marine mammal behavior. However, undertaking a process to derive defensible exposure-response relationships is complex (*e.g.,* NMFS previously attempted such an approach, but is currently re-evaluating the approach based on input collected during peer review of NMFS (2016)). A recent systematic review by Gomez *et al.* (2016) was unable to derive criteria expressing these types of exposure-response relationships based on currently available data.

NRDC consistently cites Nowacek *et al.* (2015) in public comments, suggesting that this paper is indicative of a scientific consensus that NMFS is missing or ignoring. We note first that while NRDC refers to this paper as a ''study'' (implying that it presents new scientific data or the results of new analyses of existing scientific data), the paper in fact makes policy recommendations rather than presenting any new science. The more substantive reviews presented by Southall *et al.* (2007) and Gomez *et al.* (2016) were unable to present any firm recommendations, as noted above. Other than suggesting a 50 percent midpoint for a probabilistic function, Nowacek *et al.* (2015) offer minimal detail on how their recommended probabilistic function should be derived/implemented or exactly how this midpoint value (*i.e.,* 140 dB rms) was derived (*i.e.,* what studies support this point). In contrast with elements of a behavioral harassment function that NRDC indicates as important in their comments, Nowacek *et al.* (2015) does not make distinctions between any species or species groups and provide no quantitative recommendations for acknowledging that behavioral responses can vary by species group and/or behavioral context. In summary, little substantive support is provided by Nowacek *et al.* (2015) for the proposal favored by NRDC and it is treated in that paper as a vague recommendation with minimal support offered only in a one-page supplementary document rather than well-supported scientific consensus, as the commenter suggests.

NMFS disagrees that establishing species-specific thresholds is practical (*i.e.,* this approach would make assessments unnecessarily onerous by creating numerous thresholds to evaluate). Additionally, there is scientific evidence that grouping thresholds by broad source category (Gomez *et al.,* 2016) or taxonomic group (NMFS, 2018) is supportable. NMFS currently uses data/thresholds from surrogate species/groups to represent those species/groups where data are not available.

Overall, while we agree that there may be methods of assessing likely behavioral response to acoustic stimuli that better capture the variation and context-dependency of those responses than the simple step-function used here, there is no agreement on what that method should be or how more complicated methods may be implemented by applicants. NMFS is committed to continuing its work in developing updated guidance with regard to acoustic thresholds, but pending additional consideration and process is reliant upon an established threshold that is reasonably reflective of available science.

In support of exploring new methods for quantitatively predicting behavioral harassment, we note NMFS's recently published proposed incidental take regulations for geophysical surveys in the Gulf of Mexico (83 FR 29212; June 22, 2018), which propose using the modeling study first published in BOEM's associated EIS (Appendix D in BOEM, 2017) to estimate take. This study evaluated potential disruption of behavioral patterns that could result from a program of airgun surveys, using both the 160-dB step function and a probabilistic risk function similar to that suggested by Nowacek *et al.* (2015), but with a midpoint set at 160 dB for the majority of species, rather than 140 dB. This function, described in Wood *et al.* (2012), includes for most species a 10 percent probability of behavioral harassment at 140 dB, with subsequent steps of 50 percent at 160 dB and 90 percent at 180 dB. Of note, use of this generic function resulted in lower numbers of estimated takes than did use of the 160-dB step function. Therefore, while use of the probabilistic risk function may allow for more specific quantitative consideration of contextual issues and variation in individual responses, our use of the 160-dB step function is conservative in that the number of resulting takes is higher. NMFS will continue to explore quantitative refinement of the behavioral harassment threshold where there is available information to support methodologies that better reflect the variation in individual responses. However, the current threshold allows for an appropriate, and often conservative, enumeration of predicted takes by Level B harassment, which support robust negligible impact and small numbers analyses.

Comment: Nowacek *et al.* stated that use of the 160-dB threshold would be specifically problematic for beaked whales, as these species demonstrate behavioral response at levels below 160 dB rms and occupy certain areas of the specific geographic region in high densities.

Response: Please see our previous comment response regarding use of the 160-dB threshold for behavioral harassment. With regard to the expected significance of takes by harassment specifically for beaked whales, we acknowledge that beaked whales are documented as being a particularly behaviorally sensitive species in response to noise exposure. This information is considered in our negligible impact analyses (''Negligible Impact Analyses and Determinations'') and informed our evaluation of the mitigation necessary to satisfy the least practicable adverse impact standard (''Mitigation''). We require implementation of three year-round closures of submarine canyon areas expected to provide important habitat for beaked whales, a seasonal closure of the area off of Cape Hatteras cited by the commenters, and have required expanded shutdown requirements for beaked whales. Additionally, regarding the specific levels at which they are behaviorally harassed by exposure to noise from airguns, we note that there are no data on beaked whale responses to airgun noise, and their hearing sensitivity in the frequency range of signals produced by airguns is notably lower than their sensitivity in the frequency range of the sonar sources for which data is available indicating that they have responded at lower levels (in other words, noise from an airgun must be louder than a sonar pulse for them to hear it as the same level).

Comment: NRDC and others stated that if NMFS does not revise existing behavioral harassment thresholds, it should use the acoustic threshold for continuous noise (*i.e.,* 120 dB rms) rather than the threshold for intermittent sound sources (*i.e.,* 160 dB rms). NRDC contends that, as a result of reverberation and multipath arrivals, the impulsive signal produced by airguns is more similar to a continuous noise at greater distances from the source and,

therefore, use of the 120-dB ''continuous'' noise threshold is more appropriate than the 160-dB threshold for intermittent sound sources.

Response: NMFS acknowledges that as airgun shots travel through the environment, pulse duration increases because of reverberation and multipath propagation. However, we disagree that the 120-dB rms threshold for continuous noise—which was based on behavioral responses of baleen whales to drilling (Malme *et al.,* 1984; Richardson *et al.,* 1990)—is more appropriate than the intermittent noise threshold of 160-dB rms for evaluating potential behavioral harassment resulting from airgun noise. The 160-dB threshold was derived from data for mother-calf pairs of migrating gray whales (Malme *et al.,* 1983, 1984) and bowhead whales (Richardson *et al.,* 1985, 1986) behaviorally responding when exposed specifically to noise from airguns. The Richardson *et al.* (1985, 1986) studies included controlled approaches with a full-scale airgun array firing at 7.5 km from the animals. Thus, behavioral responses observed in these studies account for changes in the pulse duration associated with propagation.

In addition, there is a prevalent misconception in comments from NRDC and others regarding Level B harassment, as defined by the MMPA. NRDC cites multiple observations of behavioral reactions or of changes in vocal behavior in making statements supporting their overall recommendation that behavioral harassment thresholds be lower. However, these observations do not necessarily constitute evidence of disruption of behavioral patterns (Level B harassment) rather than simple reactions to often distant noise, which may provoke a reaction when discernable above ambient noise levels.

For example, changes in mysticete vocalization associated with exposure to airgun surveys within migratory and non-migratory contexts have been observed (*e.g.,* Castellote *et al.,* 2012; Blackwell *et al.,* 2013; Cerchio *et al.,* 2014). The potential for these changes to occur over large spatial scales is not surprising for species with large communication spaces, like mysticetes (*e.g.,* Clark *et al.,* 2009), although not every change in a vocalization would necessarily rise to the level of a take.

Comment: NRDC claims that NMFS misapplies the MMPA's statutory definition of harassment by adopting a probability standard other than ''potential'' in setting thresholds for auditory injury, stating that a take estimate based on ''potential'' should either count take from the lowest exposure level at which hearing loss can occur or establish a probability function that accounts for variability in the acoustic sensitivity of individual marine mammals. Instead, NRDC states that NMFS derived auditory injury thresholds from average exposure levels at which tested marine mammals experience hearing loss, which discounts instances of hearing loss at lower levels of exposure. The comment goes on to state that for purposes of take estimation, thresholds based on mean or median values will lead to roughly half of an exposed cohort experiencing the impacts that the threshold is designed to avoid, at levels that are considered ''safe,'' therefore resulting in substantial underestimates of auditory injury. NRDC makes similar statements with regard to the 160-dB threshold for Level B harassment.

Response: The technical guidance's (NMFS, 2018) onset thresholds for temporary threshold shift (TTS) for non-impulsive sounds encompass more than 90 percent of available TTS data (*i.e.,* for mid-frequency cetaceans, only two data points are below the onset threshold, with maximum point only 2 dB below), and in some situations 100 percent of TTS data (*e.g.,* high-frequency cetaceans; although this group is data-limited). Thus, the technical guidance thresholds provide realistic predictions, based on currently available data, of noise-induced hearing loss in marine mammals. For impulsive sounds, data are limited to two studies, and NMFS directly adopted the TTS onset levels from these two studies for the applicable hearing groups.

Our **Federal Register** notice announcing the availability of the original technical guidance (81 FR 51694; August 4, 2016; NMFS, 2016), indicated that onset of auditory injury (PTS) equates to Level A harassment under the MMPA. We explained in that notice that because the acoustic thresholds for PTS conservatively predict the onset of PTS, they are inclusive of the ''potential'' language contained in the definition of Level A harassment. See 81 FR 51697, 51721.

Regarding Level B harassment, based on the language and structure of the definition of Level B harassment, we interpret the concept of ''potential to disturb'' as embedded in the assessment of the behavioral response that results from an act of pursuit, torment, or annoyance (collectively referred to hereafter as an ''annoyance''). The definition refers to a ''potential to disturb'' by causing disruption of behavioral patterns. Thus, an analysis that indicates a disruption in behavioral patterns establishes the ''potential to disturb.'' A separate analysis of ''potential to disturb'' is not needed. In the context of an authorization such as this, our analysis is forward-looking. The inquiry is whether we would reasonably expect a disruption of behavioral patterns; if so, we would conclude a potential to disturb and therefore expect Level B harassment. We addressed NRDC's concerns regarding the scientific support for the Level B harassment threshold in a previous comment response.

Comment: The Center for Regulatory Effectiveness (CRE) does not agree with NMFS's use of the technical acoustic guidance (NMFS, 2016, 2018) for purposes of evaluating potential auditory injury. CRE claims that (1) NMFS's use of the guidance conflicts with Executive Order 13795 (''Implementing an America-First Offshore Energy Strategy''); (2) the guidance violates the Office of Management and Budget's (OMB) Peer Review Bulletin and Guidance Document Bulletin and implementing Memoranda; (3) violates Information Quality Act (IQA) guidelines; and (4) violates Executive Orders 12866 (''Regulatory Planning and Review'') and 13771 (''Reducing Regulation and Controlling Regulatory Costs''). Regarding the IQA, CRE states that NMFS does not have an OMB-approved Information Collection Request (ICR) associated with the guidance, and is therefore violating the IQA. The CRE also claims that NMFS's use of the guidance violates the MMPA requirement that all mitigation requirements be practicable, as the guidance supposedly requires monitoring and reporting requirements and other mitigation requirements that are impossible to comply with.

Response: NMFS disagrees that use of the technical guidance results in any of the claims listed by CRE. First, the use of the technical guidance does not conflict with Executive Order 13795. Section 10 of the Executive Order called for a review of the technical guidance (NMFS, 2016) as follows: ''The Secretary of Commerce shall review for consistency with the policy set forth in Section 2 of this order and, after consultation with the appropriate Federal agencies, take all steps permitted by law to rescind or revise that guidance, if appropriate.'' To assist the Secretary in the review of the technical guidance, NMFS solicited public comment via a 45-day public comment period (82 FR 24950; May 31, 2017) and hosted an interagency consultation meeting with representatives from ten federal agencies (September 25, 2017). NMFS

provided a summary of comments and recommendations received during this review to the Secretary, and per the Secretary's approval, issued a revised version of the technical guidance in June 2018 (83 FR 28824; NMFS, 2018).

Second, NMFS did comply with the OMB Peer Review Bulletin and IQA Guidelines in development of the technical guidance. The technical guidance was classified as a Highly Influential Scientific Assessment and, as such, underwent three independent peer reviews, at three different stages in its development, including a follow-up to one of the peer reviews, prior to its dissemination by NMFS. In addition, there were three separate public comment periods. Responses to public comments were provided in a previous **Federal Register** notice (81 FR 51694; August 4, 2016). Detailed information on the peer reviews and public comment periods conducted during development of the guidance are included as an appendix to the guidance, and are detailed online at: *www.cio.noaa.gov/services_programs/prplans/ID43.html.*

Furthermore, the technical guidance is not significant for purposes of Executive Orders 12866 or 13771 or OMB's Bulletin entitled, ''Agency Good Guidance Practices'' for significant guidance documents. 72 FR 3432 (January 25, 2007). Nevertheless, the technical guidance follows the practices and includes disclaimer language suggested by the OMB Bulletin to communicate effectively to the public about the legal effect of the guidance. Finally, with regard to the claim that NMFS's use of the technical guidance violates the MMPA requirement that all mitigation requirements be practicable, as the guidance supposedly requires monitoring and reporting requirements and other mitigation requirements that are impossible to comply with, we reiterate that mitigation and monitoring requirements associated with an MMPA authorization or ESA consultation or permit are independent management decisions made in accordance with statutory and regulatory standards in the context of a proposed activity and comprehensive effects analysis and are beyond the scope of the technical guidance. The technical guidance does not mandate mitigation or monitoring. Finally, there is no collection of information requirement associated with the technical guidance, so no ICR is required.

Comment: Several groups raised concerns regarding use of the technical acoustic guidance (NMFS, 2016, 2018), claiming that the guidance is not based on the best available science and underestimates potential auditory injury. NRDC specifically cited many supposed issues with the guidance, including adoption of ''erroneous'' models, broad extrapolation from a small number of individuals, and disregarding ''non-linear accumulation of uncertainty.'' NRDC suggests that NMFS retain the historical 180-dB rms Level A harassment threshold as a ''conservative upper bound'' or conduct a ''sensitivity analysis'' to ''understand the potential magnitude'' of the supposed errors. Oceana stated that NMFS should not make a decision about the proposed IHAs while the technical guidance is under review.

Response: The original 2016 technical guidance and revised 2018 guidance is a compilation, interpretation, and synthesis of the scientific literature that provides the best available information regarding the effects of anthropogenic sound on marine mammals' hearing. The technical guidance was classified as a Highly Influential Scientific Assessment and, as such, underwent three independent peer reviews, at three different stages in its development, including a follow-up to one of the peer reviews, prior to its dissemination by NMFS. In addition, there were three separate public comment periods, during which time we received and responded to similar comments on the guidance (81 FR 51694), and more recent public and interagency review under Executive Order 13795. While new information may help to improve the guidance in the future, and NMFS will review the available literature to determine when revisions are appropriate, the final guidance reflects the best available science and all information received through peer review and public comment. Given the systematic development of the guidance, which was also reviewed multiple times by both independent peer reviewers and the public, NRDC's use of the phrase ''arbitrary and capricious'' is unreasonable.

The guidance updates the historical 180-dB rms injury threshold, which was based on professional judgement (*i.e.,* no data were available on the effects of noise on marine mammal hearing at the time this original threshold was derived). NMFS does not believe the use of the technical guidance provides erroneous results. The 180-dB rms threshold is plainly outdated, as the best available science indicates that rms SPL is not even an appropriate metric by which to gauge potential auditory injury (whereas the scientific debate regarding behavioral harassment thresholds is not about the proper metric but rather the proper level or levels and how these may vary in different contexts). NRDC's advice to return to use of the 180-dB threshold is inconsistent with its criticism of the 160-dB rms criterion for Level B harassment. However, as we said in responding to comments criticizing the Level B harassment criterion, development of an updated threshold(s) is complicated by the myriad contextual and other factors that must be considered and evaluated in reaching appropriate updated criteria. See our response to comment on the Level B harassment threshold.

Sound Field Modeling

Comment: The MMC noted differences in the estimated Level B harassment radii provided in ION and Spectrum's applications, noting that since the largest discrepancies were observed at shallow water sites, it is likely that geoacoustic properties were responsible. Although both ION and Spectrum used sediment data from cores collected during the Ocean Drilling Program, the data was based on samples from different sites and potentially different assumptions as to sediment attenuation. The MMC provided related recommendations: (1) NMFS should determine whether ION's or Spectrum's estimated zones are the most appropriate and require that both companies use the same set of zones; (2) NMFS should require each of the five companies to conduct sound source verification (SSV) in waters less than 100 m and use that data to inform and adjust the extent of Level B harassment zones as necessary; and (3) NMFS should determine the appropriate baseline geoacoustic model for the region in concert with BOEM, ION, and Spectrum, and then require this in future IHAs for similar activities in the region.

Response: NMFS appreciates the MMC's attention to this matter, but disagrees that it is necessarily appropriate to require use of the same data or approaches to modeling sound fields when there is not clearly a ''most appropriate'' approach. Sound field modeling for both ION and Spectrum was conducted by experts in the field. We appropriately approved both applicants' applications as adequate and complete, determining that both used appropriate data inputs and acceptable modeling approaches. Subsequently, both applications were made available for public review in order to better inform NMFS's preparation of proposed IHAs; no such concerns were raised. Importantly, we recognize that there is no model or approach that is always the most appropriate and that there may be multiple approaches that may be

considered acceptable. Having determined that both applicants used appropriate data and acceptable modeling approaches, it would be inappropriate to require one to change their approach to conform to the other because of differences in the results. Given our confidence in the data inputs and modeling approaches used, we find that a requirement to conduct SSV studies is not warranted, despite discrepancies in modeling results. As is appropriate, NMFS would consider the appropriateness of data inputs and modeling approaches for any future applications but, in keeping with our response here, will not necessarily enforce use of one dataset or modeling approach when others may be considered as equally representative of the best available scientific data and techniques.

Comment: One individual suggested that, because the representative airgun array used in BOEM's sound field modeling was characterized as having a source level lower than that of arrays planned for use by the applicants, use of BOEM's sound field modeling could lead to an underestimate of takes.

Response: Numerous factors combine in the sound field modeling provided by BOEM to result ultimately in estimates of sound fields at different locations. BOEM's modeling was performed to be reasonably representative of the types of sources that would be used in future surveys, recognizing that actual sources may vary somewhat from what was considered in the sound field modeling. We disagree that these minor differences would have meaningful impacts on the ultimate result of the exposure estimation process, and find that the modeling provided by BOEM was reasonably representative of what would occur during actual surveys and, therefore, acceptable to use for informing the take estimates for these surveys.

Comment: One individual stated that NMFS does not fully consider the implications of different weather phenomena in acoustic propagation, and that in failing to account for variations in ocean and weather conditions, the average estimates of propagation and take are biased downward. The same individual also claimed that NMFS did not adequately consider ocean floor sediment composition in modeling expected sound fields, and states again that this would likely result in higher numbers of take.

Response: While NMFS acknowledges that discrete weather phenomena could result in propagation being more or less efficient than anticipated under a seasonal average scenario (*i.e.,* one element of propagation modeling is the use of sound velocity profiles that are season-specific within the specific geographic region), the commenter provides no basis for concluding that such phenomena would lead overall to the estimated takes being biased downward. Further, the sound field modeling approaches taken by the applicants (and in BOEM's PEIS) follow state-of-science approaches and are reasonable when considering the need to model propagation year-round and over a wide geographic area. The commenter provides no specific recommendation for how the suggestion should be accomplished. With regard to sediment composition, the applicants' sound field modeling considered sediment characteristics at 15 representative modeling sites throughout the region, and the commenter does not provide any evidence to back the claim that variability in actual sediment composition would result in bias to take estimates in a particular direction or provide any specific recommendation to remedy the perceived flaw.

Comment: Ocean Conservation Research (OCR) noted that NMFS did not consider a secondary transmission path in the mixed layer above the marine thermocline that behaves as a surface duct, stating that, while the propagation in this transmission path is dependent on the wavelength of the source, the angle of incidence, the depth of the mixed layer, and the surface conditions, the attenuation characteristics are more consistent with the cylindrical spreading model. OCR goes on to claim that, assuming cylindrical propagation of surface ducted noise, typical airgun noise would require 13 km to attenuate to a received level of 180 dB rms.

Response: Although OCR is correct to point out that the mechanism of sound propagation is complex in the ocean environment, with the potential formation of a surface duct as a result of the mixed layer above the permanent thermocline, the conclusion derived by OCR that typical airgun noise would require 13 km to attenuate to a received level of 180 dB rms is unsupported.

First, oceanographic conditions in the mid-Atlantic region do not support a persistent surface duct, which usually occurs after a storm or consistently cool and windy weather. A reduction of surface wind velocity and the warming of the surface water will quickly break down a surface duct and cause the downward refraction of a shallow source (*e.g.,* source from an airgun array) due to a negative sound velocity profile above the thermocline.

Second, as stated above, the formation of a surface duct requires strong wind gusts and a high sea state, which are not ideal conditions for conducting a seismic survey given the need to tow a large array of airguns and long streamers. Thus, even if a surface duct is formed, it is very unlikely that a seismic survey would continue under such conditions.

Third—as OCR correctly pointed out—sound propagation in a surface duct is dependent on the wavelength of the source, the angle of incidence, the depth of the mixed layer, and the surface conditions. Among these parameters, the depth of the mixed layer is typically determined by the wind speed and sea state. While relatively low wind speed may support a weak, shallow surface duct, such a duct cannot support propagation of airgun sound, which is predominantly low-frequency. Jensen *et al.* (2011) provide the following equation that determines the cutoff frequency (frequency below which sound will not propagate) given the depth of an isothermal surface layer:

$$f_0 \approx \frac{1500}{0.008D^{3/2}}$$

where f_0 is the cutoff frequency in Hz and D is the depth in meters of an isothermal surface layer. As an example, for a cutoff frequency to be around 100 Hz, the surface duct needs to be at least 150 m deep. In general, shallow ducts (D <50 m) are more common, but they are only effective waveguides for frequencies above 530 Hz, which also suffer high scattering loss due to the rough sea surface under these weather conditions.

Finally, most acoustic rays from an airgun array are emitted at very steep angles to be contained within the surface duct waveguide.

For these reasons, we do not believe surface ducts in the mid-Atlantic region, if they exist, would contribute noticeably to propagation for sound emitted from airguns.

Comment: NRDC stated that NMFS used unrealistic and non-conservative assumptions about spreading loss, bottom composition, and reverberation in its propagation analysis and claimed that the analysis does not represent the best available science. NRDC stated that, for propagation loss, NMFS incorrectly assumed that normal propagation conditions would apply, such as not accounting for surface ducting (and BOEM only assumed moderate surface ducting in 3 of 21 modeled areas). Furthermore, NRDC stated that low-

frequency propagation along the seabed can spread in a planar manner, and can propagate with more efficiency than indicated by cylindrical propagation. Finally, NRDC asserted that NMFS cannot accept the assumptions in three applications (CGG, TGS, and WesternGeco) that proposed surveys will cover areas with soft or sandy bottoms. NRDC claims that NOAA's own models indicate that there is a likelihood of coral bottom habitat in the survey area, and many hard-bottom habitat areas were not modeled by BOEM and consequently incorporated by NMFS.

Response: Regarding sound propagation in a surface duct, please refer to the above response to a similar comment from OCR. As stated earlier, oceanographic conditions in the mid-Atlantic region do not support a persistent surface duct, particularly for low-frequency sound propagation. Therefore, the modeling of a moderate surface duct for airgun noise propagation is a conservative measure. Also as stated earlier, frequency and launch angle of the source play a major role in surface ducting. This information is clearly stated by D'Spain *et al.* (2006) with regard to the 2000 beaked whale stranding in the Bahamas, *i.e.,* that the surface duct ''. . . effectively traps mid to high frequency sound radiated by acoustic sources within the duct, such as surface ship sonars . . .'' and that ''[a]t low frequencies, the sound is no longer effectively trapped by the duct because the acoustic wavelength. . . . is too large in comparison to the duct thickness.''

NRDC's statement that ''low-frequency propagation along the seabed can spread in a planar manner . . . can propagate with significantly greater efficiency than cylindrical propagation would indicate'' is incorrect. Any acoustic wave can be approximated for plane wave propagation at sufficiently far range (R) for a region (W) such that $W \leq (\lambda R)^{1/2}$, where λ is the wavelength. This plane wave approximation has no bearing on the efficiency of sound propagation.

Finally, substrate types for propagation modeling are based on grain size, porosity, and shear velocity, etc., and ''coral bottom'' is not one of them. In fact, the roughness of the coral habitat would cause severe bottom loss due to scattering. Based on published literature, bottom types of the region are mostly composed of sand (*e.g.,* Stiles *et al.,* 2007; Kaplan, 2011). Therefore, the use of sand and clay for propagation modeling is appropriate. The acoustic modeling provided by BOEM (2014a) appropriately and reasonably accounts for variability in bottom composition throughout the planned survey area.

Comment: Some groups noted that the different approaches taken to acoustic modeling make it difficult to compare takes. Specifically, TGS, CGG, and Western relied on the acoustic modeling provided in BOEM's PEIS, while ION and Spectrum performed their own modeling. In addition, Spectrum and ION used a restricted suite of sound velocity profiles, matching the seasons when they intend to conduct their planned surveys. The comment letter from Nowacek *et al.* adds an assertion that this difficulty in comparing takes is problematic when NMFS is trying to assess whether the activities impact only small numbers or cause negligible impacts, and state that they ''can find no evidence in the Notice that NMFS took account of these significant problems when attempting to evaluate the impacts of the IHAs.''

Response: As stated in a previous response to an MMC comment, NMFS disagrees that the different approaches taken to sound field modeling constitute a problem at all, much less a significant one. BOEM's PEIS provides a sound analysis of expected sound fields in a variety of propagation conditions, including water depth, bottom type, and season, for a representative airgun array. ION and Spectrum conducted similar sound field modeling, but with the added advantage of modeling the specific array planned for use and limiting use of sound velocity profiles to the time period when the survey is planned to occur. No commenter provided any rational basis for disputing that these methods are appropriate or that they used the best available information and modeling processes. Regardless of differences in the sound field modeling processes, one would not expect that the take estimates are directly comparable, precisely because the surveys are planned for different locations, using different sound sources, and, for some companies, operating at different times of year. We disagree the various modeling approaches cause some problem for conducting appropriate negligible impact and/or small numbers analyses; both of these findings are appropriately made in consideration of a given specified activity. Therefore, comparison of the take numbers across IHAs is not a relevant consideration. We disagree that differences in approaches across the applications are arbitrary. On the contrary, we carefully evaluated each applicant's approaches to take estimation and, while they are indeed different in some respects, each applicant uses accepted approaches. Unlike NRDC, we recognize that there is no model or approach that is always the most appropriate and that there may be multiple approaches that may be considered acceptable. Far from ''parroting'' the applicants' assessments, as NRDC implies, NMFS made substantial changes where necessary, including complete revision of North Atlantic right whale take estimates for all applicants, revision of take estimates for all species using the best available density data (*i.e.,* Roberts *et al.,* 2016) for ION and Spectrum, and revised assessment of potential Level A harassment for all applicants. NMFS strongly disagrees that ''grossly inconsistent'' data or methods were used for any applicant in the analyses described herein.

Comment: One individual noted that it is not apparent how NMFS accounted for high-frequency sounds, which has implications for potential takes by Level A harassment for species that hear better at higher frequencies. The commenter wrote that airguns produce pulses with most energy at low frequencies (around 10 Hz), but that these pulses contain significant energy at frequencies up to more than 100 kHz, claiming that high-frequency hearing specialists can be affected at distances of 70 km or more. The commenter cited Bain and Williams (2006) in support of the latter claim.

Response: In considering the potential impacts of higher-frequency components of airgun noise on marine mammal hearing, one needs to account for energy associated with these higher frequencies and determine what energy is truly ''significant.'' Tolstoy *et al.* (2009) conducted empirical measurements, demonstrating that sound levels (*i.e.,* one-third-octave and spectral density) associated with airguns were at least 20 dB lower at 1 kHz compared to higher levels associated with lower frequencies (below 300 Hz). These levels were even lower at higher frequencies beyond 1 kHz. Thus, even though high-frequency cetaceans may be more susceptible to noise-induced hearing loss at higher frequencies, it does not mean that a source produces a sufficiently loud sound at these higher frequencies to induce a PTS (*i.e.,* auditory injury). For example, Bain and Williams (2006) indicated ''airguns produced energy above ambient levels at all frequencies up to 100 kHz (the highest frequency measured), although the peak frequency was quite low.'' However, a finding that airgun signals contain energy ''above ambient'' and are detectable at frequencies up to 100 kHz does not mean that these levels are high enough to result in auditory injury. The commenter does not describe what is

meant by ''significant'' energy, but there is no information to suggest that these higher-frequency noise components are sufficient to cause auditory injury at ranges beyond those described in Table 5.

Furthermore, Bain and Williams (2006) focus on behavioral responses of marine mammals to airgun surveys, rather than on potential impacts on hearing. Harbor porpoises, while considered a high-frequency cetacean in terms of hearing, are also often categorized as a particularly sensitive species behaviorally (*i.e.,* consistently responds at a lower received level than other species; Southall *et al.,* 2007). We agree that harbor porpoises are more likely to avoid loud sound sources, such as airgun arrays, at greater distances. However, this means that these species are even less likely to incur some degree of threshold shift.

Marine Mammal Densities

Comment: The MMC recommended that NMFS require TGS and Western to use the Roberts *et al.* (2016) model, rather than the approach described herein (see ''Estimated Take''). MMC describes several perceived problems with the approach taken by TGS and Western, including that they do not adequately account for availability and detection biases, and that their approach does not use the same habitat-based approach to predicting density. Overall, they state that it does not make sense for applicants to use different density estimates for the same area.

Response: Please see ''Estimated Take'' for a full description of take estimation methodologies used by TGS and Western. First, we note that the applicants did carefully consider the Roberts *et al.* data in addition to other available sources of data. In fact, these two applicants did use the Roberts *et al.* data for a group of nine species, while devising an alternate methodology for a separate group of seven species that did not meet a specific threshold for sightings data recommended by Buckland *et al.* (2001). Further, these applicants did account for bias, correcting densities using general *g*(0) values for aerial and vessel surveys for each species as published in the literature.

As stated below and in our Notice of Proposed IHAs, we determined that their alternative approach (for seven species or species groups) is acceptable. We recognize that there is no model or approach that is always the most appropriate and that there may be multiple approaches that may be considered acceptable. The alternative approach used for seven species actually uses the most recent data, and does so in a way that conforms with recommended methods for deriving density values from sightings data. We do not believe that one or the other approach is non-representative of the best available science and methodologies.

Comment: NRDC criticized NMFS's use of the Roberts *et al.* (2016) model outputs for purposes of deriving abundance estimates, as used in NMFS's small numbers analyses. NRDC states that we should use the NMFS Stock Assessment Report (SAR) abundance estimates for this purpose, while allowing that model-predicted abundance estimates may be used for ''data-deficient'' stocks. NRDC implies that use of model-predicted abundances would overestimate actual abundances, apparently based on the fact that the density models are informed by many years of data rather than only the most recent year of data. Where model-predicted abundance estimates are used, NRDC recommends that we adjust the averaged model outputs to the lower bound of the standard deviation estimated by the model for each grid cell.

Response: The approach recommended by NRDC is plainly inappropriate. Comparing take estimates generated through use of the outputs of a density model to an unrelated abundance estimate provides a meaningless comparison. As explained in our Notice of Proposed IHAs, in most cases we compare the take estimates generated through use of the density outputs to the abundance predicted through use of the model precisely to provide a meaningful comparison of predicted takes to predicted population. To illustrate this, we provide the extreme example of the Gulf of Mexico stock of Clymene dolphin. NMFS's three most recent SAR abundance estimates for this stock have fluctuated between 129 and 17,355 animals, *i.e.,* varying by a maximum factor of more than 100. For most species, such fluctuations across these ''snapshot'' abundance estimates (*i.e.,* that are based on only the most recent year of survey data) reflect interannual variations in dynamic oceanographic characteristics that influence whether animals will be seen when surveying in predetermined locations, rather than any true increase or decline in population abundance. In fact, NMFS's SARs typically caution that trends should not be inferred from multiple such estimates, that differences in temporal abundance estimates are difficult to interpret without an understanding of range-wide stock abundance, and that temporal shifts in abundance or distribution cannot be effectively detected by surveys that only cover portions of a stock's range (*i.e.,* U.S. waters). The corresponding density model for Gulf of Mexico Clymene dolphins predicts a mean abundance of 11,000 dolphins. Therefore, in this example, NRDC would have us compare takes predicted by a model in which 11,000 dolphins are assumed to exist to the most recent (and clearly inaccurate) abundance estimate of 129 dolphins. Our goal in assessing predicted takes is to generate a meaningful comparison, which is accomplished in most cases through use of the model-predicted abundance.

SAR abundance estimates have other issues that compromise their use in creating meaningful comparisons here. As in the example above, use of multiple years of data in developing an abundance estimate minimizes the influence of interannual variation in over- or underestimating actual abundance. Further, SAR abundance estimates are typically underestimates of actual abundance because they do not account for availability bias due to submerged animals—in contrast, Roberts *et al.* (2016) do account for availability bias and perception bias on the probability of sighting an animal—and because they often do not provide adequate coverage of a stock's range. The SAR for the Canadian East Coast stock of minke whales provides an instructive example of the latter. In the 2015 SARs, NMFS presented a best abundance estimate of 20,741 minke whales, reflecting data that provided adequate (but not complete) coverage of the stock's range. In the 2016 SARs, NMFS claims an abundance estimate of 2,591 whales for this same stock (albeit with caveats) simply because the survey data covering the Canadian portion of the range was no longer included in determining the best abundance estimate. We assume that again, based on this comment, NRDC would have us compare the minke whale take estimates to this plainly incomplete abundance estimate.

NRDC appears to claim that the SARs are an appropriate representation of ''actual'' abundance, whereas the Roberts *et al.* (2016) predictions are not. NRDC also appears to claim, without substantiation, that an abundance estimate derived from multiple years of data would typically overestimate actual abundance. However, these estimates are not directly comparable—not because one represents a ''snapshot,'' while one represents multiple years of data, but because one does not correct for one or more known biases against the probability of observing animals

during survey effort, while the other does. Because of this important caveat, NMFS's SAR abundance estimates should not be considered ''actual'' abundance more than any other accepted estimate. Therefore, when multiple estimates of a stock's abundance are available, they should be evaluated based on quality, *e.g.,* does the estimate account for relevant biases, does it best cover the stock's range, does it minimize the effect of interannual variability, and, importantly, should provide a meaningful comparison. In summary, NRDC's comment reflects an inaccurate interpretation of the available information, and NMFS strongly disagrees with the recommended approach.

Take Estimates

Comment: The Associations (representing oil and gas industry interests) state that ''NMFS substantially overestimates the number of incidental takes predicted to result'' from the specified activities. The comment goes on to discuss the ''biased modeling that is intentionally designed to overestimate take'' provided in BOEM's 2014 PEIS. Other industry commenters repeat these points verbatim.

Response: The Associations' statement that NMFS has substantially overestimated takes is incorrect. First, in large part the take estimates are those presented by the applicants (although in some cases NMFS has made changes to the presented estimates in accordance with the best available information). Second, two applicants conducted their own independent sound field modeling, which NMFS accepted. In fact, BOEM and these two applicants followed best practices and used the best available information in conducting state-of-the-science sound field modeling. The Associations' complaints include no substantive recommendations for improvement.

NMFS participated in development of the acoustic modeling through its status as a cooperating agency in development of BOEM's PEIS. We strongly disagree with the Associations' characterization of the modeling conducted by BOEM and with the BOEM statements cited by the Associations. While the modeling required that a number of assumptions and choices be made by subject matter experts, some of these are purposely conservative to minimize the likelihood of underestimating the potential impacts on marine mammals represented by a specified level of survey effort. The modeling effort incorporated representative sound sources and projected survey scenarios (both based on the best available information obtained by BOEM), physical and geological oceanographic parameters at multiple locations within U.S. waters of the mid- and south Atlantic and during different seasons, the best available information regarding marine mammal distribution and density, and available information regarding known behavioral patterns of the affected species. Current scientific information and state-of-the-art acoustic propagation and animal movement modeling were used to reasonably estimate potential exposures to noise. NMFS's position is that the results of the modeling effort represent a conservative but reasonable best estimate. These comments provide no reasonable justification as to why the modeling results in overestimates of take, instead seemingly relying on the mistaken notion that real-time mitigation would somehow reduce actual levels of acoustic exposure, and we disagree that ''each of the inputs is purposely developed to be conservative''—indeed, neither the Associations nor BOEM provide any support for the latter statement. Although it may be correct that conservativeness accumulates throughout the analysis, the Associations do not adequately describe the nature of conservativeness associated with model inputs or to what degree (either quantitatively or qualitatively) such conservativeness ''accumulates.''

Comment: One individual stated that NMFS should consider how ''animal behavioral response can condition exposure,'' noting that behavioral responses may result in effects to the potential amount and intensity of take. We believe the commenter is suggesting that the way any specific animal moves through the water column in initial response to the sound can change the manner in which they are subsequently further exposed to the sound.

Response: The commenter seemingly indicated that some species should be expected to dive downwards rather than exhibit lateral avoidance. While we agree that this may occur, we do not agree that this would result in an increase in intensity of take—and such an occurrence could not by definition result in an increase in the absolute amount of take, as the animal in question would already be considered ''taken.'' Given relative motion of the vessel and the animal, there is no evidence to support that avoidance of the noise through downward, rather than lateral, movement would result in a meaningful increase in the duration of exposure, as implied by the commenter.

Comment: The Associations stated that it is unclear whether the take estimates include repeated exposures and that, if so, the estimates do not identify the number of repeated exposures, instead presenting a total number of estimated exposures by species. The Associations state that NMFS must perform additional analysis to identify the actual number of individual marine mammals that may be incidentally taken.

Response: The take estimates presented in our Notice of Proposed IHAs, and those shown in Table 6 of this notice, represent total estimated instances of exposure. We agree with the Associations that an understanding of the numbers of individuals affected by the total estimated instances of exposure is relevant, both for the small numbers analysis (a small numbers analysis is appropriately made on the basis of individuals taken rather than total takes, when such information is available) but also for assessing potential population-level impacts in a negligible impact analysis. We also agree that this information is relevant to these analyses and important to use, when available. In fact, one applicant (TGS) provided an analysis of individuals exposed; following review of public comments and re-evaluation of TGS's application, we considered this information in our small numbers analysis for TGS. However, without such information, an assumption that the total estimated takes represent takes of different individuals is acceptable in that it represents a conservative estimate of the total number of individuals taken made in the absence of sufficient information to differentiate between individuals exposed and instances of exposure, and is also generally a reasonable approach given the large, dispersed spatial scales over which the surveys operate. The MMPA does not require that NMFS undertake any such analysis and, in fact, sufficient information is not typically available to support such an analysis.

Comment: NRDC states that masking results in take of marine mammals, and that NMFS must account for this in its take estimates.

Response: We addressed our consideration of masking in greater detail in a previous response. We acknowledge that masking may impact marine mammals, particularly baleen whales, and particularly when considered in the context of the full suite of regulated and unregulated anthropogenic sound contributions overlaying an animal's acoustic habitat. However, we do not agree that masking effects from the incremental noise contributions of individual activities or sound sources necessarily, or typically,

rise to the level of a take. While it is possible that masking from a particular activity may be so intense as to result in take, we have no information suggesting that masking of such intensity and duration would occur as a result of the specified activities. As described in our previous comment response, potential effects of a specified activity must be accounted for in a negligible impact analysis, but not all responses or effects result in take nor are those that do always readily quantified. In this case, while masking is considered in the analysis, we do not believe it will rise to the level of take in the vast majority of exposures. However, specifically in the case of these five surveys, in the unanticipated event that any small number of masking incidents did rise to the level of a take, we would expect them to be accounted for in the quantified exposures above 160 dB. Given the short duration of expected noise exposures, any take by masking in the case of these surveys would be most likely to be incurred by individuals either exposed briefly to notably higher levels or those that are generally in the wider vicinity of the source for comparatively longer times. Both of these situations would be captured in the enumeration of takes by Level B harassment, which is based on exposure at or above 160 dB, which also means the individual necessarily spent a comparatively longer time in the adjacent area ensonified below 160 dB, but in which masking might occur if the exposure was notably longer.

Comment: NRDC, the MMC, and others state that NMFS's Level A harassment exposure analysis contains potentially significant errors. The MMC recommends that NMFS (1) provide company-specific Level A harassment zones for each functional hearing group, and (2) re-estimate the numbers of Level A harassment. NRDC states that, by relying on BOEM's 2014 PEIS, NMFS did not use the best available science, *e.g.,* use of earlier density data (DoN, 2007) rather than Roberts *et al.* (2016). NRDC goes on to cite as an additional flaw of the analysis that ''NMFS assumes that auditory take estimates for high-frequency cetaceans depend on the exposure of those species to single seismic shots . . . even though the weighted auditory injury zone for high-frequency cetaceans extends as far as 1.5 kilometers [. . . .] The size of the injury zone suggests that NMFS' assumption about high-frequency cetaceans is incorrect, and that the agency should calculate auditory injury by applying both the peak-pressure threshold and a metric that accounts for exposure to multiple shots (*e.g.,* the cumulative sound energy thresholds included in NMFS' guidance).''

Response: As described in ''Estimated Take,'' NMFS revised the approach to assessing potential for auditory injury, and associated authorization of take by Level A harassment. NMFS disagrees that the prior approach for the proposed IHAs contained ''significant errors.'' As stated in our Notice of Proposed IHAs, we used the information available to us and made reasonable corrections to account for applicant-specific information. However, following review of public comments, we determined it appropriate to re-evaluate the analysis and subsequently revised our approach as described in ''Estimated Take.'' This revised approach is simplified in its use of the available information while providing a reasonable assessment of the likely potential for auditory injury, and has the advantage of not relying on the BOEM PEIS results. While the PEIS results remain a reasonable assessment of potential effects from a programmatic perspective, and were based on the best available cetacean density information at the time the analyses were conducted, they do not use the best cetacean density information currently available (Roberts *et al.,* 2016), and also did not recognize that the potential for Level A harassment occurrence for mid-frequency cetaceans is discountable (described in detail in ''Estimated Take''). However, the second portion of NRDC's comment is incorrect: The peak pressure injury zones referred to by NRDC as extending as far as 1.5 km are not weighted for hearing sensitivity, as it is inappropriate to do so for exposure to peak pressure received levels (NMFS, 2018). Applicant-specific zones are shown in Table 5; all zones based on accumulation of energy are very small for high-frequency cetaceans. It is unclear what NRDC's recommendation to ''calculate auditory injury by applying both the peak-pressure threshold and a metric that accounts for exposure to multiple shots'' means, as the former is predominant for high-frequency cetaceans, while zones based on the latter are essentially non-existent. As recommended by the MMC, we have provided company-specific Level A harassment zones for each functional hearing group (see Table 5).

Comment: One individual asserted that NMFS fails to account for variability in group size and distribution of various species, stating that while the best estimate of take may be a fraction of an individual in practice either no individuals will be taken, or one or more groups will be taken. The individual suggested that NMFS should decide whether it may authorize one or more large groups, rather than estimates of a fraction of an individual.

Response: We agree with this comment. Accordingly, and as described in our Notice of Proposed IHAs, we did not propose to authorize take less than the average group size for any species. In fact, our take authorization for a group of species deemed ''rare'' was based entirely on an assumption of one encounter with a group, *i.e.,* we authorize take equating to one average group size.

Comment: NRDC asserts that NMFS fails to account for forms of injury that are reasonably anticipated, stating that permanent hearing loss (*i.e.,* Level A harassment) may occur through mechanisms other than PTS, and that behaviorally-mediated injury may occur as a result of exposure to airgun noise. NRDC states that NMFS must account for these mechanisms in its assessment of potential injury.

Response: NMFS is aware of the work by Kujawa and Liberman (2009), which is cited by NRDC. The authors report that in mice, despite completely reversible threshold shifts that leave cochlear sensory cells intact, there were synaptic level changes and delayed cochlear nerve degeneration. However, the large threshold shifts measured (*i.e.,* maximum 40 dB) that led to the synaptic changes shown in this study are within the range of the large shifts used by Southall *et al.* (2007) and in NMFS's technical guidance to define PTS onset (*i.e.,* 40 dB). It is unknown whether smaller levels of temporary threshold shift (TTS) would lead to similar changes or what may be the long-term implications of irreversible neural degeneration. The effects of sound exposure on the nervous system are complex, and this will be re-examined as more data become available. It is important to note that NMFS's technical guidance incorporated various conservative factors, such as a 6–dB threshold shift to represent TTS onset (*i.e.,* minimum amount of threshold shift that can be differentiated in most experimental conditions); the incorporation of exposures only with measured levels of TTS (*i.e.,* did not incorporate exposures where TTS did not occur); and assumed no potential of recovery between intermittent exposures. NMFS disagrees that consideration of likely PTS is not sufficient to account for reasonably expected incidents of auditory injury.

There is no conclusive evidence that exposure to airgun noise results in behaviorally-mediated forms of injury. Behaviorally-mediated injury (*i.e.,* mass stranding events) has been primarily

associated with beaked whales exposed to mid-frequency naval sonar. Tactical sonar and the alerting stimulus used in Nowacek *et al.* (2004) are very different from the noise produced by airguns. One should therefore not expect the same reaction to airgun noise as to these other sources.

Comment: TGS recommends that NMFS (1) recalculate take estimates to account for mitigation; (2) remove take estimates associated with the disallowed use of a mitigation gun; and (3) ensure that we do not double-count takes when considering takes by both Level A and Level B harassment.

Response: We agree with these recommendations and have done as requested; please see ''Estimated Take'' for further detail. We do note that, with regard to accounting for mitigation in calculating take estimates, our analysis involved only an accounting of take avoided for certain species as a result of the implementation of time-area restrictions. We did not attempt to account for the potential efficacy of other mitigation requirements in avoiding take.

Comment: The Florida Department of Environmental Protection (FLDEP) wrote that NMFS needs to be cautious in relying on the efficacy of mitigation measures to estimate take by Level A harassment, particularly with regard to North Atlantic right whales. They noted additional information on the effectiveness of proposed mitigation is necessary.

Response: While we agree with the commenters that caution is warranted in assuming that standard mitigation measures, such as shutdowns, will be effective in avoiding Level A harassment, we note that our estimation of likely take by Level A harassment does not substantively rely on such assumptions. As described in ''Estimated Take,'' auditory injury of mid-frequency cetaceans is highly unlikely, for reasons unrelated to mitigation. In estimating likely Level A harassment of high-frequency cetaceans, we did not consider mitigation at all, as the instantaneous exposures expected to result in auditory injury are amenable to a straightforward quantitative estimate. However, our Level A harassment take estimates for low-frequency cetaceans are based on a more qualitative analysis that does consider the implementation of mitigation, as is appropriate. We do not assume in any case that real-time mitigation would be totally effective in avoiding such instances, but for the theoretical injury zone sizes considered here for low-frequency cetaceans, which are based on the accumulation of energy, it is reasonable to assume that large whales may be observed when close to the vessel. Therefore, shutdown may be implemented and accumulation of energy halted such that actual instances of injury should not be considered likely. Our estimated instances of Level A harassment for low-frequency cetaceans consider the expected frequency of encounter for different species and the expectation that mitigation will be effective in avoiding some instances of Level A harassment, but also the likelihood that for some species that would be encountered most frequently, some instances of Level A harassment are likely unavoidable. Specifically for the right whale, we primarily consider that our required time-area restriction will avoid most acute exposures of the species (or that comparable protection will be achieved through implementation of a NMFS-approved mitigation and monitoring plan at distances between 47–80 km offshore) (as shown in the very low numbers of estimated take by Level B harassment, which account for the time-area restriction). Given such a low assumed encounter rate, the likelihood of Level A harassment for the species is correctly considered discountable. Please see our discussion in ''Estimated Take'' for further detail.

Comment: NRDC asserts that NMFS has failed to account for the effects of stress on marine mammals.

Response: As NRDC acknowledges, we addressed the available literature regarding potential impacts of stress resulting from noise exposure in marine mammals. As described in that discussion, stress responses are complicated and may or may not have meaningful impacts on marine mammals. NRDC implies that NMFS must (1) enumerate takes resulting from stress alone and (2) specifically address stress in its negligible impact analyses. The effects of stress are not straightforward, and there is no information available to inform an understanding of whether it is reasonably likely that an animal may experience a stress response upon noise exposure that would not be accounted for in NMFS's enumeration of takes via exposure to noise exceeding 160 dB. NRDC provides no useful information as to how such an analysis might be carried out. With regard to NMFS's negligible impact analyses, we believe that the potential effects of stress are addressed and subsumed within NMFS's considerations of magnitude of effect and likely consequences. Similarly, NRDC provides no justification as to why stress would appropriately be considered separately in these analyses, and no useful recommendation as to how to do so, if appropriate. We believe we have appropriately acknowledged the potential effects of stress, and that these potential effects are accounted for within our overall assessment of potential effects on marine mammals.

Comment: The MMC recommends that NMFS (1) determine whether the specific animat density used by Spectrum is appropriate and (2) depending on the outcome of that assessment, either authorize uncorrected take numbers from Spectrum's application, or re-estimate the numbers of Level B harassment takes using a higher animat density.

Response: We appreciate the MMC's consideration of this issue. Following evaluation of the comment, we confirm that the animat density used by Spectrum is appropriate. As stated by Marine Acoustics, Inc. (MAI)—which has years of experience in the field of acoustic modeling and performed the modeling for Spectrum (as well as ION) according to state-of-the science best practices—the modeled animat density value was determined through a sensitivity analysis that examined the stability of the predicted estimate of exposure levels as a function of animat density. The modeled density was determined to accurately capture the full distributional range of probabilities of exposure for the proposed survey, and is therefore appropriate. In describing the original modeling, MAI stated that in most cases the animat density represented a higher density of animats in the simulation than occurs in the real world. This ''over-population'' allowed the calculation of smoother distribution tails, and in the final analysis all results were normalized back to the actual estimated density for the species or group in question. This remains the case when using the revised density estimates from Roberts *et al.* (2016). We disagree with MMC's contention that the mitigation assumptions used by Spectrum in modeling Level B harassment takes were inappropriate; therefore, we retain the estimates proposed for authorization (as modified using the newer Roberts *et al.* (2016) density values).

Comment: The FLDEP stated that NMFS should account for uncertainty in take estimates, including uncertainty about marine mammal density, sound propagation models, and auditory thresholds, and that these factors should ''all manifest as uncertainty around take estimates and be reported in and considered for IHAs.''

Response: We agree with the commenter that it would be useful to

understand the degree of confidence in take estimates through some measure of uncertainty around the estimate, and that uncertainty can accrue through all of the mentioned aspects of the take estimation process. However, we believe that the take estimates are reasonable best estimates. Measuring uncertainty around a take estimate is not something that has been accomplished in the past, and the commenter provides no recommendation as to how they believe this should be done.

Comment: The NAMA stated that an IHA should be revoked if it is found that a take by Level A harassment has occurred.

Response: Level A harassment, which is defined as an act with the potential to injure a marine mammal, may be authorized through an IHA, as we have done here.

Comment: The New York State Department of Environmental Conservation stated that the amount of takes by Level A harassment proposed for humpback whales is considerable when considered in context of the ongoing UME, and that NMFS should give more consideration to this concern.

Response: We have considered the ongoing effects of the humpback whale UME in our evaluation. We also reiterate that Level A harassment refers to injury, and therefore cannot be directly equated to serious injury or mortality, and further that the estimated takes by Level A harassment likely represent only onset of mild PTS. However, separately, we have revised our estimates of Level A harassment for all species (see ''Estimated Take''), resulting in much lower estimates for humpback whales. The revised results of this analysis should obviate the concern expressed here.

Comment: OCR stated that NMFS should consider the potential use of ancillary noise sources (*e.g.,* side-scan or multibeam bottom profiling sonars) in estimating take, and notes that these sources have been associated with marine mammal strandings.

Response: We did consider this potential avenue of acoustic exposure. We understand that, generally, vessel operators plan to use standard navigational echosounders (single beam) operated at relatively high frequencies (>18 kHz). In addition, it is possible that some applicants may use a low-level acoustic pinger to help position their towed gear. It is possible that some marine mammals could detect and react to signals from these sources (although this is less likely for low-frequency cetaceans, and these species would not likely detect signals from these systems if they are operated above 35 kHz). However, the vast majority of the time echosounders would be in use, so would airguns which have much higher source levels and are expected to result in more severe reactions than any associated with echosounders specifically. We would expect that in most cases, any response would be to airguns rather than the echosounder itself. We recognize that there would be limited use of echosounders or pingers while airguns are not active, for example, when vessels are in transit from port to areas where surveys will occur. However, we do not believe this results in meaningful exposure to marine mammals since, given the lower source levels and higher frequencies of echosounders and pingers, animals would need to be very close to the transducer to receive source levels that would produce a behavioral response (Lurton, 2016), much less one that would result in a response of a degree considered to be take.

In extreme circumstances, some echosounders and pingers may also have the potential to cause injury, and in one case evidence indicates such a system likely played a contributing role in a cetacean stranding event. However, injury (or any threshold shift) is even less likely than behavioral responses since animals would need to be even closer to the transducer for these to occur. It is also important to note that the system implicated in the stranding event was a lower-frequency (12–kHz), higher-power deepwater mapping system; typical navigational systems, including those that the applicants here would use, would have lower potential to cause similar responses. Kremser *et al.* (2005) concluded the probability of a cetacean swimming through the area of exposure when such sources emit a pulse is small, as the animal would have to pass at close range and be swimming at speeds similar to the vessel in order to receive multiple pulses that might result in sufficient exposure to cause TTS. This finding is further supported by Boebel *et al.* (2005), who found that even for echosounders with source levels substantially higher than those proposed here, TTS is only possible if animals pass immediately under the transducer. Burkhardt *et al.* (2013) estimated that the risk of injury from echosounders was less than three percent that of vessel strike, which is considered extremely unlikely to occur such that it is discountable. In addition, modeling by Lurton (2016) of multibeam echosounders indicates that the risk of injury from exposure to such sources is negligible.

Navigational echosounders are operated routinely by thousands of vessels around the world, and to our knowledge, strandings have not been correlated with their use. The echosounders and pinger proposed for use differ from sonars used during naval operations, which generally have higher source levels, lower frequencies, a longer pulse duration, and more horizontal orientation than the more downward-directed echosounders. The sound energy received by any individuals exposed to an echosounder during the proposed seismic survey activities would be much lower relative to naval sonars, as would be the duration of exposure. The area of possible influence for the echosounders is also much smaller, consisting of a narrow zone close to and below the source vessels as described previously for TTS and PTS. Because of these differences, we do not expect the proposed echosounders and pinger to contribute to a marine mammal stranding event. In summary, any effects that would be considered as take are so unlikely to occur as a result of exposure from ancillary acoustic sources as to be considered discountable.

Marine Mammal Protection Act—General

Comment: Several groups indicated a belief that NMFS's proposal to issue the five IHAs contradicts Congressional intent behind the MMPA. For example, Clean Ocean Action (COA) stated that issuance of the IHAs would be incompatible with the original intent of the MMPA. Sea Shepherd Legal stated that the legislative history of the MMPA makes clear that the precautionary principle must be applied and bias must favor marine mammals, and opines that NMFS's proposed issuance of the IHAs ''undermines the MMPA's prioritization of conservation.''

Response: NMFS disagrees that these actions contradict any requirement of the MMPA or are contrary to Congressional intent as expressed in relevant provisions of the statute. Neither the MMPA nor NMFS's implementing regulations include references to, or requirements for, the precautionary approach, nor is there a clear, agreed-upon description of what the precautionary approach is or would entail in the context of the MMPA or any specific activity. Nevertheless, the MMPA by nature is inherently protective, including the requirement to mitigate to the lowest level practicable (''least'' practicable adverse impacts, or ''LPAI,'' on species or stocks and their habitat). This requires that NMFS assess measures in light of the LPAI standard. To ensure that we fulfill that requirement, NMFS considers all

potential measures (*e.g.,* from recommendations or review of available data) that have the potential to reduce impacts on marine mammal species or stocks, their habitat, or subsistence uses of those stocks, regardless of whether those measures are characterized as ''precautionary.''

Comment: Several groups stated that the duration of the public comment period was inadequate. A group of fourteen U.S. Senators urged NMFS to extend the comment period to at least 150 days (30 for each applicant). They wrote that publishing the notice of proposed IHAs had little notice, a short comment period, and no public hearings, adding that the notice of proposed IHAs addresses two applications that NMFS had not previously made available for public review. Some commenters decried what they perceived as a lack of stakeholder outreach. Multiple groups requested that NMFS hold public hearings in the affected regions about the proposed IHAs and their potential impacts.

Response: NMFS has satisfied the requirements of the MMPA, which requires only that NMFS publish notice of a proposed authorization and request public comment for a period of 30 days. In fact, NMFS exceeded this requirement by extending the public comment period by 15 days, for a total period of 45 days. By publishing a joint notice of the five proposed IHAs rather than five separate concurrent notices, NMFS provided for more efficient public review and comment on these substantially similar actions. Although NMFS acknowledges that these are five separate actions, there is no requirement to provide for consecutive review periods (*i.e.,* five 30-day periods totaling 150 days). Although not required, NMFS in 2015 published a notice of receipt of applications received to afford opportunity for public review and comment. Therefore, NMFS provided an opportunity for review of the applications for 30 days followed by a 45-day review of the proposed IHAs, for a total of 75 days of review—far above what is required by the MMPA. As stated earlier in this document, the additional two applications received following the 2015 review were substantially similar to those offered for review, and we determined that publishing a notice of their receipt would not provide any additional useful information.

Overall, we believe that there has been sufficient opportunity for public engagement with regard to the proposed surveys, through opportunities associated with NMFS's consideration of the requested IHAs under the MMPA and those associated with BOEM's consideration of requested permits under OCSLA (or through other associated statutory requirements). The public, coastal states, and other stakeholders have had substantial opportunity for involvement via processes related to the Coastal Zone Management Act (CZMA), NEPA, OCSLA, and the MMPA. In 2014, BOEM completed their PEIS, with NOAA acting as a cooperating agency in development of the PEIS. During EIS scoping, BOEM offered two separate comment periods and held seven public meetings in coastal states. The draft PEIS was made available for public review and comment for 94 days. Public hearings were held in eight coastal states. Subsequently, the final PEIS was made available for public comment for 90 days prior to BOEM's issuance of a Record of Decision. After completion of the 2014 PEIS, BOEM made all geophysical survey permit requests available for public review and comment for 30 days. With NMFS's participation, BOEM subsequently held eight open house meetings in coastal states for the public to learn more about the proposed surveys and to provide input to the permitting process. In addition, NOAA and BOEM engaged with coastal states as required by the CZMA federal consistency provision.

Comment: NRDC states that the specified activities have the potential to kill and seriously injure marine mammals, and that NMFS cannot therefore authorize the requested incidental take via an IHA. NRDC specifically contends that behavioral disturbance (*i.e.,* Level B harassment) can result in more severe outcomes (*i.e.,* Level A harassment or serious injury or mortality) through secondary effects, and that NMFS must consider this. Similarly, Oceana and other commenters suggest that Level A harassment (*i.e.,* auditory injury) cannot be authorized via an IHA, as it is equivalent to serious injury or mortality. In this same vein, commenters relate Level A harassment to potential biological removal (PBR) levels, a metric used to evaluate the significance of removals from a population (*i.e.,* serious injury or mortality).

Response: We strongly disagree that mortality or serious injury are reasonably anticipated outcomes of these specified activities, and the commenters do not provide compelling evidence to the contrary. Instead, commenters present speculative potentialities, including the contention that behavioral disturbance will lead to heightened risk of strike or predation. Moreover, the specific example given by NRDC—that the migratory path for right whales lies ''in the middle of the'' survey area—is plainly incorrect. The migratory path for right whales lies along the continental shelf (Schick *et al.,* 2009; Whitt *et al.,* 2013; LaBrecque *et al.,* 2015), whereas the survey area extends out to 350 nmi from shore, with most survey effort planned for waters where right whales do not occur (*i.e.,* waters greater than 1,500 m deep; Roberts *et al.,* 2017). More importantly, we require that applicants maintain a minimum standoff distance of 90 km from shore from November through April (or that comparable protection be achieved through implementation of a NMFS-approved mitigation and monitoring plan at distances between 47–80 km offshore), encompassing the expected migratory path and season and obviating any concern regarding potential secondary effects on migrating right whales.

Separately, section 101(a)(5)(D) of the MMPA, which governs the issuance of IHAs, indicates that the ''the Secretary shall authorize . . . . taking by harassment [. . . .]'' The definition of ''harassment'' in the MMPA clearly includes both Level A and Level B harassment.

Last, PBR is defined in the MMPA (16 U.S.C. 1362(20)) 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'' and is a measure to be considered when evaluating the effects of mortality or serious injury on a marine mammal species or stock. Level A harassment is not equivalent to serious injury and does not ''remove'' an individual from a stock. Therefore, it is not appropriate to use the PBR metric to directly evaluate the effects of Level A harassment on a stock in the manner suggested by commenters.

Comment: ION expressed concern regarding proposed IHA language indicating that ''taking of any other species of marine mammal is prohibited and may result in the modification, suspension, or revocation'' of an IHA, requesting that NMFS remove this language. Applicants also expressed concern about not being able to avail themselves of the IHAs while they are effective.

Response: The referenced language is standard text in issued IHAs, which acknowledges that, while unlikely and unexpected, species for which take is not authorized may be observed and unintentionally taken. Absent extenuating circumstances, it is unlikely that such an occurrence would result in

the suspension or revocation of an IHA. Rather, in the event that an observation is made of an unusual species for which take is not authorized, we would consider whether it is likely that the take warrants a modification of the IHA in order to include future take authorization for that species, or whether it is more likely that the observation would not occur again. NMFS has also included a provision for an IHA holder to request suspension of the IHA when operations must cease for reasons outside the holder's control, excluding certain circumstances, for a limited period.

Least Practicable Adverse Impact

Comment: NRDC believes NMFS relies on a ''flawed interpretation'' of the least practicable adverse impact standard. They state that NMFS (1) wrongly imports a population-level focus into the standard, contrary to the ''clear'' holding of the Ninth Circuit in *NRDC* v. *Pritzker;* (2) inappropriately ''balances'' or weighs effectiveness against practicability without sufficient analysis, counter to *Pritzker,* using the seasonality of Area #5 and NMFS's core abundance approaches as examples; and (3) must evaluate measures on the basis of practicability (which connotes feasibility), not practicality (which connotes usefulness)—and evaluating on the basis of practicality would be arbitrary and capricious.

Response: We carefully evaluated the Ninth Circuit's opinion in *Pritzker* and believe we have fully addressed the Court's concerns. Our discussion of the least practicable adverse impact standard in the section entitled ''Mitigation'' explains why we believe a population focus is a reasonable interpretation of the standard. With regard to the second point, we disagree that the Ninth Circuit's opinion requires such a mechanical application of the factors that must be considered in assessing mitigation options. Finally, we agree with the commenter that we must evaluate measures on the basis of practicability, and for these IHAS we have done so. Our assessment of measures for practicability looked at appropriate considerations, as demonstrated by our discussion in this Notice. This included cost and impact on operations. We note that although not directly relevant for these IHAs, in the case of a military readiness activity, practicality of implementation is explicitly part of the practicability assessment. Thus, the two concepts are not entirely distinct.

Comment: In determining whether proposed IHAs meet the least practicable adverse impact (LPAI) standard, the MMC recommends that NMFS (1) identify the potential adverse impacts that it has identified and is evaluating; (2) specify what measures might be available to reduce those impacts; and (3) evaluate whether such measures are practicable to implement. The MMC further suggests that NMFS provided ''virtually no analysis to support'' our conclusions.

Response: The MMC identifies a specific manner in which it recommends NMFS consider applicable factors in its least practicable adverse impact analysis, however, NMFS has clearly articulated the agency's interpretation of the LPAI standard and our evaluation framework in the ''Mitigation'' section of this notice. NMFS disagrees that analysis was not provided to support our least practicable adverse impact findings. Specifically, NMFS identifies the adverse impacts that it is considering in the LPAI analysis, and comprehensively evaluates an extensive suite of measures that might be available to reduce those impacts (some of which are adopted and some that are not) both in the context of their expected ability to reduce impacts to marine mammal species or stocks and their habitat, as well as their practicability (see ''Mitigation'' and ''Negligible Impact Analyses and Determinations'' sections).

Comment: TGS recommended that NMFS ''model how many shut-down and delay actions would be expected for a survey'' in evaluating practicability, suggesting that ''animat modeling could be used to accomplish this estimate.''

Response: NMFS is not aware of data sources that would appropriately inform such an analysis, and does not agree that such an analysis is either practical or necessary. Moreover, we believe we have addressed the commenter's concern by removing a number of shutdown measures (in response to other public comments) that we determined were likely ineffective and/or impracticable or otherwise unwarranted, thus minimizing the accumulation of potential for shutdown and delay actions. We also note that seismic operators have successfully and practicably implemented shutdowns in multiple regions, both in the United States and in other countries where seismic mitigation protocols have been prescribed, and that larger shutdown zones have previously been required of operators in the U.S. Arctic as well as for research seismic cruises, without any known practicability issues. We have appropriately accounted for issues related to practicability in our analysis of the appropriate suite of required mitigation measures.

Negligible Impact

Comment: As described briefly in a previous comment and response, NRDC asserts that NMFS should conduct a combined negligible impact analysis for all five specified activities, in consideration of the aggregate take across all five surveys in the same geographical region, over the same period of time, and with ''substantially similar impacts on marine mammals.'' NRDC states that NMFS's failure to do so does not meet our legal obligations under the MMPA and is ''contrary to common sense and principles of sound science.'' Other commenters offer similar comments. NRDC cites to legislative history that indicates ''specified activity'' includes all actions for which ''the anticipated effects will be substantially similar.'' H.R. Rep. No. 97–228 (Sept. 16, 1981), as reprinted in 1981 U.S.C.C.A.N. 1458, 1469. Further, NRDC cites to NMFS's 1989 implementing regulations as further evidence that NMFS must ''evaluate the impacts resulting from all persons conducting the specified activity, not just the impacts from one entity's activities.'' Based on this, NRDC argues that NMFS must make a finding that the authorized activity—which includes all five IHA applications—will have a negligible impact on the affected species or stocks.

Response: We considered five distinct specified activities and, therefore, performed five distinct negligible impact analyses. As we said in a previous response to comment, we believe the ''specified activity'' for which incidental take coverage is being sought under section 101(a)(5)(D) is appropriately defined and described by the applicant. Here there are five specified activities, with a separate applicant for each.

Although NRDC's comment correctly cites the pertinent language from section 101(a)(5)(D) (which was enacted in 1994), it refers to legislative history from 1981 in support of its argument. But that legislative history corresponds to Congress' enactment of the provision for incidental take regulations. Because the IHA provisions were added in 1994, citations from the 1981 legislative history cannot accurately be referenced as statements made ''in enacting this provision.'' More substantively, the sentence from which NRDC quotes was, in our view, for the purpose of instructing the agencies to avoid promulgating incidental take regulations that are overly broad in their scope (''It is the intention of the Committee that [. . .] the specified activity [. . .] be narrowly identified so that

the anticipated effects will be substantially similar.''). Similarly, the discussion from NMFS's and the U.S. Fish and Wildlife Service's 1989 implementing regulations (again, before the 1994 enactment of section 101(a)(5)(D)) was in reference to section 101(a)(5)(A), the provision for incidental take regulations. There the focus was on ensuring that the negligible impact evaluation for an incidental take regulation under section 101(a)(5)(A)—*not* incidental harassment authorizations under section 101(a)(5)(D)—included the effects of the total taking by all the entities anticipated to be conducting the activity covered by the incidental take regulation.

We do not mean to suggest that the legislative history for section 101(a)(5)(A) and our implementing regulations that preceded enactment of section 101(a)(5)(D) have no application to that section. We recognize there is considerable overlap between the two provisions. However, there are enough differences that the two provisions should not be casually conflated with one another.

Comment: The Associations state that they concur with NMFS's preliminary determinations of negligible impact on the affected species or stocks. However, their comments go on to claim that the ''magnitude'' and ''impact'' ratings that inform our negligible impact determinations as part of our negligible impact analysis framework are overly conservative, and that they disagree with these aspects of our negligible impact analyses.

Response: We appreciate the Associations' concurrence with our overall determinations. However, we disagree with the statements regarding aspects of our negligible impact analyses, and feel that these statements to some degree reflect a misunderstanding of the framework elements. In support of their assertion, the Associations claim that ''high'' and ''moderate'' magnitude ratings ''have never been observed in the multi-decade history of offshore seismic exploration [. . . .]'' Magnitude ratings reflect only the amount of take that is estimated, as well as the spatial and temporal scale over which the take is expected to occur in relation to what is known regarding a stock's range and seasonal movements; therefore, it is incorrect to reference what has or has not ''been observed'' in disputing the validity of the given magnitude ratings. The Associations also claim that no survey has had more than an ''insignificant'' impact on a marine mammal species or stock, without explaining the meaning that they assign to this term in context of their comments or providing any evidence (as we have stated, lack of evidence of ''significance'' does not constitute evidence of ''insignificance''). As this term bears no relevance to the MMPA's ''negligible impact,'' we cannot comment on the claim. With regard to the Associations' comment that our assigned impact ratings are too high, we again disagree (noting that these ratings are developed using the formula described for our negligible impact framework); however, absent any constructive recommendations relating to the development of the impact ratings or our framework overall, we cannot respond further.

Comment: The MMC recommends that NMFS evaluate the numbers of Level A harassment takes, in concert with the Level B harassment takes, using the negligible impact analysis framework.

Response: This comment appears based on a mistaken assumption that we ''assessed only the proposed Level B harassment takes'' in our negligible impact analyses. It is correct that we did not define quantitative metrics relating to amount of potential take by Level A harassment. However, as we state in the section entitled ''Negligible Impact Analyses and Determinations,'' the authorized taking by Level A harassment is so low as to not warrant such detailed analysis. We addressed the likely impacts of the minimal amount of takes expected by Level A harassment, stating that the expected mild PTS would not likely meaningfully impact the affected high-frequency cetaceans, and may have minor effects on the ability of affected low-frequency cetaceans to hear conspecific calls and/or other environmental cues. For all applicants, the expected effects of Level A harassment on all stocks to which such take may occur is appropriately considered de minimis.

Comment: NRDC claims that NMFS underestimates the ''magnitude'' component of the negligible impact analyses.

Response: NRDC suggests that the negligible impact framework used in our Notice of Proposed IHAs positions a ''de minimis'' amount of take as determinative of an ultimate ''de minimis'' impact rating. Although not stated explicitly by NRDC, we agree that this was inappropriate and have revised this aspect of our negligible impact framework. In effect, the proposed approach meant that a de minimis amount of take, which would necessarily lead to a de minimis magnitude rating, rendered considerations of likely consequences for affected individuals irrelevant. For example, mysticete whales with a de minimis amount of take were automatically assigned an overall de minimis impact rating, as consequences were considered not applicable in cases where a de minimis magnitude rating was assigned. However, the assessed level of potential consequences for individual baleen whales of ''medium''—which is related to inherent vulnerabilities of the taxon and other existing population stressors, and is therefore not dependent on the specific magnitude rating—would still exist, regardless of the amount of take. Under our revised approach, a mysticete whale with a de minimis amount of take is assigned a low impact rating, in light of the medium consequences rating. These changes are described further in the section entitled ''Negligible Impact Analyses and Determinations.''

NRDC asserts that impacts resulting from each of the five separate specified activities on the endangered North Atlantic right whale would be greater than negligible, stating that it is ''inconceivable'' that impacts should be considered anything less than ''high,'' regardless of the expected avoidance of right whales in time and space. We have addressed concerns regarding North Atlantic right whales in greater detail elsewhere in these comment responses. While we acknowledge that there will be some effects to individual right whales, as it is not possible to conduct these activities without the potential for impacts to whales that venture outside of areas where they are expected to occur or that undertake migration at atypical times, impacts to the population are in fact effectively minimized for each of these specified activities. As described later in this document, we have revised our exposure analysis for right whales using the latest and best available scientific information, and have appropriately revised our prescribed mitigation on the basis of that information, as well as public comment, in such a way as to reasonably avoid almost all potential right whale occurrence. We also include real-time mitigation that would minimize the effect of any disturbance on a right whale, in the unexpected event that an individual was encountered in the vicinity of a survey. Accordingly, the impact ratings for mysticetes are at least ''low'' versus ''de minimis'' (as stated above, we agree that the impact rating should likely be greater than de minimis given the inherent vulnerabilities of the species).

NRDC goes on to state that NMFS uses a ''non-conservative'' metric in characterizing the amount of take, and

suggests that we should adopt Wood *et al.* (2012)'s more conservative approach for ESA-listed species. NRDC does not explain how this recommendation will better satisfy the statutory requirements of the MMPA. As stated by Wood *et al.* (2012), development of metrics for assessment of the magnitude of effect is considered particularly subjective. Rather than invent new metrics in the absence of any specific rationale or guidance, we retain use of those given by Wood *et al.,* which are produced through expert judgment. We disagree that the more conservative approach applied by Wood *et al.* (2012) for ESA-listed species is appropriate. We believe that the assessment of amount of take is a generic consideration, *i.e.,* that the metrics used to assess this factor are appropriately applied similarly to all species. Contextual factors, such as the status of the species, are applied elsewhere in the analysis, *e.g.,* through consideration of likely consequences to individuals or as a second-order function of the mitigation that is developed in reflection of specific concerns about a given species. NRDC's implication that we did not take account of vulnerable populations in our negligible impact framework is incorrect.

Comment: NRDC asserts that the evaluation of likely consequences to individuals from species other than mysticete whales in our negligible impact analyses is ''problematic.''

Response: Overall, NRDC basically provides a blanket suggestion that for all species impacts should be considered to be higher than we have determined after careful consideration of the available science. NRDC also repeatedly claims that we have provided no rational basis for our findings. While we acknowledge that we bear the responsibility to support our statutory findings, we believe we have satisfied that requirement and, further, NRDC does not provide adequate justification or evidence to support their claims.

For sperm whales, NRDC demands that the likely consequences to individuals be considered ''high'' rather than ''medium,'' as we have done (on the basis of presumed heightened potential for disruption of foraging activity). In so doing, NRDC primarily relies upon Miller *et al.* (2009), as has NMFS in assuming some heightened potential for foraging disruption. However, the evidence provided by the available literature is not nearly as clear as NRDC's comment implies. We agree that the work of Miller *et al.* (2009) indicates that sperm whales in the Gulf of Mexico are susceptible to disruption of foraging behavior upon exposure to relatively moderate sound levels at distances greater than the required general exclusion zone. However, NRDC misstates the results of the study in claiming that a nearly 20 percent loss in foraging success was documented. Rather, the authors report that buzz rates (a proxy for attempts to capture prey) were approximately 20 percent lower, meaning that the appropriate interpretation would be that foraging activity (versus foraging success) was reduced by 20 percent (Jochens *et al.,* 2008). This is an important distinction, as the former implies a cessation of activity—which may include increased resting bouts at the surface—during the relatively brief period that the surveys transit through the whale's foraging area, whereas the latter implies that the whale is continuing to expend energy in the hunt for food, without reward. Moreover, while we do believe that these results support our contention that exposure to survey noise can impact foraging activity, other commenters have interpreted them differently, *e.g.,* by focusing on the finding that exposed whales did not change behavioral state during exposure or show horizontal avoidance (a finding replicated in other studies, *e.g.,* Madsen *et al.,* 2002; Winsor *et al.,* 2017), or that the finding of reduced buzz rates was not a statistically significant result. In referencing Bowles *et al.* (1994), NRDC fails to state that the observed cessation of vocalization was likely in response to a low-frequency tone (dissimilar to airgun signals), though a distant airgun survey was noted as producing signals that were detectable above existing background noise. However, most importantly, we expect that the context of these transitory 2D surveys—as compared with 3D surveys that may occur for a longer duration in a given location, or with repeated survey activity as may occur in an area such as the Gulf of Mexico—means that the potential impacts of the possible reduction in foraging activity (*i.e.,* likely consequences on individuals) is limited. More recently, Farmer *et al.* (2018) developed a stochastic life-stage structured bioenergetic model to evaluate the consequences of reduced foraging efficiency in sperm whales, finding that the ultimate effects on reproductive success and individual fitness are largely dependent on the duration and frequency of disturbance—which are expected to be limited in relation to these specified activities. Thus, we believe our conclusion of ''medium'' likely consequences is appropriate.

With regard to *Kogia* spp., NRDC again suggests that NMFS must increase the level of assumed severity for likely consequences to individuals. While we agree that the literature with regard to kogiid life history is sparse, what literature is available (as cited in our Notice of Proposed IHAs) indicates that these species should be considered as having a reasonable compensatory ability when provoked to temporary avoidance of areas in the vicinity of active surveys. None of NRDC's statements on this topic support their contention that these consequences should be considered as more severe, *i.e.,* the notion that there is little information available regarding stock structure is not related to the likely consequences to individuals of disturbance. NRDC assumes that such temporary avoidance necessarily results in ''displacement from optimal to suboptimal habitat'' without any support. Moreover, it appears that NRDC misapprehends the conceptual underpinnings of our negligible impact analytical framework. The expected degree of disturbance (''take'') is determined in the ''Estimated Take'' section, and then is coupled with an understanding of the spatial and temporal scale of such disturbance relative to the stock range. Only then is this comprehensive magnitude rating combined with the expectation of the likely consequences of the given magnitude of effect to yield an overall impact rating that is then considered with other relevant contextual factors, such as mitigation and stock status, in informing the negligible impact determination (Figure 5). By seemingly conditioning its premise on the acoustically sensitive nature of kogiids, which is incorporated into the take estimates and accounted for in the mitigation requirements, NRDC would have us overly weight this aspect of their life history. Our assigned consequences for *Kogia* spp. is appropriate and based on the limited available literature.

Similarly, for delphinids (for which NRDC also urges a more severe assumption of likely consequence to individuals of the given disturbance), NRDC states that the consequences must be considered higher when the magnitude is high. Again, this is a misapprehension of the framework: The assigned ''consequences'' factor is independent of the magnitude rating, and is designed to account for aspects of a species life history that may make individuals from that species more or less susceptible to a biologically significant degree of impact from a

given level of disturbance. NRDC's additional statements regarding delphinids appear to again cherry-pick available literature in support of its preferred position, *e.g.,* NRDC cites reactions of dolphins to Navy training involving explosive detonations (a dissimilar activity) and suggests that spotted dolphins are susceptible to greater disturbance on the basis of Weir (2008), claiming that this paper indicates ''pronounced response of spotted dolphins to operating airguns'' and supposedly heightened sensitivity. We do agree that the available observational data (*e.g.,* Barkaszi *et al.,* 2012; Stone, 2015a) show that, in contrast to common anecdotal statements suggesting that dolphins do not react at all to airgun noise, dolphins overall show increased distances to the noise source or even avoidance when airguns are operating. However, as stated elsewhere, these reactions may not even be appropriately considered as take (*e.g.,* Ellison *et al.,* 2012), much less take to which some meaningful biological significance should be assigned. In fact, Weir (2008) concludes that, while spotted dolphin encounters occurred at a significantly greater distance from the airgun array when the guns were firing, there was no evidence of displacement from the study area, indicating that even for this supposedly more sensitive species, greater likely consequences would not be expected. As indicated by Weir (2008), these responses may be short-term and also occur over relatively short ranges from the source.

NRDC concludes its criticism of this aspect of our negligible impact analyses by demanding that we weight this assessment of likely consequences to individuals more highly in the determination of the overall impact rating. However, this appears to again evidence a misapprehension of our framework and its function. We certainly agree that an activity that is found to take small numbers of marine mammals may not be found to satisfy the negligible impact standard. However, here, as in their criticism of NMFS's approach to the small numbers analysis, NRDC inappropriately conflates the two findings. Here, NRDC seems to confuse a low magnitude of effect with the independent small numbers finding, rather than understand this magnitude factor as an important input to the development of the impact rating. As described in greater detail in our section entitled ''Negligible Impact Analyses and Determinations,'' the impact rating represents the coupling of the magnitude rating and the likely consequences to individuals in order to represent the potential impact to the stock (before considering other contextual factors). Therefore, although the likely consequences to individuals of incidental take may be high, if the magnitude of effect is low, then the impact to the stock will not likely be high. NRDC's example indicates that it prefers that the likely consequences to individuals be determinative of the impact rating, *i.e.,* they state that it is inappropriate for a low magnitude rating and high consequences rating to couple to produce a moderate impact rating. Our development of these rating matrices (Tables 8 and 9) are based on expert review (Wood *et al.,* 2012) and appropriately account for the factors illustrated in Figure 5.

Comment: NRDC claims that the negligible impact analyses are inappropriately reliant upon the prescribed mitigation and, further, that the mitigation will be ineffective.

Response: First, NMFS did not rely solely on the mitigation in order to reach its findings under the negligible impact standard. As is stated in our specific analyses, consideration of the implementation of prescribed mitigation is one factor in the analyses, but is not determinative in any case. In certain circumstances, mitigation is more important in reaching the negligible impact determination, *e.g.,* when mitigation helps to alleviate the likely significance of taking by avoiding or reducing impacts in important areas. Second, while NRDC dismisses the importance of our prescribed mitigation by stating that it is ''unsupported by evidence,'' NRDC offers no support for their conclusions.

For example, with regard to the North Atlantic right whale, consideration of the mitigation in our negligible impact analyses was appropriate. That is, it was appropriate to weigh heavily in our analyses mitigation that would avoid most exposures of right whales to noise at levels that would result in take. We acknowledge that our proposed mitigation for right whales was not sufficient. As described in greater detail in previous comment responses, as well as in the section entitled ''Mitigation,'' we re-evaluated our proposed mitigation in light of the public comments we received and on the basis of the best available information.

NRDC elsewhere stresses the importance of developing appropriate habitat-based mitigation—that is, avoiding impacts in areas of importance for marine mammals—and not relying solely on ''real-time'' mitigation (*e.g.,* shutdowns) that allows impacts in those areas but minimizes the duration and intensity of those impacts. Yet despite our development of time-area measures for those species where the available information supports it, NRDC discounts the benefit of avoiding disturbance of sensitive and/or deep-diving species in areas where they are expected to be resident in greatest numbers. Claims that our prescribed time-area restrictions are ineffective and ''unsubstantiated''—and therefore apparently should not be considered in our negligible impact analyses—are contradicted by NRDC's statements that habitat-based mitigation are necessary (''Time and place restrictions designed to protect important habitat can be one of the most effective available means to reduce the potential impacts of noise and disturbance on marine mammals.'' (Citing p. 61 of NRDC's letter)). However, our revised time-area restriction for right whales (or requirement that comparable protection is achieved through implementation of a NMFS-approved mitigation and monitoring plan at distances between 47–80 km offshore) may have alleviated some of the concerns expressed in the comment.

NRDC also misunderstands the degree to which we rely on shutdowns for sensitive or vulnerable species, including right whales and beaked whales, at extended distances. We agree that these measures in and of themselves are not likely to carry substantial benefit, especially for cryptic species such as beaked whales that are unlikely to be observed. The prescribed habitat-based mitigation, *i.e.,* time-area restrictions, is obviously more important in minimizing impacts to these species. However, having determined practicability, we also believe that it makes sense to minimize the duration and intensity of disturbance for these species when they are observed, and so include them in the suite of prescribed measures and discuss them where appropriate. Despite their dismissal of these requirements, we presume NRDC agrees that the duration and intensity of disturbance of sensitive species should be minimized where practicable.

In summary, we have prescribed practicable mitigation that largely eliminates takes of North Atlantic right whales, as indicated by the best available science and further minimizes impacts by mitigating for duration and intensity of exposures. Separately, we have developed mitigation that protects use of some of the most important habitat in the region for other sensitive species. We consider these measures appropriately as mitigating factors in the

context part of our negligible impact analyses.

Comment: Oceana asserts that our findings of negligible impact are improper. In so doing, they make points that are substantively responded to elsewhere in these comment responses. In addition, they also make repeated reference to the PBR value, claiming that where harassment takes exceed the PBR value for a stock, NMFS must deny the IHA request for failure to meet the negligible impact standard.

Response: We reiterate that the PBR metric concerns levels of allowable removals from a population, and is not directly related to an assessment of negligible impact for these specified activities, which do not involve any expected potential for serious injury or mortality. As noted previously, PBR is not an appropriate metric with which to evaluate Level B harassment and NMFS has described and used an analytical framework that is appropriate. We appropriately do consider levels of ongoing anthropogenic mortality from other sources, such as commercial fisheries, in relation to calculated PBR values as an important contextual factor in our negligible impact analysis framework, but a direct comparison of takes by harassment to the PBR value is not germane. While it is conceptually possible to link disturbance to potential fitness impacts to individuals over time (*e.g.,* population consequences of disturbance), we have no evidence that is the case here.

Small Numbers

Comment: The MMC and multiple commenters recommend that NMFS provide additional explanation to support its selection of the 30-percent limit on marine mammal taking as meeting the small numbers determination for the proposed authorizations. NRDC states that the interpretation of ''small numbers'' presented by NMFS in our Notice of Proposed IHAs is contrary to the plain meaning and purpose of the MMPA, in part because NMFS did not provide a reasoned basis for the take limit proposed (*i.e.,* 30 percent) (MMC and others similarly recommended that NMFS provide additional explanation to support its selection of the 30-percent limit on marine mammal taking as meeting the small numbers determination for the proposed authorizations). NRDC makes four specific claims. First, NRDC states that 30 percent cannot be considered a ''small number.'' Second, NRDC states that Congress intended that takes be limited to ''infrequent, unavoidable'' occurrences, and that NMFS has not explained why the taking would infrequent or unavoidable. Third, NRDC contends that NMFS should define different small numbers thresholds on the basis of conservation status of individual species. Finally, NRDC believes that NMFS must account for ''additive and adverse synergistic effects'' that may occur due to multiple concurrent surveys in conducting a small numbers analysis.

Response: NMFS agrees that the Notice of Proposed IHAs did not provide adequate reasoning for the 30 percent limit. Please see the ''Small Numbers Analyses'' section of this Notice. However, we disagree with NRDC's arguments on this topic. Although NMFS has struggled to interpret the term ''small numbers'' given the limited legislative history and the lack of a biological underpinning for the concept, we have clarified and better described our approach to small numbers. As discussed in the section entitled ''Small Numbers Analyses,'' we describe that the concept of ''small numbers'' necessarily implies that there would also be quantities of individuals taken that would correspond with ''medium'' and ''large'' numbers. As such, we have established that one-third of the most appropriate population abundance number—as compared with the assumed number of individuals taken—is an appropriate limit with regard to ''small numbers.'' This relative approach is consistent with Congress's statement that ''[small numbers] is not capable of being expressed in absolute numerical limits'' (H.R. Rep. No. 97–228).

NRDC claims that a number may be considered small only if it is ''little or close to zero'' or ''limited in degree.'' While we do not accept that a dictionary definition of the word ''small'' is an acceptable guide for establishment of a reasoned small numbers limit, we also note that NRDC cherry-picks the accepted definitions in support of its favored position. The word ''small'' is also defined by Merriam-Webster Dictionary as ''having comparatively little size,'' which comports with the small numbers interpretation developed by NMFS and offered here. See *www.merriam-webster.com/dictionary/small.* NRDC cherry-picks the relevant language by claiming that Congress intended that the agency limit takes to those that are ''infrequent, unavoidable'' occurrences. The actual Congressional statement is that taking of marine mammals should be ''infrequent, unavoidable, or accidental.'' This language implies that allowable taking may in fact be frequent if it is unavoidable or accidental, both of which are the case, even though, in the case of a large-scale, sound-producing activity in areas where marine mammals are present, the takes are not ''infrequent.''

The argument to establish a small numbers threshold on the basis of stock-specific context is unnecessarily duplicative of the required negligible impact finding, in which relevant biological and contextual factors are considered in conjunction with the amount of take.

Similarly, NRDC's assertion that take from multiple specified activities should be considered in additive fashion when making a small numbers finding is not required by section 101(a)(5)(D) of the MMPA. We are unclear whether the logic presented in this comment suggests only that a single small numbers analysis should be undertaken for the five separate specified activities considered herein, or whether NRDC believes that all ''taking'' to which a given stock may be subject from all ongoing anthropogenic activities should be considered in making a small numbers finding for a given specified activity. Regardless, these suggestions from NRDC are not founded in any relevant requirement of statute or regulation, discussed in relevant legislative history, or supported by relevant case law.

Comment: The MMC recommends that, in developing generally applicable guidance for using a proportional standard to make small numbers determinations, NMFS either use a sliding scale that accounts for the abundance of the species or stock or explain why it believes that a single standard should be applied in all cases. The MMC offers two examples, on either end of a spectrum, in illustrating its point. First, MMC provides the example of a small population of marine mammals, stating that ''taking the entire population may arguably constitute a small number.'' Second, the MMC provides the example of a large population of marine mammals, stating that ''certain types of taking from large populations . . . push the limit of what reasonably may be considered a small number.''

Response: NMFS disagrees that such a ''sliding scale'' is necessary or appropriate. Under the ''one-third'' interpretation offered here, and on which we base our small numbers analyses, take equating to greater than one-third of the assumed individuals in the population would not be considered small numbers, other than in certain extenuating circumstances, such as the brief exposure of a single group of marine mammals (as is authorized

herein for each applicant for such species as the killer whale). In both of the MMC's examples, the MMC evidently reverts to an absolute magnitude of the number on the ends of the spectrum, without regard for the amount of individuals taken relative to the size of the population. Historically, such an approach may have served as a meaningful limit on actual removals from a population, prior to the development of the PBR metric, but is not a useful consideration when evaluating takes by Level B harassment from sound exposure. There is no meaningful way to define what should be considered as a ''small'' number on the basis of absolute magnitude, and the MMC offers no such interpretation or justification.

Comment: The Associations provide a discussion of several topics relating to ''small numbers'' and recommend that NMFS's small numbers findings be thoroughly explained in the record for these actions.

Response: We agree that the basis for each finding should be explained. Please see our revised explanation in ''Small Numbers Analyses.''

Comment: Oceana claims that NMFS is in violation of the MMPA's ''small numbers'' requirement for a variety of reasons, including that we authorize takes of the ''critically endangered'' North Atlantic right whale and because we authorize takes of species for which there are no available abundance estimates, and relates the potential biological removal metric to the small numbers finding. Oceana and many other commenters also make reference to a supposed ''Federal court defined'' take limit of 12 percent of the appropriate stock abundance.

Response: The reference to a ''Federal court defined'' take limit of 12 percent for small numbers likely comes from a 2003 district court opinion (*Natural Resources Defense Council* v. *Evans,* 279 F.Supp.2d 1129 (N.D. Cal. 2003)). However, given the particular administrative record and circumstances in that case, including the fact that our small numbers finding for the challenged incidental take rule was based on an invalid regulatory definition of small numbers, we view the district court's opinion regarding 12 percent as *dicta.* Moreover, since that time the Ninth Circuit Court of Appeals has upheld a small numbers finding that was not based on a quantitative calculation. *Center for Biological Diversity* v. *Salazar,* 695 F.3d 893 (9th Cir. 1012). Second, while we agree that there are stocks for which no abundance estimate is presented in NMFS's SARs, there are other available abundance estimates for all impacted stocks. However, more importantly, there is no requirement in the MMPA to authorize take only for stocks with available abundance estimates, or even that a small numbers finding must necessarily be based on a quantitative comparison to stock abundance. We are required only to use the best available scientific information in making a small numbers finding; this information may be quantitative or qualitative, and may relate to relevant stock information other than its overall abundance. Finally, the PBR metric defines a level of removals from a population (*i.e.,* mortality) that would allow that population to remain at its optimum sustainable population level or, if depleted, would not increase the population's time to recovery by more than 10 percent. We reiterate that it is inappropriate to make comparisons between takes by harassment and the PBR value for any stock.

Comment: The MMC recommends that NMFS include both the numbers of Level A and B harassment takes in its analysis of small numbers.

Response: We agree that this is appropriate and have done so. Please see ''Small Numbers Analyses,'' later in this document, for full detail.

Comment: TGS states that NMFS should better explain what it views as the most appropriate abundance estimate for each stock.

Response: Please see our revised discussion of this topic in the section entitled, ''Description of Marine Mammals in the Area of the Specified Activities.''

Comment: Several commenters described problems with NMFS's proposed approach to ensuring that actual take estimates remained below the small numbers threshold proposed in our Notice of Proposed IHAs, *i.e.,* a requirement for monthly interim reporting and a proposed process by which companies would correct observations of marine mammals to obtain an estimate of total takes.

Response: We agree with many of the points raised by commenters. However, we discuss only the fundamental underlying issue here, *i.e.,* our proposed small numbers analyses, which did not fully utilize all the information that was available to refine the number of individuals taken and prompted development of a proposed reporting scheme that was roundly criticized. The small numbers analyses, described in our Notice of Proposed IHAs, resulted in erroneous assessments that enumerated take estimates for some applicants and some species would exceed the proposed small numbers threshold. In order to ensure that the proposed threshold would not be exceeded, we proposed that applicants would submit monthly interim reports, including estimates of actual numbers of takes (proposed to be produced via correction of numbers of observed animals for certain biases using factors described in Carr *et al.* (2011)), such that an authorization could be revoked if actual take exceeded the proposed small numbers threshold. While we believe it is appropriate to correct such observations in order to best understand the actual number of takes (discussed elsewhere in these comment responses), we agree that this proposal was inappropriate, *i.e.,* that NMFS should not issue an incidental take authorization for an activity for which a small numbers threshold is expected to be exceeded. Additionally, such an approach results in a clearly impracticable situation for applicants, who commit substantial expenditure towards conducting a given survey plan, but who then may be allowed to complete only a portion of the plan.

In summary, as a result of our review of public comments, we re-evaluated the relevant available information and produced revised small numbers analyses (see ''Small Numbers Analyses,'' later in this document). The revised small numbers analyses alleviated the need for the proposed take reporting scheme and cap, which were also challenged by multiple applicant and public commenters.

Mitigation, Monitoring, and Reporting

Comment: NRDC states that year-round closure is required in the area off Cape Hatteras. This recommendation was also made by a group of scientists from the University of North Carolina-Wilmington (D.A. Pabst, W.A. McLellan, and A.C. Johnson; hereafter, ''Pabst *et al.*'').

Response: In this case, NRDC presents substantial evidence of the year-round importance of this habitat to marine mammals (evidence cited by NMFS in proposing the area as a seasonal closure); we agree that this habitat is of year-round importance. We did not base the development of this area as a seasonal restriction because of some assumption that the area is only important for a portion of the year (though the specific seasonal timing is based on increased density of sperm whales; see ''Mitigation''). Rather, our development of this area as a seasonal restriction was in consideration of practicability under the MMPA's least practicable adverse impact standard. We believe NRDC's comment inappropriately minimizes the element

of practicability in a determination of the measures that satisfy the standard. In this case, the area is of critical interest to all applicants—based on the dated historical survey information from the region, this area is considered to potentially be most promising in terms of hydrocarbon reserves. Therefore, an absolute proscription on any given applicant's ability to collect data in this area would be impracticable. In such a case where practicability concerns would preclude inclusion of an otherwise valid measure, the measure must be necessary to a finding of negligible impact (*i.e.,* the negligible impact determination cannot be made and the authorization may not be issued absent the measure) in order to supersede the practicability concerns. While NRDC presents substantial evidence of the importance of this area for the marine mammals that use it, they do not grapple with the practicability question or justify why the closure must be year-round for a negligible impact determination to be made.

We disagree with NRDC's apparent contention that surveys conducted in this region are likely to result in the death of resident beaked whales. As we discussed in our Notice of Proposed IHAs, we recognize the importance of the concepts described in Forney *et al.* (2017), *i.e.,* that for resident animals, it is possible that displacement may lead to effects on foraging efficiency that could impact individual vital rates. However, no evidence is presented that severe acute impacts are a reasonably anticipated outcome for surveys that will pass through such habitat in a matter of days.

We also disagree with NRDC's summary dismissal of the benefit of completely restricting survey activity in the habitat for a portion of the year. The benefit of a restriction targeting resident animals is sensibly scaled to the duration of the restriction and/or the timing of the restriction in relation to reproductive behavior. However, we believe that a full season without acute noise exposure, at minimum, for those animals will provide meaningful benefit, including but not limited to avoidance of the stress responses of concern to NRDC elsewhere in their comments.

Comment: Regarding NMFS's proposed time-area restriction in waters off Cape Hatteras, Pabst *et al.* state that recent data from acoustic monitoring suggest that sperm whales are more abundant in this area during winter.

Response: NMFS's initial proposal was to require implementation of this restriction from July through September, in recognition of the limited available visual survey data. As noted by commenters, visual survey data do suggest that sperm whales are most common in the Cape Hatteras region in summer (Roberts *et al.,* 2016). The commenters go on to note, however, that more recently available acoustic monitoring data indicates that the highest number of sperm whale detections were made in winter when visual survey effort was most limited (Stanistreet *et al.,* 2018). While we disagree with the commenters' larger point, *i.e.,* that the ''Hatteras and North'' restriction should be in effect year-round (addressed in previous comment response), we agree with their interpretation of the data that sperm whales are more abundant in winter. Upon review of this newly available data, we determined it appropriate to revise the timing of this restriction to January through March, as described in ''Mitigation.''

Comment: NRDC, the MMC, and multiple other commenters state that NMFS must expand protection of North Atlantic right whale habitat. Many commenters referred to the spatial aspect of the proposed restriction, though some commenters also referred to the temporal aspect.

Response: We agree with the comments referencing the spatial designation, and we are spatially expanding the seasonal restrictions intended to protect right whale migratory habitat, in addition to reproductive habitat and for general protection of right whales (or requiring that comparable protection is achieved through implementation of a NMFS-approved mitigation and monitoring plan at distances between 47–80 km offshore). Our determination in this regard and development of this expanded protection are described in greater detail elsewhere in these comment responses, as well as in the section entitled ''Mitigation.'' However, we disagree that the available evidence supports expansion of this area temporally. Pabst *et al.,* in recommending a temporal expansion, reference an analysis of the composition and distribution of individual right whale sightings archived by the North Atlantic Right Whale Consortium from 1998 through 2015 performed by one of the comment authors. While this analysis (as well as more recent acoustic monitoring data; *e.g.,* Davis *et al.* (2017)) suggests that right whales are present in the area in all months of the year, it also shows that very few occurred outside of the time window and outside of the year-round 30-km coastal restriction. During this period, only five archived sightings occurred outside of the November through April period and outside of 30 km from shore. Further, it would be impracticable to completely close this area to survey activity year-round. As we have acknowledged, it is possible that whales will be present beyond this area, or that whales will be present within this area but at times outside when migration is expected to occur. However, we base the time-area restriction on our best understanding of where and when most whales will be expected to occur.

Comment: Several industry commenters provided comments regarding NMFS's proposed exception to shutdown requirements for certain species of dolphin. The Associations stated that, while they appreciate the exception, it should apply to all dolphin species, regardless of behavior. They add that no shutdowns for dolphins are warranted. CGG also criticized the proposed behavior-based exception, instead suggesting that a power-down requirement be applied as an alternative. CGG favorably stated that such a requirement would ''allow for a tolerable hole in the acquired seismic data and will not require the vessel to immediately terminate the survey line and carry out a six hour circle for infill'' and that use of power-downs rather than shutdowns in these circumstances would result in substantial savings in operating costs. TGS stated simply that NMFS ''should consider clarifying and better addressing bow-riding dolphins'' and also recommended that NMFS clarify and better define how to determine if animals are stationary (in reference to NMFS's proposed behavior-based requirements for dolphins).

Response: Following review of the available information and public comments, NMFS agrees that a general exception to the standard shutdown requirement is warranted for small delphinids, without regard to behavior. We agree with TGS and other commenters that the intended behavior-based exception was poorly defined. However, we do not agree that the available evidence supports certain commenters' assertions that seismic surveys do not have any adverse effects on dolphin species. As discussed in ''Mitigation,'' auditory injury is not expected for dolphins, but the reason for dolphin behavior around vessels (when they are attracted) is not understood and cannot be assumed to be harmless. In fact, the analyses of Barkaszi *et al.* (2012), Stone (2015a), and Stone *et al.* (2017) show that dolphins do avoid working vessels.

That said, the available information does not suggest that such reactions are likely to have meaningful energetic

effects to individuals such that the effectiveness of such measures outweighs the practicability concerns raised by commenters, in terms of the operational costs as well as the difficulty of implementation. All variations of a conditional shutdown exception proposed to date (by either NMFS or BOEM) that include exceptions based on animal behavior have been criticized, in part due to the subjective on-the-spot decision-making such schemes would require of PSOs. NMFS finds these criticisms warranted. If the mitigation requirements are not sufficiently clear and objective, the outcome may be differential implementation across surveys as informed by individual PSOs' experience, background, and/or training. Therefore, the removal of such measures for small delphinids is warranted in consideration of the available information regarding the effectiveness of such measures in mitigating impacts to small delphinids and the practicability of such measures.

As noted above, one commenter suggested that a power-down requirement would be practicable (though we note that this alternative was offered against the backdrop of broader claims that no measures should be required). We considered modifying the behavior-based shutdown requirement contained in our proposed IHAs to CGG's suggested general power down requirement. However, following consultation with applicants and with BOEM, we determined that the circumstances of this particular commenter (CGG) with regard to practicability may not be broadly transferable, and that a power down requirement would potentially lead to the need for termination of survey lines and infill of the line where data were not acquired if a power down was performed according to accepted practice, in which the power down condition would last until the dolphin(s) are no longer observed within the exclusion zone. As noted in our Notice of Proposed IHAs, the need to revisit missed track line to reacquire data is likely to result in an overall increase in the total sound energy input to the marine environment and an increase in the total duration over which the survey is active in a given area.

We disagree with comments that no shutdown requirements should apply to any delphinid species, regardless of behavior. Here we refer to ''large delphinids'' and ''small delphinids'' as shorthand for generally deep-diving versus surface-dwelling/bow-riding groups, respectively, although the important distinction is their dive behavior rather than their size. As noted above, industry commenters have asserted that no shutdown requirements are warranted for any species of dolphin, stating that the best available science does not support imposing such requirements. The comments acknowledge that small delphinids are more likely to approach survey vessels than large delphinids, but claim without supporting data that there is no evidence that large delphinids will benefit from a shutdown requirement. In contrast to the typical behaviors of (and observed effects on) the small delphinid species group, the typical deep diving behavior of the relatively rarely occurring large delphinid group of species makes these animals potentially susceptible to interrupted/delayed feeding dives, which can cause energetic losses that accrue to affect fitness. As described in greater detail elsewhere in this Notice, there are ample data illustrating the responses of deeper diving odontocetes (including large delphinids) to loud sound sources (including seismic) to include interrupted foraging dives, as well as avoidance with increased speed and stroke rate, both of which may contribute to energetic costs through lost feeding opportunities and/or increased energy demands. Significant advances in study of the population consequences of disturbance are informing our understanding of how disturbances accrue to effects on individual fitness (reproduction and survival) and ultimately to populations via the use of energetic models, where data are available for a species, and expert elicitation when data are still limited. The link between behavioral disturbance, reduced energy budgets, and impacts on reproduction and survival is clear, as is the value in reducing the probability or severity of these behavioral disturbances where possible. Therefore, we find that there is support for the effectiveness of the standard shutdown requirement as applied to the large delphinid species group.

Further, the claim of industry commenters that shutdowns for these deep-diving species would be impracticable was not accompanied by supporting data. The data available to NMFS demonstrates that this requirement is practicable. For example, Barkaszi *et al.* (2012)'s study of observer data in the Gulf of Mexico from 2002–08 (1,440 bi-weekly reports) shows that large delphinids were sighted on only 1.4% of survey days, and that of these sightings, only 58% were within the 500-meter exclusion zone.

Comment: Many commenters expressed concern regarding the efficacy of the prescribed visual and acoustic monitoring methods, stating that species could go undetected. Some commenters offer specific recommendations for changes to staffing requirements. Finally, some of these commenters state that NMFS should require operators to cease work in low-visibility conditions, because of the difficulty in detecting marine mammals in such conditions.

Response: While we disagree with some specific comments regarding efficacy, we agree with the overall point that there are limitations on what may reasonably be expected of either visual or acoustic monitoring. While visual and acoustic monitoring effectively complement each other, and acoustic monitoring is the most effective monitoring method during periods of impaired visibility, there is no expectation that such methods will detect all marine mammals present. In general, commenters appear to misunderstand what we claim with regard to what such monitoring may reasonably be expected to accomplish and/or the extent to which we rely on assumptions regarding the efficacy of such monitoring in reaching the necessary findings. We appropriately acknowledge these limitations in prescribing these monitoring requirements, while stating why we believe that visual and acoustic monitoring, and the related protocols we have prescribed, are an appropriate part of the suite of mitigation measures necessary to satisfy the MMPA's least practicable adverse impact standard. However, our findings of negligible impact and/or small numbers are in no way conditioned on any presumption of monitoring efficacy. With regard to specific staffing requirements, those prescribed herein are based on typical best practices and on review of all available literature concerning such practices. Commenters do not offer compelling information that their proffered recommendations achieve the appropriate balance between enhancement of monitoring effectiveness and the costs (including both monetary costs as well as costs in terms of berth space), and we retain the requirements originally specified. Finally, any requirement to cease operations during low visibility conditions, including at night, would not only be plainly impracticable, it would also likely result in greater impacts to marine mammals, as such a measure would require operations to continue for roughly twice the time.

Such comments do not align with the principles we laid out in the ''Proposed Mitigation'' section of our Notice of Proposed IHAs, in which we discussed the definitively detrimental effects of increased time on the water and/or increased or unnecessary emission of sound energy into the marine environment, versus the potential and uncertain negative effect of proceeding to most efficiently conclude survey activity by conducting operations even in low visibility conditions.

Comment: NRDC asserts that NMFS does not fulfill the MMPA's requirement to prescribe mitigation achieving the ''least practicable adverse impact'' to marine mammal habitat, and specifically notes that NMFS does not separately consider mitigation aimed at reducing impacts to marine mammal habitat, as the MMPA requires.

Response: We disagree. Our discussion of least practicable adverse impact points out that because habitat value is informed by marine mammal presence and use, in some cases there may be overlap in measures for the species or stock and for use of habitat. Here we have identified time-area restrictions based on a combination of factors that include higher densities and observations of specific important behaviors of the animals themselves, but also clearly reflect preferred habitat. In addition to being delineated based on physical features that drive habitat function (*e.g.,* bathymetric features, among others), the high densities and concentration of certain important behaviors (*e.g.,* feeding) in these particular areas clearly indicates the presence of preferred habitat. Also, NRDC asserts that NMFS must ''separately'' consider measures aimed at marine mammal habitat. The MMPA does not specify that effects to habitat must be mitigated in separate measures, and NMFS has clearly identified measures that provide significant reduction of impacts to both ''marine mammal species and stocks and their habitat,'' as required by the statute. Last, we note that NRDC acknowledges that NMFS's measures would reduce impacts on ''acoustic habitat.''

Comment: The MMC recommended that, if NMFS is to require a time-area restriction to protect spotted dolphins in shelf waters, the restriction should be expanded from June through August to June through September. This recommendation was made on the basis of spotted dolphins likely being most abundant in this area during summer. Similarly, TGS stated that NMFS should better support its determination of seasonality for the proposed restriction.

Response: Following review of public comments, NMFS determined that this proposed time-area restriction was unlikely to be effective in accomplishing its intended purpose, while imposing practicability costs on applicants. As explained in greater detail in the ''Mitigation'' section, we have eliminated this proposed requirement. Therefore, the MMC's recommendation is no longer relevant.

Comment: NRDC states that NMFS must require larger buffer zones around the required time-area restrictions. TGS stated that NMFS should better support its choice of 10 km as a buffer distance.

Response: NRDC provides several reasons why they believe that the required standard 10-km buffer zones are insufficient. NRDC claims several supposed ''erroneous and misplaced assumptions'' in the sound field modeling that informs our standard buffer zone, which we have refuted elsewhere in these comment responses. More substantively, NRDC returns again to its suggestion that a different threshold must be used to represent Level B harassment. We have also addressed this comment elsewhere. Here, we reiterate that BOEM's sound field modeling, which was conducted in accordance with the best available scientific information and methods, and which remains state-of-the-science, indicates that the mean distance (considering 21 different scenarios combining water depth, season, and bottom type) to the 160-dB isopleth would be 6,838 m (range 4,959–9,122 m). Our required 10-km buffer is appropriate in conservatively accounting for the potential for sound exceeding the 160-dB isopleth.

Comment: NRDC stated that in order to adequately develop habitat-based protections for marine mammals, NMFS should, in addition to consideration of Roberts *et al.* (2016) and other relevant information, follow certain guidelines to protect baleen whale stocks and other marine mammals: (1) Continental shelf waters and waters 100 km seaward of the continental slope; (2) waters within 100 km of all islands and seamounts that rise within 500 m of the surface; and (3) high productivity regions not included under the previous two guidelines. Although NRDC's recommendation is unclear, we assume that the commenter intends that we designate such areas as year-round closures to survey activity.

Response: NMFS relied on the best available scientific information (*e.g.,* Stock Assessment Reports, Roberts *et al.,* 2016, 2017; numerous study reports from Navy-funded monitoring and research in the specific geographic region) in assessing density, distribution, and other information regarding marine mammal use of habitats in the study area. In addition, NMFS consulted LaBrecque *et al.* (2015), which provides a specific, detailed assessment of known Biologically Important Areas (BIA). Although BIAs are not a regulatory designation, the assessment is intended to provide the best available science to help inform regulatory and management decisions about some, though not all, important cetacean areas. BIAs, which may be region-, species-, and/or time-specific, include reproductive areas, feeding areas, migratory corridors, and areas in which small and resident populations are concentrated. Because the BIA assessment may not include all important cetacean areas, NMFS went beyond this evaluation in conducting a core abundance analysis for all species on the basis of the Roberts *et al.* (2016) cetacean density models (described in detail in our Notice of Proposed IHAs). NMFS then weighed the results of the core abundance analysis for each species in context of the anticipated effects of each specified activity, other stressors impacting the species, and practicability for the applicants in determining the appropriate suite of time-area restrictions (see ''Mitigation''). Outside of these time-area restrictions, NMFS is not aware of any evidence of other habitat areas of particular importance, or of any compelling evidence that the planned time-area restrictions should be modified in any way when benefits to the species and practicability for applicants are considered together.

Regarding NRDC's recommended guidelines, we disagree that these would be appropriate for use in determining habitats for protection in this circumstance. The guidelines come from a white paper (''Identifying Areas of Biological Importance to Cetaceans in Data-Poor Regions'') written by NMFS scientists for consideration in identifying such areas in relation to mitigation development for the incidental take rule governing the U.S. Navy's Surveillance Towed Array Sensor System Low Frequency Active (SURTASS LFA) sonar activities, which was applicable for much of the world's oceans, including in many so-called data-poor areas. NMFS convened a panel of subject matter experts tasked with helping to identify areas that met our criteria for offshore biologically important areas (OBIAs) for marine mammals relevant to the Navy's use of SURTASS LFA sonar, and the white paper offered guidance on alternate

methods for considering data-poor areas, in view of the fact that data on cetacean distribution or density do not exist for many areas of the world's oceans. However, such is not the case for the specific geographic region considered here. In fact, the white paper was specifically developed to provide methods for data-poor areas as an alternative to use of a global habitat model (Kaschner *et al.,* 2006) when such use was determined to result in both errors of omission (exclusion of areas of known habitat) and commission (inclusion of areas that are not known to be habitat). Here, we do not face the same lack of data sufficient to inform the designation of appropriate habitat-based restrictions. As described previously, we made use of advanced habitat-based predictive density models, an existing assessment of BIAs in the region, and a substantial body of data from monitoring and research concerning cetacean distribution and habitat use in sensitive areas of the region. Finally, were we to follow NRDC's apparent recommendation in closing all of the areas covered by the guidelines to survey activity, the resulting mitigation would not be practicable for applicants, as a substantial portion of the planned survey area would not be available.

Comment: NRDC states that NMFS should consider time-area closures for additional species.

Response: We did consider habitat-based protections for species additional to those discussed in the time-area restrictions section of ''Mitigation.'' For all affected species, we evaluated the environmental baseline (*i.e.,* other population-level stressors), the nature and degree of effects likely to be the result of the specified activities, and the information available to support the development of appropriate time-area restrictions. We determined that the available information supported development of the measures for the North Atlantic right whale, sperm whales, beaked whales, and pilot whales. For other species, context does not justify additional protections and/or the available information does not support the designation of any specific area for protection. NRDC suggests that such measures should be developed for the humpback whale, sei whale, fin whale, and blue whale. However, NRDC neither adequately justifies the recommendation, offering only cursory reference to the ongoing humpback whale UME (but not referencing the otherwise strong health of the West Indies DPS) and summarily providing dire conclusions regarding the supposed effects on all baleen whales, notwithstanding that at least two of these species (the sei whale and blue whale) are anticipated as being unlikely to experience any meaningful impacts from the specified activities. We addressed NRDC's recommended use of a 2010 ''white paper'' in the previous comment response; other than this apparent recommendation that nearly the entirety of the survey area (*e.g.,* continental shelf waters and waters 100 km seaward of the continental slope; waters within 100 km of all islands and seamounts that rise within 500 m of the surface; and high productivity regions not included under the previous two guidelines) be declared as a protected area, NRDC offers no useful recommendation as to the designation of protections for these species. Our development of habitat-based protections was conducted appropriately in light of relevant information regarding the environmental baseline, expected effects of the specified activities, and information regarding species use of the planned survey area.

Comment: NRDC states that our development of time-area restrictions was performed inadequately, and Pabst *et al.* also challenged our use of core abundance areas. TGS stated that we should better support our use of the 25 percent core abundance area in determining the time-area restrictions, and that we should better describe our consideration of practicability.

Response: NRDC's primary complaint is that our use of the ''core abundance area'' concept was inadequate, and other commenters appear to believe that the core abundance area was the determining factor in the delineation of restriction areas. These comments misapprehend our use of core abundance areas, as we did not use the core abundance areas to define habitat-based protections. To clarify, these core abundance areas did not define the designated time-area restrictions, but rather informed and supported our definition of the appropriate areas. Further, there is no ''correct'' answer regarding the proportion of core abundance that should inform development of habitat-based protections. In part, our analysis of core abundance areas defined by varying proportions of the population simply helped us to adequately visualize areas within the specific geographic region that would reasonably be expected to protect a substantive portion of the population within a relatively well-defined area. In some cases, this helped to confirm that stable habitat, *i.e.,* habitat defined by bathymetric features rather than dynamic oceanographic characteristics and which would be expected to provide important habitat to certain species, is indeed predicted to host high abundance of these species.

NRDC's comment regarding the sperm whale is illustrative. NRDC refers simply to the 5 percent core abundance area for sperm whales as ''entirely inadequate.'' However, when analyzing multiple different core abundance areas for the species, we find that it is predicted as being broadly distributed over slope waters throughout much of the year, *i.e.,* there is little discrete habitat defined in a way that is suitable for protection through a restriction on effort. Therefore, we did not define the protections on the sole basis of the core abundance area analysis. Rather, the core abundance area analysis helped to highlight that sperm whales should be expected to be present year-round in certain deepwater canyons (which also provide important habitat for beaked whales); the spatial definition of these areas does not in fact align with the predicted core abundance area, but rather with the bathymetric features that provide the conditions that lead to the predictions of high abundance in the first place, as is appropriate. Separately, the 5 percent core abundance area highlighted that, in contrast with the broad slope area over which sperm whales are generally expected to occur, a discrete area off of Cape Hatteras (*i.e.,* ''The Point'') would be expected to provide attractive habitat to sperm whales throughout the year, thus enabling us to include this area, with other areas of importance for the sperm whale and other species, in the conglomerate ''Hatteras and North'' (Area #4).

Our definition of the Hatteras and North area was primarily informed by review of the available literature (as described in our Notice of Proposed IHAs), which shows that, for example, beaked whales are consistently present in particular waters of the shelf break region at all times of year (*e.g.,* McLellan *et al.,* 2018; Stanistreet *et al.,* 2017); relatively high numbers of sperm whales are present off of Cape Hatteras year-round (but particularly in the winter) (Stanistreet *et al.,* 2018); and pilot whales have a strong affinity for the shelf break at Cape Hatteras and waters to the north (*e.g.,* Thorne *et al.,* 2017). These findings provided a strong indication that the area should be afforded some degree of protection in the form of restriction on effort, while the core abundance analysis both supported these findings and provided a more quantitative basis upon which to delineate the specific area.

We also acknowledge the important role that practicability for applicants plays in defining the appropriate suite of mitigation requirements to satisfy the MMPA's least practicable adverse impact standard, including design of habitat-based protections. Where a negligible impact finding is not conditioned upon the implementation of specific mitigation, prescription of mitigation must consider impacts on practicability. As stated above, protection of additional habitat for the sperm whale—given no basis on which to specify targeted protections beyond those included herein—would necessarily involve restricting access to large swaths of the specific geographic region. Based on our understanding of applicant considerations, such significant restrictions would likely lead to an applicant's determination that the survey would not take place, as the return on investment would not justify the expenditure, *i.e.,* a clear-cut case of a fatal practicability issue. In the absence of necessity (*i.e.,* the measure must be prescribed in order to make a finding of negligible impact), it would not be permissible to require such stringent restrictions.

NRDC goes on to cite ''important passive acoustic detections, opportunistic sightings, and other data'' that we have supposedly ignored, and cites the New York Bight (an area outside the specific geographic region) as an area illustrating the supposed failure of the density models to adequately highlight important habitat. NRDC also references biologically important areas; as described later in this document, we reviewed available information regarding BIAs (LaBrecque *et al.,* 2015) and there are no additional identified BIAs in the region.

In summary, and contrary to NRDC's statements, we did not rely exclusively on the core abundance analysis to define restriction areas. While we may have inadvertently overemphasized this important aspect of our process in the description provided in our Notice of Proposed IHAs, we evaluated the available literature to inform our understanding of rough areas suitable for protection (or characteristics that might provide such areas), subsequently refining our analysis through use of core abundance analysis to identify specific areas where features expected to provide important habitat overlap with actual predictions of high abundance and/or to refine the specific boundaries of areas that the literature indicated to be of importance. We appropriately based our definition of time-area restrictions on the available literature as well as on our analysis of core abundance areas.

Comment: ION requests that we reconsider the proposed time-area restrictions, based on a supposed lack of effects to right whales from noise exposure, the lack of evidence for serious injury, death, or stranding of beaked whales due to noise exposure from airgun surveys, and the possibility that deepwater canyon closures could be timed to coincide seasonally with the lowest density of sperm whales.

Response: We refer to the discussions provided in our Notice of Proposed IHAs regarding ''Potential Effects of the Specified Activity on Marine Mammals'' and detailing the rationale and basis for our designation of time-area restrictions in ''Proposed Mitigation.'' We stand by this information as supporting our assumptions regarding likely effects of marine mammals and the need for such time-area restrictions, and regarding the basis upon which we designated specific restrictions. Specifically, we have designated the relatively small deepwater canyon areas as year-round closures due to the likelihood that they provide year-round habitat to beaked whales and possibly sperm whales, while resulting in relatively minor practicability impacts. ION claims that these three deepwater canyon closures would result in ''large gaps in the seismic data acquired,'' but the map provided as Figure 1 in ION's letter does not support this contention, instead showing that only very small portions of several planned survey lines pass through these areas.

Comment: CGG suggests that NMFS should evaluate observational data submitted during the course of the survey and only require time-area restrictions ''if potential significance of behavioral disruption and potential for longer-term avoidance exists as a result of acoustic exposure'' from the survey.

Response: We disagree that this would be the appropriate approach to implementation of required restrictions. We also note that CGG mistakenly states that distribution of some species targeted in our design of restrictions is modeled through use of stratified models, implying that not enough information exists on which to base such restrictions. Our restriction areas target coastal bottlenose dolphins, North Atlantic right whales, beaked whales, sperm whales, and pilot whales, none of which are modeled through stratified models. More importantly, the entire premise of time-area restrictions is that, on the basis of a reasoned consideration of available information regarding the anticipated impacts to the affected species or stocks, their status, use of habitat, and practicability for applicants, restrictions on survey effort to completely or partially avoid sensitive habitat are appropriate. Moreover, it would not be appropriate to allow the surveys to occur in those places, thereby potentially allowing the impacts to sensitive habitat and/or disruption of critical behaviors at important places and/or times, and expect that observational data collected during the survey would adequately indicate that the restriction should in fact be in place.

Comment: The Associations state that right whale dynamic management areas (DMA) should not be used as operational restriction areas, and that areas designated to identify the presence of right whales cannot be used for multiple purposes, *e.g.,* to reduce risk of ship strike and to avoid harassment.

Response: The DMA concept recognizes that aggregations of right whales can occur outside of areas and times where they predictably and consistently occur, and it can be applied in various contexts. The DMA construct is used to help reduce risk of ship strike for right whales in association with NMFS's regulations for vessel speed limits in prescribed ''seasonal management areas'' (73 FR 60173; October 10, 2008; extended by 78 FR 73726; December 9, 2013). In that regard, when a specific aggregation of right whales is sighted, NMFS ''draws'' a temporary zone (*i.e.,* DMA) around the aggregation and alerts mariners. DMAs are in effect for 15 days when designated and automatically expire at the end of the period, but may be extended if whales are re-sighted in the same area.

The DMA concept also was used between 2002 and 2009 to protect unexpected aggregations of right whales that met an appropriate trigger by temporarily restricting lobster trap/pot and anchored gillnet fishing in the designated area (gear modifications have since replaced those requirements).

As we have stated, it is critically important to avoid impacts to right whales when possible and to minimize impacts when they do occur. Because DMAs identify aggregations of right whales, it is appropriate to restrict operations in these areas when DMAs are in effect. While we acknowledge that this requirement will impose operational costs, if the establishment of a DMA results in the need for a survey to temporarily move to another location, such concerns are weighted appropriately here in determining that this measure should be included in the suite of mitigation necessary to achieve the least practicable adverse impact.

Comment: ION suggests that NMFS reconsider its position on use of mitigation sources and power-downs, *i.e.,* that NMFS should allow these approaches to reduce operational impacts of required mitigation.

Response: We maintain that use of a ''mitigation source''—commonly understood to involve firing of a single airgun for extended periods of time to avoid the need for pre-clearance and/or ramp-up—is inappropriate here. Our position on this is not based on a lack of evidence that the mitigation source would be effective—indeed, we agree that it is reasonable to assume some degree of efficacy for a mitigation gun in providing a ''warning'' to marine mammals, as we discuss in reference to use of ramp-up. Our determination is instead based on a consideration that unnecessary introduction of sound energy into the water, as occurs during use of a mitigation source, is necessarily a deleterious impact, whereas the alternative—allowance of start-up at times of poor visibility—may result in negative impacts to individual marine mammals in the vicinity, but this is not certain.

Comment: Several commenters criticized our proposal to require shutdowns upon detection of certain species or circumstances (*e.g.,* beaked whales, right whales, whales with calves) at any distance. The Associations suggest that such requirements are ''unreasonable'' because they require shutdowns ''for circumstances in which no Level A or Level B harassment will occur,'' and recommend that such measures be limited to power-down only for detections within 1,000 m. The Associations also contend that these measures will have negative impacts on the effectiveness of visual PSOs, stating that the result would be that ''observers will be constantly monitoring an unlimited zone, which [. . .] may undermine the effectiveness of their monitoring of the 1,000 m zone.'' CGG makes similar claims, adding that these measures would result in a substantial increase in operating costs.

Response: We first note that the minimum Level B harassment zone for any survey, in any location, would be beyond the likely detection distance for visual observers, even under ideal conditions, *e.g.,* the smallest threshold radius out of 21 modeled scenarios from BOEM's PEIS was almost 5 km. Therefore, the Associations' claim that shutdowns at any distance would occur in circumstances where there is no harassment is incorrect. Overall, we disagree with these comments, as well as those specific comments we respond to below, which assert that such measures are not warranted. In these cases, we have identified species or circumstances with particular sensitivities (in conjunction with, in some cases, a high magnitude of authorized take) for which we believe it appropriate to minimize the duration and intensity of the behavioral disruption, as well as to minimize the potential for auditory injury (for low- and high-frequency cetaceans). However, while we also disagree that trained, experienced professional PSOs would somehow misunderstand our intent and spend undue time focusing observational effort at distances beyond approximately 1,000 m from the acoustic source (*i.e.,* the zone within which we assume that monitoring is typically focused, though not necessarily exclusively), in order to ensure that this potential is minimized, and to alleviate to some degree the operational cost associated with shutdowns at any distance, we limit these shutdowns to within 1.5 km (versus at any distance). The rationale for this distance is explained later in this document in ''Mitigation.''

Comment: Several commenters criticized the proposal to require shutdowns based upon aggregations of six or more marine mammals in a state of travel, stating that such a measure is ''vague and unbounded'' and would be impracticable due to the large number of shutdowns that may result.

Response: We acknowledge that this measure, as described in our Notice of Proposed IHAs, does not likely carry benefits commensurate with the likely costs and is therefore impracticable. However, the provided description was in error in that it inadvertently suggested requirements beyond what we intended, *i.e.,* we did not intend that this measure would apply to species that commonly occur in large groups, such as dolphins. We have modified this requirement to clearly state that it applies only to aggregations of large whales (*i.e.,* baleen whales and sperm whales), and to eliminate the behavioral aspect of the requirement, as recommended by commenters. Contrary to claims of commenters, this measure (as clarified/revised) is warranted, in that minimization of disruption for aggregations of resting and/or socializing whales is important and also practicable. As described above, the shutdown requirement is bounded by a maximum distance of 1.5 km.

Comment: Multiple industry commenters criticized the proposed requirement for shutdowns upon observation of a diving sperm whale centered on the forward track of the source vessel, stating that the proposal was unclear and likely unworkable.

Response: We agree with commenters (though we disagree with associated, unsupported statements regarding lack of effects to sperm whales), and have removed this measure.

Comment: TGS stated that we should remove the requirement (specific to TGS) to shut down upon observation of any fin whale.

Response: For reasons described in greater detail in the section entitled ''Mitigation,'' we agree with this comment and have removed the measure.

Comment: The Associations and other industry commenters state that the requirement for shutdowns upon observation of large whales with calf is not warranted and will be ''very impracticable because of the large number of . . . shutdowns it will generate.''

Response: We disagree with these comments and retain this requirement, albeit within the 1.5 km zone versus ''at any distance.'' As we discuss in the ''Mitigation'' section, groups of whales are likely to be more susceptible to disturbance when calves are present (*e.g.,* Bauer *et al.,* 1993), and disturbance of cow-calf pairs could potentially result in separation of vulnerable calves from adults. Separation, if it occurred, could be exacerbated by airgun signals masking communication between adults and the separated calf (Videsen *et al.,* 2017). Absent separation, airgun signals can disrupt or mask vocalizations essential to mother-calf interactions. Given the consequences of potential loss of calves in context of ongoing UMEs for multiple mysticete species, as well as the functional sensitivity of the mysticete whales to frequencies associated with airgun survey activity, we believe this measure is warranted by the MMPA's least practicable adverse impact standard. Commenters provide no justification for the claim that this measure will result in a large number of shutdowns.

Comment: Several industry commenters also suggest that there is not adequate justification for enhanced shutdown requirements for right whales, beaked whales, or *Kogia* spp. These commenters all provide the same points verbatim (paraphrased here): (1) Because the primary threat facing right whales are entanglement with fishing gear and ship strikes, enhanced shutdowns have no impact on the causes of right whale decline; (2) while acknowledging that beaked whales are acoustically sensitive, they claim that evidence does not exist regarding

sensitivity to airgun noise; and (3) *Kogia* spp. are grouped with high-frequency cetaceans (and thus are subject to greater propensity for auditory injury) on the basis of studies of harbor porpoise; therefore, this classification is invalid.

Response: These claims lack merit, and we retain these requirements (albeit within the 1.5 km zone versus ''at any distance''). We agree that the primary threats to right whales are entanglement and ship strike, but the deteriorating status of the population (discussed in detail in the section entitled ''Description of Marine Mammals in the Area of the Specified Activities'') indicates that impacts to individual right whales should be avoided where possible and otherwise minimized. The preponderance of evidence clearly demonstrates that beaked whales are acoustically sensitive species. While beaked whale stranding events have been associated with use of tactical sonar, indicating that this specific noise source may be more likely to result in behaviorally-mediated mortality, the lack of such association with airgun surveys does not mean that beaked whales are less acoustically sensitive to the noise source. The same holds for *Kogia* spp., albeit with less evidence for these cryptic species. However, commenters' claim regarding the classification of these species into the high-frequency hearing group holds no merit. The best available scientific information, while limited, indicates that these species are appropriately classed as high-frequency cetaceans; commenters provide no evidence to the contrary. While no data exists regarding *Kogia* spp. hearing, these species were appropriately classified as high-frequency cetaceans by Southall *et al.* (2007) on the basis of high-frequency components of their vocalizations. More recent data confirms that *Kogia* spp. use high-frequency clicks (Merkens *et al.,* 2018) and, by extension, that their classification as high-frequency cetaceans is appropriate.

Comment: The MMC recommends that NMFS require shutdowns upon acoustic detection of sperm whales, as is required for beaked whales and *Kogia* spp.

Response: We agree with the MMC that shutdowns due to the presence of sperm whales should not be limited to visual detection alone. This recommendation appears to reflect some ambiguity in the description of proposed mitigation provided in our Notice of Proposed IHAs, as it was our intent to prescribe mitigation in accordance with this recommendation. In conjunction with modifications to the proposed mitigation (described in full in the section entitled ''Mitigation''), we require that shutdowns be implemented upon confirmed acoustic detection of any species (other than delphinids) within the relevant exclusion zone.

Comment: NRDC and other commenters state that NMFS should prescribe requirements for use of ''noise-quieting'' technology. NRDC elaborates that in addition to requiring noise-quieting technology (or setting a standard for ''noise output''), NMFS should ''prescribe targets to drive research, development, and adoption of alternatives to conventional airguns.''

Response: We agree with commenters that development and use of quieting technologies, or technologies that otherwise reduce the environmental impact of geophysical surveys, is a laudable objective and may be warranted in some cases. However, here the recommended requirements are either not practicable or are not within NMFS's authority to require. To some degree, NRDC misunderstands our discussion of this issue as presented in our Notice of Proposed IHAs. We recognize, for example, that certain technologies, including the Bolt eSource airgun, are commercially available, and that certain techniques such as operation of the array in ''popcorn'' mode may reduce impacts when viable, depending on survey design and objectives. However, a requirement to use different technology from that planned or specified by an applicant—for example, a requirement to use the Bolt eSource airgun—would necessarily require an impracticable expenditure to replace the airguns planned for use. NRDC offers no explanation for why such an incredible cost imposition (in the millions of dollars) should be considered practicable. Separately, NRDC appears to suggest that NMFS must require or otherwise incentivize the development of wholly new or currently experimental technologies. In summary, while we agree that noise quieting technology is beneficial, the suggestions put forward by commenters are either impracticable or outside the authority provided to NMFS by the MMPA. However, NMFS would consider participating in related efforts by NRDC or any other commenter interested in these technologies.

Comment: NRDC claims that NMFS fails to consider mitigation to reduce ship strike in right whale habitat. Separately, NRDC states that NMFS should consider extending ship-speed requirements to all project vessels within ''the North Atlantic right whale BIA.''

Response: We disagree with NRDC's contention. All project vessels are required to adhere to vessel speed requirements. Indeed, the ship speed restrictions in these IHAs are required of all vessels associated with the surveys, regardless of length, whereas NMFS's ship speed regulations apply only to vessels greater than 65 ft in length. We agree with NRDC that ship speed requirements are warranted for all project vessels in designated areas to minimize risk of strike for right whales. However, we are unclear what specific area NRDC may mean in referencing ''the North Atlantic right whale BIA.'' We require that all project vessels adhere to a 10-kn speed restriction when in any seasonal or dynamic management area, or critical habitat.

Comment: Industry commenters were unanimous in expressing concern regarding required vessel strike avoidance mitigation measures, notably regarding safety for operators. In particular, recommendations to reduce speed and shift engines to neutral in certain circumstances were viewed as unsafe for vessels towing gear.

Response: We agree with the concerns expressed by commenters, and clarify that it was not our intent to require such measures for vessels towing gear. Safety of human life is paramount, and where legitimate concerns exist we agree that required mitigation must reflect such concerns. We have revised our discussion of vessel strike avoidance measures (see ''Mitigation'') to clarify that the primary requirements are (1) all vessels must observe a 10-kn speed limit when transiting right whale critical habitat, SMAs, or DMAs, and (2) all vessels must observe separation distances identified in ''Mitigation,'' to the extent practicable as relates to safety. These requirements do not apply to the extent that a vessel is restricted in its ability to maneuver and, because of the restriction, cannot comply or in any case where compliance would create an imminent and serious threat to a person or vessel. Speed alterations (aside from the 10-kn restriction, when applicable), alterations in course, and shifting engines to neutral are recommendations for how separation distances may be achieved but are not requirements, and do not apply to any vessel towing gear.

Comment: ION requests clarification on specific ''precautionary measures'' required in order to minimize potential for vessel strike, citing the following text from our Notice of Proposed IHAs: ''Vessel speeds must also be reduced to 10 kn or less when mother/calf pairs, pods, or large assemblages of cetaceans are observed near a vessel. A single

cetacean at the surface may indicate the presence of submerged animals in the vicinity of the vessel; therefore, precautionary measures should be exercised when an animal is observed.''

Response: We clarify here that the latter statement, *i.e.,* ''precautionary measures should be exercised when an animal is observed,'' carries no specific requirements. We intend only that vessel operators act cautiously in accordance with established practices of seamanship to avoid striking observed animals. The requirements of the former statement, *i.e.,* that vessel speeds must be reduced when mother/calf pairs, pods, or large assemblages of cetaceans are observed near a vessel, applies only to those specific circumstances, *i.e.,* not in speculative fashion if a single animal or small group of animals is observed.

Comment: One individual stated that NMFS should require applicants to monitor propagation conditions, suggesting that this could be accomplished through use of conductivity, temperature, and depth (CTD) measurement devices, and that vessels should not be allowed to operate when propagation is ''exceptionally efficient.''

Response: The commenter does not specify what propagation conditions should be considered ''exceptionally efficient.'' Regardless, we do not agree that such a requirement is warranted. The sound field modeling conducted by BOEM and by the applicants that did not make use of BOEM's modeling is purposely designed to reflect a reasonable range of propagation conditions that are expected to be encountered in the region. This does not mean that there will never be unexpected conditions that may result in propagation beyond the modeled distances. However, this potential does not require that operators cease operating, as such a requirement would be fraught with uncertainty and potentially result in significant additional operating costs.

Comment: NRDC makes several recommendations relating to the use of ramp-up.

Response: First, NRDC states that NMFS should require that ramp-up occur over several stages in order to minimize exposure. We agree with NRDC on this point, but are confused by the recommendation, which appears to restate the ramp-up procedures described by NMFS in our Notice of Proposed IHAs. Second, NRDC states that we ''should give greater consideration to the requirements that apply after shutdown periods.'' Again, we are unclear as to what NRDC's specific recommendation is, but NRDC appears to criticize the allowance of an array restart without ramp-up, assuming that constant observation has been maintained without marine mammal detection. NRDC does not state what they believe to be the problem with this allowance, and we believe that it is consistent with current practice and appropriate in context of the ''least practicable adverse impact.'' Finally, NRDC asserts that the half-hour cutoff ''perversely incentivizes'' continuous firing to avoid the delay of pre-clearance and ramp-up. This is another confusing statement, as we explicitly disallow airgun firing when not necessary for data acquisition, *e.g.,* during line turns.

Comment: NRDC complains that the standard 500-m exclusion zone is ''plainly insufficient to prevent auditory injury,'' and many other commenters echo these comments regarding the sufficiency of the prescribed exclusion and buffer zones.

Response: We have acknowledged that some limited occurrence of auditory injury is likely, for low- and high-frequency cetaceans. However, we disagree that a larger standard exclusion zone is warranted. As we explained in our Notice of Proposed IHAs, our intent in prescribing a standard exclusion zone distance is to (1) encompass zones for most species within which auditory injury could occur on the basis of instantaneous exposure; (2) provide additional protection from the potential for more severe behavioral reactions (*e.g.,* panic, antipredator response) for marine mammals at relatively close range to the acoustic source; (3) provide consistency and ease of implementation for PSOs, who need to monitor and implement the exclusion zone; and (4) to define a distance within which detection probabilities are reasonably high for most species under typical conditions. Our use of 500 m as the zone is not based directly on any quantitative understanding of the range at which auditory injury would be entirely precluded or any range specifically related to disruption of behavioral patterns. Rather, we believe it is a reasonable combination of factors. In summary, a practicable criterion such as this has the advantage of familiarity and simplicity while still providing in most cases a zone larger than relevant auditory injury zones, given realistic movement of source and receiver. Increased shutdowns, without a firm idea of the outcome the measure seeks to avoid, simply displace survey activity in time and increase the total duration of acoustic influence as well as total sound energy in the water (a goal we believe NRDC supports).

We agree that, when practicable, the exclusion zone should encompass distances within which auditory injury is expected to occur on the basis of instantaneous exposure. For high-frequency cetaceans, these distances range from 355–562 m for four of the five applicants (Table 5). For Spectrum, the predicted distance is significantly larger (1,585 m). However, we require an extended exclusion zone of 1.5 km for certain sensitive species, including *Kogia* spp. This means that only one rarely occurring species (harbor porpoise), and for only one applicant, is left unprotected from potential auditory injury in terms of the prescribed distance of the exclusion zone. Moreover, it is unlikely that harbor porpoise would even be detected at distances greater than 500 m. Potential auditory injury for low-frequency cetaceans is based on the accumulation of energy, and is therefore not a straightforward consideration. For example, observation of a whale at the distance calculated as being the ''injury zone'' does not necessarily mean that the animal has in fact incurred auditory injury. Rather, the animal would have to be at the calculated distance (or closer) as the mobile source approaches, passes, and recedes from the exposed animal, being exposed to and accumulating energy from airgun pulses the entire time, as is implied by the name of the ''safe distance'' methodology by which such zone distances are calculated. Therefore, we disagree that it is sensible to create a larger exclusion zone on the basis of the calculated injury zones (although we note that the extended 1.5 km exclusion zone is required for right whales). We also note that the maximum distance cited by NRDC (4,766 m) was an error in our Notice of Proposed IHAs (corrected later in this document; see ''Level A harassment'' in the ''Estimated Take'' section). In fact, the calculated injury distances for two applicants are less than the standard 500-m zone, while those calculated for the remaining three applicants range from 757–951 m. In keeping with the four broad goals outlined above, and in context of the information given here, our standard 500-m exclusion zone is appropriate.

Comment: Several industry commenters criticized the requirement for use of a buffer zone, in addition to the standard 500-m exclusion zone, claiming in part that use of such a buffer is ''counterintuitive.''

Response: Having received multiple comments indicating confusion regarding the proposed measure, we first clarify that the requirement is for a 500-m buffer zone in addition to the 500-m standard exclusion zone, *i.e.,* total typical monitoring zone of 1,000 m, and that the implementation of this requirement relates primarily to the pre-clearance period, when the full 1,000-m zone must be clear of marine mammals prior to beginning ramp-up. During full-power firing, the buffer zone serves only as a sort of ''warning'' area, where the observation of marine mammals should incite readiness to shut down, should those animals enter the 500-m shutdown zone.

We disagree that this measure is counterintuitive, an assertion based on the apparent sense that a larger zone should be in effect when the array is firing and a smaller zone prior to firing. On the contrary, we believe it important to implement a larger zone during pre-clearance, when naïve animals may be present and potentially subject to severe behavioral reactions if airguns begin firing at close range. While the delineation of zones is typically associated with shutdown, the period during which use of the acoustic source is being initiated is critical, and in order to avoid more severe behavioral reactions it is important to be cautionary regarding marine mammal presence in the vicinity when the source is turned on. This requirement has broad acceptance in other required protocols: The Brazilian Institute of the Environment and Natural Resources requires a 1,000-m pre-clearance zone (IBAMA, 2005), the New Zealand Department of Conservation requires that a 1,000-m zone be monitored as both a pre-clearance and a shutdown zone for most species (DOC, 2013), and the Australian Department of the Environment, Water, Heritage and the Arts requires an even more protective scheme, in which a 2,000-m ''power down'' zone is maintained for higher-power surveys (DEWHA, 2008). Broker *et al.* (2015) describe the use of a precautionary 2-km exclusion zone in the absence of sound source verification (SSV), with a minimum zone radius of 1 km (regardless of SSV results). We believe that the simple doubling of the exclusion zone required here is appropriate for use as a pre-clearance zone.

Comment: In writing about the exception made for dolphins from the shutdown requirements, NRDC states that ''more analysis is . . . needed of the potential costs and benefits of excluding bow-riding dolphins from the exclusion zone requirement.''

Response: We recognize the concerns raised by NRDC, and agree that the reasons for bow-riding behavior are unknown and, further, that in context of an active airgun array, the behavior cannot be assumed to be harmless. However, dolphins have a relatively high threshold for the onset of auditory injury and, for small delphinids, more severe adverse behavioral responses are less likely given the evidence of purposeful approach and/or maintenance of proximity to vessels with operating airguns. With regard to the former point, Finneran *et al.* (2015) exposed bottlenose dolphins to repeated pulses from an airgun and measured no TTS. Therefore, the biological benefits of shutting down for small delphinids are expected to be comparatively low, whereas, as indicated through public comment on these proposed actions, the costs of the shutdowns for survey operators is high. Therefore, our consideration of this subject, as addressed in an earlier comment response, indicates that a general (rather than behavior-based) small delphinid exception to the standard shutdown requirement is an appropriate part of the suite of mitigation measures necessary to effect the least practicable adverse impact.

Comment: One individual stated that NMFS should require ''trackline design'' that minimizes the potential for stranding, including by requiring that companies run their nearshore lines at times of reduced propagation efficiency.

Response: The commenter does not specify what is meant by ''nearshore,'' but we prescribe a year-round 30-km standoff from the coast. We assume that 30 km is sufficient to accomplish the commenter's objective in making the recommendation.

Comment: The Associations and other industry commenters raise several concerns regarding the PSO requirements. These are: (1) Concern regarding NMFS's requirement to review PSO qualifications and associated potential for delay, with accompanying recommendation that such reviews be ''bounded by some reasonably short time period, with the default being that the observer is approved if NMFS fails to respond within that time period''; (2) concern whether vessels can ''safely accommodate'' the number of PSOs required by NMFS's staffing requirements; and (3) a claim that NMFS's requirements for PSOs will result in labor shortages, and an accompanying recommendation that these be ''guidelines'' rather than requirements.

Response: We agree with the first concern, and have clarified that NMFS will have one week to review PSO qualifications (from the time that NMFS confirms that adequate information has been submitted) and either approve or reject a PSO. If NMFS does not respond within this time, any PSO meeting the minimum requirements would automatically be approved.

We disagree with the remainder of the statement. NMFS has evaluated the appropriate PSO staffing requirements, as described in ''Mitigation,'' and we have determined that a minimum of two visual PSOs must be on duty at all times during daylight hours in order to adequately ensure visual coverage of the area around the source vessel. Applicants must account for these requirements in selecting vessels that will be suitable for their planned surveys. The Associations' third point contains an apparent misconception, in that not all PSOs must have a minimum of 90 days at-sea experience, with no more than 18 months elapsed since the conclusion of the relevant experience. As described in our Notice of Proposed IHAs and herein, a minimum of one visual PSO and two acoustic PSOs must have such experience (rather than all PSOs). The Associations also apparently believe that a requirement for professional biological observers to be ''trained biologists with experience or training in the field identification of marine mammals, including the identification of behaviors'' is a ''rigid restriction.'' We respectfully disagree with these claims, and note that no labor shortage was experienced in the Gulf of Mexico during 2013–2015 when a significantly greater amount of survey activity (*i.e.,* as many as 30 source vessels) was occurring than is considered here, with requirements similar to those described here. NMFS has discussed the PSO requirements specified herein with the Bureau of Safety and Environmental Enforcement (BSEE) and with third-party observer providers; these parties have indicated that the requirements should not be expected to result in any labor shortage.

Comment: The Associations recommend that passive acoustic monitoring should be optional, citing operational costs. ION also challenges the efficacy of PAM.

Response: We agree with the Associations that PAM complements (rather than replaces) traditional visual monitoring. However, it is now considered to be a critical component of real-time mitigation monitoring in the majority of circumstances for deep penetration airgun surveys. Acoustic monitoring supplants visual monitoring

during periods of poor visibility and supplements during periods of good visibility. As such, we strongly disagree with the Associations' outdated recommendation.

There are multiple explanations of how marine mammals could be in a shutdown zone and yet go undetected by observers. Animals are missed because they are underwater (availability bias) or because they are available to be seen, but are missed by observers (perception and detection biases) (*e.g.,* Marsh and Sinclair, 1989). Negative bias on perception or detection of an available animal may result from environmental conditions, limitations inherent to the observation platform, or observer ability. Species vary widely in the inherent characteristics that inform expected bias on their availability for detection or the extent to which availability bias is convolved with detection bias (*e.g.,* Barlow and Forney (2007) estimate probabilities of detecting an animal directly on a transect line ($g(0)$), ranging from 0.23 for small groups of Cuvier's beaked whales to 0.97 for large groups of dolphins). Typical dive times range widely, from just a few minutes to more than 45 minutes for sperm whales (Jochens *et al.,* 2008; Watwood *et al.,* 2006), while $g(0)$ for cryptic species such as *Kogia* spp. declines more rapidly with increasing Beaufort sea state than it does for other species (Barlow, 2015). Barlow and Gisiner (2006) estimated that when weather and daylight considerations were taken into account, visual monitoring would detect fewer than two percent of beaked whales that were directly in the path of the ship. PAM can be expected to improve on that performance, and has been used effectively as a mitigation tool by operators in the Gulf of Mexico since at least 2012.

We expect that PAM technology will continue to develop and improve, and look forward in the near-term to the establishment of formal standards regarding specifications for hardware, software, and operator training requirements, under the auspices of the Acoustical Society of America's (ASA) Accredited Standards Committee on Animal Bioacoustics (ANSI S3/SC1/WG3; ''Towed Array Passive Acoustic Operations for Bioacoustics Applications''). In short, we expect that PAM will continue to be an integral component of mandatory mitigation monitoring for deep penetration airgun surveys conducted in compliance with the MMPA.

Comment: Several industry commenters expressed concern regarding the potential for a large amount of shutdowns due to acoustic detections of marine mammals in circumstances where the PAM operator is unable to identify the detected species or is unable to determine the location of the detected species in relation to the relevant exclusion zone.

Response: NMFS recognizes these concerns, and appreciates the comments; however, these potential outcomes would be contrary to NMFS's intent in prescribing the use of PAM. Upon review of these comments, we find that our description of PAM use was unclear and offer clarification here. In the event of acoustic detection, shutdown must be implemented only when the PAM operator determined, on the basis of best professional judgment, that shutdown is required for the detected species and that the species is likely within the relevant exclusion zone. For example, although shutdown is required for certain genera of large delphinids, we do not require shutdown upon acoustic detection of any delphinid, as we do not expect that a PAM operator would likely be capable of distinguishing a detected delphinid to species. As in all cases, the detection would be communicated to visual observers (if on duty); if the detected animal(s) are observed visually, shutdown may be required depending on the species. Similarly, we clarify that the shutdowns required upon observation of a large whale with calf or an aggregation of six or more large whales are for visual observation only; a PAM operator cannot be expected to determine on the basis of acoustic detection whether a detected whale is with calf or is part of an aggregation of six or more. Our intent is not to be overly prescriptive, but to empower trained PAM operators to employ professional judgment in determining whether shutdown is required in the event of acoustic detection. That is, we neither require precautionary shutdowns based on acoustic detections when either the species or location cannot be determined, nor do we require absolute certainty that the detected animal is within the relevant exclusion zone if the PAM operator determines that the animal is most likely within the zone on the basis of professional judgment.

Comment: ION recommends that NMFS extend the timeframe for operation of the acoustic source during repair of the PAM system in the event of malfunction.

Response: We believe that the requirements regarding conditions under which a survey is allowed to continue in the event of PAM malfunction are appropriate. These conditions, which are based on established protocols required in New Zealand, have been implemented in other locations with no known reports of undue hardship. We also note that ION does not recommend any alternative. We will be open to considering alternatives in the future, but retain these requirements here.

Comment: ION questions NMFS's intentions regarding pre-clearance requirements at nighttime, requesting that NMFS clarify that observation with PAM satisfies this requirement.

Response: Ramp-up of the acoustic source, when necessary, may occur at times of poor visibility (including nighttime), assuming that a pre-clearance period has been observed. If the pre-clearance period occurs at nighttime, the pre-clearance watch would be conducted only by the acoustic observer. We clarify that, indeed, observation with PAM satisfies the pre-clearance watch requirement at night.

Comment: TGS requests clarification of what they interpret as contradictory instructions with regard to when visual observations must occur.

Response: We clarify here that visual observation, *i.e.,* two visual PSOs on duty, is required during all daylight hours (30 minutes prior to sunrise through 30 minutes following sunset, regardless of visibility) when use of the acoustic source is planned, from 30 minutes prior to ramp-up through one hour after ceasing use of the source (or until 30 minutes after sunset). In addition, visual observation is to occur 30 minutes prior to and during nighttime ramp-up.

Comment: NRDC suggests that NMFS should consider requiring use of thermal detection as a supplement to visual monitoring.

Response: We appreciate the suggestion and agree that relatively new thermal detection platforms have shown promising results. Following review of NRDC's letter, we considered these and other supplemental platforms as suggested. However, to our knowledge, there is no clear guidance available for operators regarding characteristics of effective systems, and the detection systems cited by NRDC are typically extremely expensive, and are therefore considered impracticable for use in most surveys. For example, one system cited by NRDC (Zitterbart *et al.,* 2013)—a spinning infrared camera and an algorithm that detects whale blows on the basis of their thermal signature—was tested through funding provided by the German government and, according to the author at a 2015 workshop concerning mitigation and monitoring

for seismic surveys, the system costs hundreds of thousands of dollars. We are not aware of its use in any commercial application. Further, these systems have limitations, as performance may be limited by conditions such as fog, precipitation, sea state, glare, water- and air-temperatures and ambient brightness, and the successful results obtained to date reflect a limited range of environmental conditions and species. NRDC does not provide specific suggestions with regard to recommended systems or characteristics of systems. We do not consider requirements to use systems such as those recommended by NRDC to currently be practicable.

Comment: Mysticetus, LLC (Mysticetus) recommends that all operators be required to use a ''modern PSO software system'' for structured data collection, real-time situational awareness and computerized mitigation decision support. They also list their recommended minimum requirements for a PSO software system. Mysticetus also recommends the creation of a centralized cloud-based database to hold all PSO-gathered data from all survey operations, and states that it should be a requirement of all operators to have their PSO software automatically upload data to this system on a regular schedule. Separately, we received a comment letter from P.N. Halpin of Duke University's Marine Geospatial Ecology Lab; the commenter provides support for the recommendation to create a cloud-based storage system to store and provide public access to PSO data and confirms that the OBIS–SEAMAP team has agreed in principle to host and disseminate such a proposed database. Mysticetus goes on to provide a number of detailed recommendations relating to how our notice might describe the capabilities of a PSO software system, such as is recommended for mandatory use, in relation to our proposed mitigation and monitoring requirements.

Response: We appreciate commenters' careful attention to improvement of required mitigation and monitoring and for their recommendations. We also appreciate the capabilities of ''modern PSO software'' described by Mysticetus, including the Mysticetus System marketed by Mysticetus, LLC. We agree that such systems may be advantageous for the operators, as well as for NMFS and for the public. However, we disagree that NMFS must mandate that one specific software system be used to accomplish the goals of the required mitigation and monitoring, so long as the requirements for mitigation, monitoring, and reporting are met.

Comment: The MMC stated that it supports our proposed requirement relating to corrections of sightings data using detection probabilities, in order to estimate numbers of actual incidents of marine mammal take. However, the MMC also suggests that our proposed use of Carr *et al.* (2011) is not the most appropriate source of such probability values, and suggests that we instead base this approach on Barlow (2015). In addition, the MMC points out that we did not explicitly state that we also intend to account for unobserved areas, and provided a recommended extrapolation method.

Response: We agree with the MMC's statements on this topic and thank them for the helpful suggestions. Although, after review of public comments, we do not require the applicants to conduct these analyses themselves (described in greater detail in the section entitled ''Monitoring and Reporting''), we intend to adopt the MMC's recommended approach in performing this analysis. We will report these corrected results in association with comprehensive reporting from the applicants.

Comment: NRDC asserts that NMFS fails to prescribe requirements sufficient to monitor and report takings of marine mammals, and further draws a comparison to ''related compliance in the Gulf of Mexico'' where they state that ''BOEM is developing an adaptive management program, which, beyond 'the standard' safety zone monitoring and reporting requirements, may include 'visual or acoustic observation of animals, new or ongoing research and data analysis, in situ measurements of sound sources' . . . .'' Multiple commenters suggested that monitoring plans should be designed and coordinated across surveys. Commenters also noted that there are many research gaps that need to be filled, and suggested that NMFS should include monitoring requirements that fill those gaps—such as marine mammal habitat use, abundance surveys, masking, mysticete hearing ranges, behavioral response thresholds, ecosystem-wide impacts, and the efficacy of mitigation measures. Specific recommendations included acoustic receivers outside the survey area to allow for recording and assessment before, during, and after surveys, as well as aerial surveys to evaluate platform-based visual monitoring.

Response: Section 101(a)(5)(D) of the MMPA indicates that any authorization NMFS issues shall include ''requirements pertaining to the monitoring and reporting of such taking by harassment.'' This broad requirement allows for a high degree of flexibility in what NMFS may accept or include as a monitoring requirement, but is not specific in identifying a threshold of what should be considered adequate monitoring. Contrary to NRDC's comments, except for IHAs in Arctic waters, NMFS's implementing regulations do not provide a specific standard regarding what required monitoring and reporting measures ''must'' accomplish. However, they do direct that ''requests,'' *i.e.,* the materials submitted by applicants, should include ''the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species, the level of taking or impacts on populations of marine mammals that are expected to be present while conducting activities, and suggested means of minimizing burdens by coordinating such reporting requirements with other schemes already applicable to persons conducting such activity.'' NRDC further extracts pieces of this language to suggest that in the case of these five applicants, they are required to coordinate with each other's monitoring efforts, ignoring the fact that the regulation points to this coordination only in support of minimizing the burden on the applicant and that it refers to coordination with ''schemes already applicable to persons conducting such activity,'' of which there are currently none. NRDC attempts to further this argument that coordination across projects is required by statute by pointing to a compliance scheme that they state is in development for the Gulf of Mexico.

However, as described elsewhere in this document, section 101(a)(5)(D) of the MMPA indicates that the analysis, the findings, and any requirements included in the development of an IHA pertain only to the specified activity—specifically, NMFS is required to include the ''requirements pertaining to the monitoring and reporting of such taking by harassment'' (referring to the taking authorized in the IHA). Notably, section 101(a)(5)(A), which applies in the case of NMFS's incidental take regulations for a specified activity for up to five years, contains similar requirements, but the requirements apply to the entirety of the activities covered under any incidental take rulemaking. Indeed, NMFS's implementing regulations indicate that ''for all petitions for regulations [. . .] applicants must provide the information requested in 216.104 on their activity as a whole.'' Therefore, it

is appropriate that a monitoring plan developed in support of BOEM's requested rulemaking to cover incidental take from activities covered by their oil and gas program in the Gulf of Mexico would address, and potentially coordinate across, multiple surveys.

Although the statute provides flexibility in what constitutes acceptable monitoring and reporting measures (increased knowledge of the species and the taking), NMFS's implementing regulations provide additional guidance as to what an applicant should submit in their requests, indicating ''Monitoring plans should include a description of the techniques that would be used to determine the movement and activities of marine mammals near the activity site(s) including migration and habitat uses, such as feeding.'' We appreciate the recommendations provided by the public, and agree that from a content standpoint, many of the recommendations could qualify as appropriate monitoring for any of these surveys. However, we note that many of the monitoring recommendations require a scale of effort that is not commensurate to the scale of either the underlying activities or the anticipated impacts of the activities on marine mammals covered by any single IHA. In other words, many of the recommended measures would necessitate complex and expensive survey designs and methods that would exceed the duration of any one activity (*e.g.,* regular distribution and abundance surveys, moored arrays for before/during/after studies) and/or require levels of collaboration, planning and permitting (behavioral response studies, aerial programs to evaluate mitigation effectiveness) that are not reasonable in the context of an activity that consists of one mobile source moving across a large area and that will last less than a year and, further, is not appropriate in the context of the comparatively smaller scale of total surveys in the Atlantic at the current time.

Most importantly, regardless of whether other monitoring plans would also suffice, we believe that the visual and acoustic monitoring required for each of these surveys meets the MMPA requirement for monitoring and reporting. NRDC implies that monitoring within 1 km of the vessel is not useful or adequate. First, the required monitoring is not limited to within a zone, as PSOs will record the required information at whatever distance they can accurately collect it—and past monitoring reports from similar platforms show useful data collected beyond 1 km. Further, even if the PSOs cannot always see, or acoustically monitor, the entire zone within which take is estimated to occur, the data collected will still be both qualitatively and quantitatively informative, as behaviors will be detectable within these distances and there are accepted methods for extrapolating sightings data to make inferences about larger areas. For these surveys, the PSOs will gather detailed information on the marine mammals both sighted and acoustically detected, their behaviors (different facets detectable visually and acoustically) and locations in relation to the sound source, and the operating status of any sound sources—allowing for a better understanding of both the impacted species as well as the taking itself.

Comment: Multiple commenters provided various comments concerning transparency and data sharing with regard to data reported to NMFS.

Response: We agree with the overall point and will make all data reported to NMFS in accordance with IHA requirements available for public review following review and approval of reports by NMFS. However, several commenters were apparently confused about the nature of data required to be reported to NMFS and/or the mechanism of reporting. For example, Oceana stated that NMFS should ''make the seismic survey data available to industry, government, and the public so that all stakeholders can make an informed cost-benefit analysis and decide whether offshore drilling should be allowed. . . .'' However, the survey data apparently referenced by Oceana is not required to be provided by the applicants to NMFS, but is provided to BOEM. Oceana also stated that NMFS should ''live stream data as often as possible as well as archive the passive acoustic monitoring feed.'' Respectfully, we are unclear as to what Oceana is referring to.

Comment: Several industry commenters took issue with the 15-km buffers that NMFS understands will be required around National Marine Sanctuaries.

Response: We described these requirements, which are a product of discussions between BOEM and NOAA's Office of National Marine Sanctuaries, in our Notice of Proposed IHAs solely for purposes of thoroughness. Here, we clarify that this standoff distance is not a requirement of NMFS and will not be included in any issued IHAs. As such, criticisms of this requirement (which we expect to be included as conditions in permits issued by BOEM) are not relevant here and we do not respond to them.

Comment: A few commenters suggested that NMFS should fully implement NOAA's Ocean Noise Strategy, which they interpreted as meaning that certain knowledge gaps on marine mammals and noise must be filled before NMFS may issue these IHAs. Another commenter said that to help support implementation of the Ocean Noise Strategy Roadmap (*cetsound.noaa.gov/Assets/cetsound/documents/Roadmap/ONS_Roadmap_Final_Complete.pdf*), the agencies (*i.e.,* NOAA and BOEM) should undertake efforts to evaluate impacts to marine mammal habitat before, during, and after surveys occur.

Response: NMFS appreciates the support for the Ocean Noise Strategy and agrees with the goal of focusing both agency science and agency-required monitoring towards filling known gaps in our understanding of the effects of noise on marine mammals wherever possible and appropriate. The Ocean Noise Strategy does not mandate any specific actions, though; rather, it directs NOAA to use our existing authorities and capacities to focus on the management, science, decision-making tool, and outreach goals outlined in the Roadmap. In the case of MMPA incidental take authorizations, NMFS must abide by statutory directive, and we have described above (both in comment response and elsewhere in the body of this Notice) our rationale for including the monitoring and reporting measures in these IHAs. In the context of MMPA authorizations, it is typically easier to apply some of the monitoring and research goals articulated in the Ocean Noise Strategy through section 101(a)(5)(A) rulemaking, as the expanded scope and longer duration of the coverage period are better suited to more complex, large-scale, or expensive approaches (*e.g.,* such as those utilized for U.S. Navy training and testing incidental take regulations).

National Environmental Policy Act

Comment: NRDC and Oceana provide a litany of complaints regarding the sufficiency of BOEM's EIS and its suitability for supporting NMFS's decision analysis, and state that NMFS must prepare a separate analysis before taking action.

Response: Following independent evaluation of BOEM's EIS, and review of public comments, NMFS determined BOEM's 2014 Final PEIS to be comprehensive in analyzing the broad scope of potential survey activities, and that the evaluation of the direct, indirect, and cumulative impacts on the human environment, including the marine environment, is adequate to

support NMFS's consideration for future issuance of ITAs to geophysical companies and other potential applicants through tiering and incorporation by reference. NMFS further determined that subsequent issuance of ITAs for survey activities is likely to fall within the scope of the analysis in the 2014 Final PEIS, particularly since the impacts of the alternatives evaluated by BOEM (1) assess impact over a much longer period of time (*i.e.,* nine years) than is analyzed by NMFS for any given ITA, (2) encompass many of the same factors NMFS historically considered when reviewing ITAs for geophysical surveys or related activity (*i.e.,* marine mammal exposures, intensity of acoustic exposure, monitoring and mitigation factors, and more), and (3) are substantially the same as the impacts of NMFS's issuance of any given ITA for take of marine mammals incidental to future applicants' survey activities. The 2014 Final PEIS also addresses NOAA's required components for adoption as it meets the requirements for an adequate EIS under the CEQ regulations (40 CFR part 1500–1508) and NOAA Administrative Order 216–6A and reflects comments and expert input provided by NOAA as a cooperating agency. Therefore, NMFS subsequently signed a Record of Decision that: (1) Adopted the Final PEIS to support NMFS's analysis associated with issuance of ITAs pursuant to sections 101(a)(5)(A) or (D) of the MMPA and the regulations governing the taking and importing of marine mammals (50 CFR part 216), and (2) in accordance with 40 CFR 1505.2, announced and explained the basis for NMFS's decision to review and potentially issue ITAs under the MMPA on a case-by-case basis, if appropriate, guided by the analyses in the Final PEIS and mitigation measures specified in BOEM's 2014 ROD.

However, following review of public comments, NMFS agrees with NRDC and other commenters who suggested that it would not be appropriate for NMFS to simply adopt BOEM's EIS (our stated approach in the Notice of Proposed IHAs). Although we disagree with claims that the EIS is deficient, it is appropriate to evaluate whether supplementation is necessary. In so doing, we consider (1) whether new information not previously considered in the EIS is now available; (2) whether that new information may change the impact analysis contained in the EIS; and (3) whether our impact conclusions may change as a result of the new information and new impact analyses. However, we further consider that the EIS was purposely developed so that additional information could be included in subsequent NEPA evaluations. Because we determined that relevant new information was in fact available, in addition to applicant-specific details, we determined it appropriate to conduct a supplemental Environmental Assessment.

NMFS determined that conducting NEPA review and preparing a tiered EA is appropriate to analyze environmental impacts associated with NMFS's issuance of separate IHAs to five different companies. NMFS further determined that the issuance of these five IHAs are ''similar'' but not ''connected actions'' per 40 CFR 1508.25(a)(3) due to general commonalities in geography, timing, and type of activity, which provides a reasonable basis for evaluating them together in a single environmental analysis. The EA also incorporates relevant portions of BOEM's Final PEIS while focusing analysis on environmental issues specific to the five IHAs. NMFS has completed the necessary environmental analysis under NEPA.

Miscellaneous

Comment: Several commenters suggest that NMFS should require the applicants to consolidate their surveys.

Response: Requiring individual applicants to alter their survey objectives and/or design does not fall within NMFS's authority. Moreover, though these multiple concurrent surveys are perceived as ''duplicative,'' they are in fact designed specifically to produce proprietary data that satisfies the needs of survey funders. As is the current practice in the Gulf of Mexico, it is within BOEM's jurisdiction as the permitting agency to require permit applicants to submit statements indicating that existing data are not available to meet the data needs identified for the applicant's survey (*i.e.,* non-duplicative survey statement), but such requirements are not within NMFS's purview. For example, NRDC claims erroneously that NMFS ''has authority under the mitigation provision of the MMPA to consider directing the companies to consolidate their surveys,'' placing such a requirement under the auspices of practicability. Leaving aside that directing any given applicant to abandon their survey plans would not in fact be practicable, it is inappropriate to consider this suggested requirement through that lens. Similarly, the MMC vaguely references section 101(a)(5)(A)(i)(II)(aa) in stating that NMFS is provided authority to require such consolidation—we assume that MMC intended to reference the parallel language at section 101(a)(5)(D)(ii)(I), which states only that NMFS shall prescribe the ''means of effecting the least practicable impact on such species or stock and its habitat.'' NMFS considers the specified activity described by an applicant in reviewing a request for an incidental take authorization; nothing in the statute provides authority to direct consolidation of independent specified activities (regardless of any presumption of duplication, about which NMFS is not qualified to judge).

The MMC specifically cites a number of collaborative surveys conducted in foreign waters, and recommends that NMFS ''work with BOEM'' to require such collaboration. However, MMC provides no useful recommendations as to how such collaboration might be achieved. Given the absence of appropriate statutory authority, we recommend that the MMC itself undertake to foster such collaboration between geophysical data acquisition companies and relevant Federal agencies as it deems necessary to protect and conserve marine mammals. NMFS looks forward to joining in such an MMC-led collaboration, as appropriate.

We also note that industry commenters stated, anticipating suggestions of this sort, that such recommendations ''are based upon a substantial misunderstanding of important technical, operational, and economic aspects of seismic surveying.'' These commenters also noted that, based on the findings of an expert panel recently convened by BOEM to study the issue of duplicative surveys (see Appendix L in BOEM, 2017), none of the surveys considered here would meet the definition established for a ''duplicate'' survey.

Comment: NRDC contends that NMFS must consider a standard requiring analysis and selection of minimum source levels. In furtherance of this overall quieting goal, NRDC also states that NMFS should consider requiring that all vessels employed in the survey activities undergo regular maintenance to minimize propeller cavitation and be required to employ the best ship-quieting designs and technologies available for their class of ship, and that we should require these vessels to undergo measurement for their underwater noise output.

Response: An expert panel convened by BOEM to determine whether it would be feasible to develop standards to determine a lowest practicable source level has determined that it would not be reasonable or practicable to develop such metrics (see Appendix L in BOEM,

2017). We appreciate that NRDC disagrees with the panel's findings, but we do not believe it appropriate to address these grievances to NMFS. NRDC further claims that NMFS's deference to the findings of an expert panel convened specifically to consider this issue is ''arbitrary under the MMPA.'' The bulk of NRDC's comment appears to be addressed to BOEM, and we encourage NRDC to engage with BOEM regarding these supposed shortcomings of the panel's findings. The subject matter is outside NMFS's expertise, and we have no basis upon which to doubt the panel's published findings. We decline to address here the ways in which NRDC claims that BOEM misunderstood the issue.

With regard to the recommended requirements to measure or control vessel noise, or to make some minimum requirements regarding the design of vessels used in the surveys, we disagree that these requirements would be practicable. While we agree that vessel noise is of concern in a cumulative and chronic sense, it is not of substantial concern in relation to the MMPA's least practicable adverse impact standard, given the few vessels used in any given specified activity. NMFS looks forward to continued collaboration with NRDC and others towards ship quieting.

Description of Marine Mammals in the Area of the Specified Activities

We refer readers to NMFS's Stock Assessment Reports (SAR; *www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments*), species descriptions provided on NMFS's website (*www.fisheries.noaa.gov/find-species*), and to the applicants' species descriptions (Sections 3 and 4 of the applications). These sources summarize available information regarding physical descriptions, status and trends, distribution and habitat preferences, behavior and life history, and auditory capabilities of the potentially affected species, and are not reprinted here.

Table 2 lists all species with expected potential for occurrence in the mid- and south Atlantic and summarizes information related to the population or stock, including potential biological removal (PBR). For taxonomy, we follow Committee on Taxonomy (2017). PBR, 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, is considered in concert with known sources of ongoing anthropogenic mortality (as described in NMFS's SARs). For status of species, we provide information regarding U.S. regulatory status under the MMPA and ESA.

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 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. Survey abundance (as compared to stock or species abundance) is the total number of individuals estimated within the survey area, which may or may not align completely with a stock's geographic range as defined in the SARs. These surveys may also extend beyond U.S. waters.

In some cases, species are treated as guilds. In general ecological terms, a guild is a group of species that have similar requirements and play a similar role within a community. However, for purposes of stock assessment or abundance prediction, certain species may be treated together as a guild because they are difficult to distinguish visually and many observations are ambiguous. For example, NMFS's Atlantic SARs assess *Mesoplodon* spp. and *Kogia* spp. as guilds. Here, we consider pilot whales, beaked whales (excluding the northern bottlenose whale), and *Kogia* spp. as guilds. In the following discussion, reference to ''pilot whales'' includes both the long-finned and short-finned pilot whale, reference to ''beaked whales'' includes the Cuvier's, Blainville's, Gervais, Sowerby's, and True's beaked whales, and reference to ''*Kogia* spp.'' includes both the dwarf and pygmy sperm whale.

Thirty-four species (with 39 managed stocks) are considered to have the potential to co-occur with the planned survey activities. Species that could potentially occur in the survey areas but are not expected to have reasonable potential to be harassed by any survey are omitted from further analysis. These include extralimital species, which are species that do not normally occur in a given area but for which there are one or more occurrence records that are considered beyond the normal range of the species. Extralimital species or stocks unlikely to co-occur with survey activity include nine estuarine bottlenose dolphin stocks, four pinniped species, the white-beaked dolphin (*Lagenorhynchus albirostris*), and the beluga whale (*Delphinapterus leucas*). For detailed discussion of these species, please see our **Federal Register** Notice of Proposed IHAs (82 FR 26244; June 6, 2017). In addition, the West Indian manatee (*Trichechus manatus latirostris*) may be found in coastal waters of the Atlantic. However, manatees are managed by the U.S. Fish and Wildlife Service and are not considered further in this document. All managed stocks in this region are assessed in NMFS's U.S. Atlantic SARs. All values presented in Table 2 are the most recent available at the time of publication and are available in the 2017 SARs (Hayes *et al.,* 2018a) and draft 2018 SARs (available online at: *www.fisheries.noaa.gov/national/marine-mammal-protection/draft-marine-mammal-stock-assessment-reports*).

TABLE 2—MARINE MAMMALS POTENTIALLY PRESENT IN THE VICINITY OF SURVEY ACTIVITIES

Common name	Scientific name	Stock	ESA/MMPA status; strategic (Y/N) [1]	NMFS stock abundance (CV, N_{min}, most recent abundance survey) [2]	Predicted mean (CV)/maximum abundance [3]	Predicted abundance outside EEZ [4]	PBR	Annual M/SI (CV) [5]
Order Cetartiodactyla—Cetacea—Superfamily Mysticeti (baleen whales)								
Family Balaenidae:								
North Atlantic right whale.	*Eubalaena glacialis*	Western North Atlantic (WNA).	E/D; Y	451 (n/a; 445; n/a)	394 (0.07) * ...	1	0.9	5.56
Family Balaenopteridae (rorquals):								
Humpback whale ...	*Megaptera novaeangliae novaeangliae.*	Gulf of Maine	-; N	896 (n/a; 896; 2015)	1,637 (0.07) */ 1,994.	8	14.6	9.8

TABLE 2—MARINE MAMMALS POTENTIALLY PRESENT IN THE VICINITY OF SURVEY ACTIVITIES—Continued

Common name	Scientific name	Stock	ESA/MMPA status; strategic (Y/N) [1]	NMFS stock abundance (CV, N_{min}, most recent abundance survey) [2]	Predicted mean (CV)/maximum abundance [3]	Predicted abundance outside EEZ [4]	PBR	Annual M/SI (CV) [5]
Minke whale	*Balaenoptera acutorostrata acutorostrata.*	Canadian East Coast	-; N	2,591 (0.81; 1,425; 2011).	2,112 (0.05) */ 2,431.	929	14	7.5
Bryde's whale	*B. edeni brydei*	None defined [6]	-; n/a	n/a	7 (0.58)/n/a	7	n/a	n/a
Sei whale	*B. borealis borealis*	Nova Scotia	E/D; Y	357 (0.52; 236; 2011)	717 (0.30) */ 1,519.	46	0.5	0.6
Fin whale	*B. physalus physalus*	WNA	E/D; Y	1,618 (0.33; 1,234; 2011).	4,633 (0.08)/ 6,538.	44	2.5	2.5
Blue whale	*B. musculus musculus*	WNA	E/D; Y	Unknown (n/a; 440; n/a).	11 (0.41)/n/a	4	0.9	Unk.
Superfamily Odontoceti (toothed whales, dolphins, and porpoises)								
Family Physeteridae:								
Sperm whale	*Physeter macrocephalus.*	North Atlantic	E/D; Y	2,288 (0.28; 1,815; 2011).	5,353 (0.12)/ 7,193.	2,456	3.6	0.8
Family Kogiidae:								
Pygmy sperm whale.	*Kogia breviceps*	WNA	-; N	3,785 (0.47; 2,598; 2011) [7].	678 (0.23)/n/a [7].	428	21	3.5 (1.0)
Dwarf sperm whale	*K. sima*	WNA	-; N					
Family Ziphiidae (beaked whales):								
Cuvier's beaked whale.	*Ziphius cavirostris*	WNA	-; N	6,532 (0.32; 5,021; 2011).	14,491 (0.17)/ 16,635 [7].	9,426	50	0.4
Gervais beaked whale.	*Mesoplodon europaeus*	WNA	-; N	7,092 (0.54; 4,632; 2011) [7].			46	0.2
Blainville's beaked whale.	*M. densirostris*	WNA	-; N					
Sowerby's beaked whale.	*M. bidens*	WNA	-; N					
True's beaked whale.	*M. mirus*	WNA	-; N					
Northern bottlenose whale.	*Hyperoodon ampullatus*	WNA	-; N	Unknown	90 (0.63)/n/a	11	Undet.	0
Family Delphinidae:								
Rough-toothed dolphin.	*Steno bredanensis*	WNA	-; N	136 (1.0; 67; 2016)	532 (0.36)/n/a	313	0.7	0
Common bottlenose dolphin.	*Tursiops truncatus truncatus.*	WNA Offshore	-; N	77,532 (0.40; 56,053; 2011).	97,476 (0.06)/ 144,505 [7].	5,280	561	39.4 (0.29)
		WNA Coastal, Northern Migratory.	D; Y	6,639 (0.41; 4,759; 2016)			48	6.1 (0.32)–13.2 (0.22)
		WNA Coastal, Southern Migratory.	D; Y	3,751 (0.60; 2,353; 2016).			23	0–14.3 (0.31)
		WNA Coastal, South Carolina/Georgia.	D; Y	6,027 (0.34; 4,569; 2016).			46	1.4–1.6
		WNA Coastal, Northern Florida.	D; Y	877 (0.49; 595; 2016)			6	0.6
		WNA Coastal, Central Florida.	D; Y	1,218 (0.35; 913; 2016)			9.1	0.4
Clymene dolphin	*Stenella clymene*	WNA	-; N	6,086 (0.93; 3,132; 1998) [8].	12,515 (0.56)/ n/a.	11,503	Undet.	0
Atlantic spotted dolphin.	*S. frontalis*	WNA	-; N	44,715 (0.43; 31,610; 2011).	55,436 (0.32)/ 137,795.	7,339	316	0
Pantropical spotted dolphin.	*S. attenuata attenuata*	WNA	-; N	3,333 (0.91; 1,733; 2011).	4,436 (0.33)/ n/a.	2,781	17	0
Spinner dolphin	*S. longirostris longirostris.*	WNA	-; N	Unknown	262 (0.93)/n/a	184	Undet.	0
Striped dolphin	*S. coeruleoalba*	WNA	-; N	54,807 (0.3; 42,804; 2011).	75,657 (0.21)/ 172,158.	15,166	428	0
Common dolphin	*Delphinus delphis delphis.*	WNA	-; N	70,184 (0.28; 55,690; 2011).	86,098 (0.12)/ 129,977.	3,154	557	406 (0.10)
Fraser's dolphin	*Lagenodelphis hosei*	WNA	-; N	Unknown	492 (0.76)/n/a	474	Undet.	0
Atlantic white-sided dolphin.	*Lagenorhynchus acutus*	WNA	-; N	48,819 (0.61; 30,403; 2011).	37,180 (0.07)/ 59,008.	368	304	57 (0.15)
Risso's dolphin	*Grampus griseus*	WNA	-; N	18,250 (0.46; 12,619; 2011).	7,732 (0.09)/ 18,377.	1,060	126	49.9 (0.24)
Melon-headed whale.	*Peponocephala electra*	WNA	-; N	Unknown	1,175 (0.50)/ n/a.	1,095	Undet.	0
Pygmy killer whale	*Feresa attenuata*	WNA	-; N	Unknown	n/a	n/a	Undet.	0
False killer whale	*Pseudorca crassidens*	WNA	-; Y	442 (1.06; 212; 2011)	95 (0.84)/n/a	35	2.1	Unk.
Killer whale	*Orcinus orca*	WNA	-; N	Unknown	11 (0.82)/n/a	4	Undet.	0
Short-finned pilot whale.	*Globicephala macrorhynchus.*	WNA	-; N	28,924 (0.24; 23,637; 2016).	18,977 (0.11)/ 35,715 [6].	2,258	236	168 (0.13)
Long-finned pilot whale	*G. melas melas*	WNA	-; N	5,636 (0.63; 3,464; 2011).			35	27 (0.18)

TABLE 2—MARINE MAMMALS POTENTIALLY PRESENT IN THE VICINITY OF SURVEY ACTIVITIES—Continued

Common name	Scientific name	Stock	ESA/ MMPA status; strategic (Y/N) [1]	NMFS stock abundance (CV, N_{min}, most recent abundance survey) [2]	Predicted mean (CV)/ maximum abundance [3]	Predicted abundance outside EEZ [4]	PBR	Annual M/SI (CV) [5]
Family Phocoenidae (porpoises):								
Harbor porpoise	*Phocoena phocoena phocoena.*	Gulf of Maine/Bay of Fundy.	-; N	79,833 (0.32; 61,415; 2011).	45,089 (0.12) */ 50,315.	91	706	255 (0.18)

[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.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments.* CV is coefficient of variation; N_{min} is the minimum estimate of stock abundance. In some cases, CV is not applicable. For the right whale, the best abundance value is based on a model of the sighting histories of individually identifiable animals (as of October 2017). The model of these histories produced a median abundance value of 451 whales (95 percent credible intervals 434–464). The minimum estimate of 440 blue whales represents recognizable photo-identified individuals.

[3] This information represents species- or guild-specific abundance predicted by habitat-based cetacean density models (Roberts *et al.,* 2016). For the North Atlantic right whale, we report the outputs of a more recently updated model (Roberts *et al.,* 2017). These models provide the best available scientific information regarding predicted density patterns of cetaceans in the U.S. Atlantic Ocean, and we provide the corresponding mean annual and maximum monthly abundance predictions. Total abundance estimates were produced by computing the mean density of all pixels in the modeled area and multiplying by its area. Roberts *et al.* (2016) did not produce a density model for pygmy killer whales off the east coast. For those species marked with an asterisk, the available information supported development of either two or four seasonal models; each model has an associated abundance prediction. Here, we report the maximum predicted seasonal abundance.

[4] The density models used to predict acoustic exposures (*e.g.,* Roberts *et al.,* 2016) provide abundance predictions for the area within the U.S. EEZ. However, the model outputs were also extrapolated to the portion of the specific geographic region outside the EEZ in order to predict acoustic exposures in that area (*i.e.,* from 200 nmi to 350 nmi offshore). Therefore, we calculated corresponding seasonal abundance estimates for this region. The maximum seasonal abundance estimate is reported.

[5] 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.

[6] Bryde's whales are occasionally reported off the southeastern U.S. and southern West Indies. NMFS defines and manages a stock of Bryde's whales that is resident in the northern Gulf of Mexico, but does not define a separate stock in the Atlantic Ocean.

[7] Abundance estimates are in some cases reported for a guild or group of species when those species are difficult to differentiate at sea. Similarly, the habitat-based cetacean density models produced by Roberts *et al.* (2016) are based in part on available observational data which, in some cases, is limited to genus or guild in terms of taxonomic definition. NMFS's SARs present pooled abundance estimates for *Kogia* spp. and *Mesoplodon* spp., while Roberts *et al.* (2016) produced density models to genus level for *Kogia* spp. and *Globicephala* spp. and as a guild for most beaked whales (*Ziphius cavirostris* and *Mesoplodon* spp.). Finally, Roberts *et al.* (2016) produced a density model for bottlenose dolphins that does not differentiate between offshore and coastal stocks.

[8] NMFS's abundance estimates for the Clymene dolphin is greater than eight years old and not considered current. PBR is therefore considered undetermined for this stock, as there is no current minimum abundance estimate for use in calculation. We nevertheless present the most recent abundance estimate.

For the majority of species potentially present in the specific geographic region, NMFS has designated only a single generic stock (*e.g.,* ''western North Atlantic'') for management purposes. This includes the ''Canadian east coast'' stock of minke whales, which includes all minke whales found in U.S. waters. For the humpback and sei whales, NMFS defines stocks on the basis of feeding locations, *i.e.,* Gulf of Maine and Nova Scotia, respectively. However, our reference to humpback whales and sei whales in this document refers to any individuals of the species that are found in the specific geographic region. These individuals may be from the same breeding population (*e.g.,* West Indies breeding population of humpback whales) but visit different feeding areas. For the bottlenose dolphin, NMFS defines an oceanic stock and multiple coastal stocks.

North Atlantic Right Whale—We provide additional discussion of the North Atlantic right whale in order to address the current status of the species, which has deteriorated since publication of our Notice of Proposed IHAs. The North Atlantic right whale was severely depleted by historical whaling, and was originally listed as endangered under the ESA in 1970. The right whale's range historically extended to the eastern North Atlantic, as well as the Denmark Strait and waters south of Greenland. However, sightings of right whales beyond their current western North Atlantic distribution are rare and the eastern North Atlantic population may be functionally extinct (Kraus and Rolland, 2007; Best *et al.,* 2001). In the western North Atlantic, a median abundance value of 451 whales in October 2017 (as reported in NMFS's draft 2018 SARs and Table 2) based on a Bayesian mark-recapture open population model, which accounts for individual differences in the probability of being photographed (95 percent credible intervals 434–464, Pace *et al.,* 2017). Accurate pre-exploitation abundance estimates are not available for either population of the species. The western population may have numbered fewer than 100 individuals by 1935, when international protection for right whales came into effect (Kenney *et al.,* 1995).

Modeling suggests that in 1980, females had a life expectancy of approximately 52 years of age (twice that of males at the time) (Fujiwara and Caswell, 2001). However, due to reduced survival probability, in 1995 female life expectancy was estimated to have declined to approximately 15 years, with males having a slightly higher life expectancy into the 20s (Fujiwara and Caswell, 2001). A recent study demonstrated that females have substantially higher mortality than males (Pace *et al.,* 2017), and as a result, also have substantially shorter life expectancies.

Gestation is approximately one year, after which calves typically nurse for around a year (Kenney, 2009; Kraus *et al.,* 2007; Lockyer, 1984). After weaning calves, females typically undergo a 'resting' year before becoming pregnant again, presumably because they need time to recover from the energy deficit experienced during lactation (Fortune *et al.,* 2012, 2013; Pettis *et al.,* 2017b). From 1983 to 2005, annual average calving intervals ranged from 3 to 5.8 years (Knowlton *et al.,* 1994; Kraus *et al.,* 2007). Between 2006 and 2015, annual average calving intervals continued to vary within this range, but in 2016 and 2017 longer calving intervals were reported (6.3 to 6.6 years in 2016 and 10.2 years in 2017; Pettis and Hamilton, 2015, 2016; Pettis *et al.,* 2017a; Surrey-Marsden *et al.,* 2017; Hayes *et al.,* 2018b). Females have been known to give birth as young as five years old, but the mean age of first parturition is about 10 years old (Kraus *et al.,* 2007).

Pregnant North Atlantic right whales migrate south, through the mid-Atlantic region of the United States, to low latitudes during late fall where they overwinter and give birth in shallow, coastal waters (Kenney, 2009; Krzystan *et al.,* 2018). During spring, these females migrate back north with their new calves to high latitude foraging grounds where they feed on large concentrations of copepods, primarily *Calanus finmarchicus* (NMFS, 2017). Some non-reproductive North Atlantic right whales (males, juveniles, non-reproducing females) also migrate south through the mid-Atlantic region, although at more variable times throughout the winter, while others appear to not migrate south, and instead remain in the northern feeding grounds year round or go elsewhere (Bort *et al.,* 2015; Morano *et al.,* 2012; NMFS, 2017). Nonetheless, calving females arrive to the southern calving grounds earlier and stay in the area more than twice as long as other demographics (Krzystan *et al.,* 2018). Little is known about North Atlantic right whale habitat use in the mid-Atlantic, but recent acoustic data indicate near year-round presence of at least some whales off the coasts of New Jersey, Virginia, and North Carolina (Davis *et al.,* 2017; Hodge *et al.,* 2015a; Salisbury *et al.,* 2016; Whitt *et al.,* 2013). Oedekoven *et al.* (2015) conducted an expert elicitation exercise to assess potential seasonal abundance of right whales in the mid-Atlantic, confirming that very low numbers of whales should be expected to be present in the region outside of the November to April timeframe. While it is generally not known where North Atlantic right whales mate, some evidence suggests that mating may occur in the northern feeding grounds (Cole *et al.,* 2013; Matthews *et al.,* 2014).

The western North Atlantic right whale population demonstrated overall growth of 2.8 percent per year between 1990 to 2010, despite a decline in 1993 and no growth between 1997 and 2000 (Pace *et al.,* 2017). However, since 2010 the population has been in decline, with a 99.99 percent probability of a decline of just under one percent per year (Pace *et al.,* 2017). Between 1990 and 2015, survival rates appeared to be relatively stable, but differed between the sexes, with males having higher survivorship than females (males: 0.985 ± 0.0038; females: 0.968 ± 0.0073) leading to a male-biased sex ratio (approximately 1.46 males per female; Pace *et al.,* 2017). During this same period, calving rates varied substantially, with low calving rates coinciding with all three periods of decline or no growth (Pace *et al.,* 2017). On average, North Atlantic right whale calving rates are estimated to be roughly half that of southern right whales (*E. australis*) (Pace *et al.,* 2017), which are increasing in abundance (NMFS, 2015c).

While data are not yet available to statistically estimate the population's trend beyond 2015, three lines of evidence indicate the population is still in decline. First, calving rates in recent years were low, with only five new calves being documented in 2017 (Pettis *et al.,* 2017a), well below the number needed to compensate for expected mortalities (Pace *et al.,* 2017). In 2018, no new North Atlantic right whale calves were documented in their calving grounds; this represented the first time since annual NOAA aerial surveys began in 1989 that no new right whale calves were observed. Long-term photographic identification data indicate new calves rarely go undetected, so these years likely represent a continuation of the low calving rates that began in 2012 (Kraus *et al.,* 2007; Pace *et al.,* 2017). Second, as noted above, the abundance estimate for 2016 is 451 individuals, down approximately 1.5 percent from 458 in 2015. Third, since June 2017, at least 20 North Atlantic right whales have died in what has been declared an Unusual Mortality Event (UME; see additional discussion of the UME below).

Analysis of mtDNA from North Atlantic right whales has identified seven mtDNA haplotypes in the western North Atlantic (Malik *et al.,* 1999; McLeod and White, 2010). This is significantly less diverse than southern right whales and may indicate inbreeding (Hayes *et al.,* 2018a; Malik *et al.,* 2000; Schaeff *et al.,* 1997). While analysis of historic DNA taken from museum specimens indicates that the eastern and western populations were likely not genetically distinct, the lack of recovery of the eastern North Atlantic population indicates at least some level of population segregation (Rosenbaum *et al.,* 1997, 2000). Overall, the species has low genetic diversity as would be expected based on its low abundance. However, analysis of 16th and 17th century whaling bones indicate this low genetic diversity may pre-date whaling activities (McLeod *et al.,* 2010). Despite this, Frasier *et al.* (2013) recently identified a post-copulatory mechanism that appears to be slowly increasing genetic diversity among right whale calves.

In recent years, there has been a shift in distribution in right whale feeding grounds, with fewer animals being seen in the Great South Channel and the Bay of Fundy and perhaps more animals being observed in the Gulf of Saint Lawrence and mid-Atlantic region (Daoust *et al.,* 2017; Davis *et al.,* 2017; Hayes *et al.,* 2018a; Pace *et al.,* 2017; Meyer-Gutbrod *et al.,* 2018). However, in recent years, a few known individuals from the western population have been seen in the eastern Atlantic, suggesting some individuals may have wider ranges than previously thought (Kenney, 2009).

Currently, no identified right whale recovery goals have been met (for more information on these goals, see the 2005 recovery plan; NMFS, 2005, 2017). With whaling now prohibited, the two major known human causes of mortality are vessel strikes and entanglement in fishing gear (Hayes *et al.,* 2018b). Some progress has been made in mitigating vessel strikes by regulating vessel speeds in certain areas (78 FR 73726; December 9, 2013) (Conn and Silber, 2013), but entanglement in fishing gear remains a major threat (Kraus *et al.,* 2016), which appears to be worsening (Hayes *et al.,* 2018b). From 1990 to 2010, the population experienced overall growth consistent with one of its recovery goals. However, the population is currently experiencing a UME that appears to be related to both vessel strikes and entanglement in fishing gear (Daoust *et al.,* 2017; see below for further discussion). In addition, the low female survival, male biased sex ratio, and low calving success indicated by recent modeling are contributing to the population's current decline (Pace *et al.,* 2017). While there are likely a multitude of factors involved, low calving has been linked to poor female health (Rolland *et al.,* 2016) and reduced prey availability (Meyer-Gutbrod and Greene, 2014, 2017; Meyer-Gutbrod *et al.,* 2018). Furthermore, entanglement in fishing gear appears to have substantial health and energetic costs that affect both survival and reproduction (Pettis *et al.,* 2017b; Robbins *et al.,* 2015; Rolland *et al.,* 2017; van der Hoop *et al.,* 2017; Hayes *et al.,* 2018b; Hunt *et al.,* 2018; Lysiak *et al.,* 2018). In fact, there is evidence of a population-wide decline in health since the early 1990s, the last time the population experienced a population decline (Rolland *et al.,* 2016). Given this status, the species resilience to future perturbations is considered very low (Hayes *et al.,* 2018b). Using a matrix population projection model, Hayes *et al.* (2018b) estimate that by 2029 the population will to decline to the 1990 estimate of 123 females if the current rate of decline is not altered. Consistent with this, recent modelling efforts by Meyer-Gutbrod and Greene (2017) indicate that that the species may decline towards

extinction if prey conditions worsen, as predicted under future climate scenarios, and anthropogenic mortalities are not reduced (Grieve *et al.,* 2017; Meyer-Gutbrod *et al.,* 2018). In fact, recent data from the Gulf of Maine and Gulf of St. Lawrence indicate prey densities may already be in decline (Devine *et al.,* 2017; Johnson *et al.,* 2013; Meyer-Gutbrod *et al.,* 2018).

Discussion of Abundance Estimates—In Table 2 above, we report two sets of abundance estimates: Those from NMFS's SARs and those predicted by Roberts *et al.* (2016)—for the latter we provide both the annual mean and maximum, for those taxa for which monthly predictions are available (*i.e.,* all taxa for which density surface models, versus stratified models, were produced). Please see Table 2, footnotes 2–3 for more detail. We provided a relatively brief discussion of available abundance estimates in the Notice of Proposed IHAs, stating that the Roberts *et al.* (2016) abundance predictions are generally the most appropriate in this case for purposes of comparison with estimated exposures (see ''Estimated Take''). This is because the outputs of these models were used in most cases to generate the exposure estimates, *i.e.,* we appropriately make relative comparisons between the exposures predicted by the outputs of the model and the abundance predicted by the model. Following review of public comments received and additional review of available information regarding abundance estimates, we provide revised and additional discussion of available abundance estimates and our use of these herein.

Because both the SAR (in most cases) and Roberts *et al.* (2016) values provide estimates of abundance only within the U.S. EEZ, whereas the specified activities (and associated exposure estimates) extend beyond this region out to 350 nmi, we calculated the expected abundance of each species in the region offshore of the EEZ out to 350 nmi. These values, reported in Table 2, are appropriately added to the Roberts *et al.* (2016) EEZ estimates to provide the total model-predicted abundance. Please see footnote 4 for more detail. Our prior use of abundance estimates that ignore the assumed abundance of animals outside the EEZ (explicit in the exposure estimation process) was an error that is rectified here.

As was described in our Notice of Proposed IHAs, NMFS's SAR abundance estimates are typically generated from the most recent shipboard and/or aerial surveys conducted, and often incorporate correction for detection bias. While these snapshot estimates provide valuable information about a stock, they are not generally relevant here for use in comparison to the take estimates, as stated above. The Roberts *et al.* (2016) abundance estimates represent the output of predictive models derived from observations and associated environmental parameters and are in fact based on substantially more data than are NMFS's SAR abundance estimates—thus minimizing the influence of interannual variability on abundance estimates. For example, NMFS's pilot whale abundance estimates from surveys conducted in 2004 and 2011 differed by 21 percent—a change not expected to represent the actual change in abundance—indicating that it may be more appropriate to use a model prediction that incorporates all available data.

The abundance values reported by Roberts *et al.* (2016), and which we largely used in our analyses in the Notice of Proposed IHAs, are mean annual abundance estimates (for species for which data are sufficient to model seasonality; for other species only a stratified model with static abundance could be produced). However, for those species for which seasonal variability could be modeled (via density surface models), abundance estimates are produced for each month (monthly maps of species distribution and associated abundance values are provided in supplementary reports for each taxon; these are available online at: *seamap.env.duke.edu/models/Duke-EC-GOM-2015/*). Following review of public comments received, we determined it appropriate to use the most appropriate maximum abundance estimate for purposes of comparison with the exposure estimate, rather than the mean. While it is appropriate to use a mean density value in estimating potential exposures over a year in order to avoid over- or under-estimation, the best actual population estimate for comparison would be the maximum theoretical population. That is, exposure estimates are most appropriately generated through use of means precisely because densities are expected to fluctuate within a study area throughout the year; however, because these fluctuations do not represent actual changes in population size, the maximum predicted abundance should be used in comparison with a given exposure estimate.

The appropriate maximum estimate for each taxon more closely represents actual total theoretical abundance of the stock as a whole, as those animals may exit the study area during other months but still exist conceptually as members of the population. The mean does not represent the actual population abundance, because although there are seasonal shifts in distribution, the actual population abundance should be as estimated for the period when the largest portion of the population is present in the area. While species may migrate or shift distribution out of the study area, total abundance of a stock changes only via births and deaths, *i.e.,* there is only one true abundance of the species. We note that for some taxa, Roberts *et al.* express confidence in the monthly model outputs, *e.g.,* where the predicted seasonal variations in abundance match those reported in the literature. However, for others they do not, *e.g.,* where there is little information available in the literature to corroborate the predicted seasonal variation. Lack of corroboration in the latter example would be a valid reason for not relying on monthly model outputs when determining the timing or location of a specific project. However, this does not impact our determination that the maximum theoretical population abundance is appropriate to use for purposes of comparison. For those taxa for which the monthly predictions are recommended for use, we use the maximum monthly prediction. For the remaining taxa for which a density surface model could be produced, we believe that use of the maximum monthly prediction may also be warranted. However, because for some of these species there are substantial month-to-month fluctuations and a corresponding lack of data in the literature regarding seasonal distribution, we use the maximum mean seasonal (*i.e.,* three-month) abundance prediction for purposes of comparison as a precaution.

For most species, we use the Roberts *et al.* (2016) abundance estimate, but substitute the appropriate maximum estimate for the mean annual estimate. Where we deviate from this practice, *e.g.,* because another available abundance estimate provides more complete coverage of the stock's range, we provide additional discussion below. We also note that, regarding SAR abundance estimates, Waring *et al.* (2015) state that the population of sperm whales found within the eastern U.S. Atlantic EEZ likely represent only a fraction of the total stock, indicating that the abundance associated with animals found in the EEZ—whether the SAR abundance or the model-predicted abundance—likely underestimate the true abundance of the relevant population. Additionally, the majority of current NMFS SAR estimates—those

based on 2011 NOAA survey effort—do not account for availability bias due to submerged animals, so these abundance estimates are likely biased low.

NMFS's abundance estimate for the North Atlantic right whale is based on models of the sighting histories of individual whales identified using photo-identification techniques. North Atlantic right whales represent one of the most intensely studied populations of cetaceans in the world with effort supported by a rigorously maintained individual sightings database and considerable survey effort throughout their range; therefore, the most appropriate abundance estimate is based on this photo-identification database. The current estimate of 451 individuals (95% credible intervals 434–464) reflects the database as of November 2017 (*www.fisheries.noaa.gov/national/marine-mammal-protection/draft-marine-mammal-stock-assessment-reports*).

The 2007 Canadian Trans-North Atlantic Sighting Survey (TNASS), which provided full coverage of the Atlantic Canadian coast (Lawson and Gosselin, 2009), provided abundance estimates for multiple stocks. The abundance estimates from this survey were corrected for perception and availability bias, when possible. In general, where the TNASS survey effort provided superior coverage of a stock's range (as compared with NOAA survey effort), we elect to use the resulting abundance estimate over either the current NMFS abundance estimate (derived from survey effort with inferior coverage of the stock range) or the Roberts *et al.* (2016) predictions (which are based on survey data from within U.S. waters). The TNASS data were not made available to the model authors (Roberts *et al.,* 2015a).

We use the TNASS abundance estimate for the minke whale and for the short-beaked common dolphin. While the TNASS survey also produced an abundance estimate of 3,522 (CV=0.27) fin whales, and similarly better represents the stock range than does NMFS's SAR estimate, this value underrepresents the maximum population predicted by Roberts *et al.* (2016). We also note that, while there appears to be some slight overlap in their coverage of stock ranges, the abundance estimates provided by the TNASS surveys and by NMFS's SAR estimates largely cover separate portions of the ranges. The TNASS effort involved aerial surveys covering the Labrador Shelf and Grand Banks, the Gulf of St. Lawrence, and the Scotian Shelf, and the abundance estimates also included the results of aerial surveys conducted by NOAA in the Bay of Fundy. NMFS's current SAR estimates reflect NOAA shipboard and aerial survey effort conducted from Florida to the lower Bay of Fundy. Therefore, the most appropriate abundance estimate for these stocks may be a combination of the abundance estimates (for common dolphin: 70,184 (SAR) + 173,486 (TNASS) = 243,670; for minke whale: 2,591 (SAR) + 20,741 (TNASS) = 23,332). Other abundance estimates that may cover additional portions of these stocks' ranges are described in Waring *et al.* (2013). However, we use only the TNASS estimates, which better cover the stock ranges, because we are uncertain about the degree of potential coverage overlap in Canadian waters.

Note that, while the same TNASS survey produced an abundance estimate of 2,612 (CV=0.26) humpback whales, the survey did not provide superior coverage of the stock's range in the same way that it did for minke whales (Waring *et al.,* 2016; Lawson and Gosselin, 2011). In addition, based on photo-identification only 39 percent of individual humpback whales observed along the mid- and south Atlantic U.S. coast are from the Gulf of Maine stock (Barco *et al.,* 2002). Therefore, we use the Roberts *et al.* (2016) prediction for humpback whales. We note that the Roberts *et al.* (2016) maximum estimate of 1,994 humpback whales likely underrepresents the relevant population, *i.e.,* the West Indies breeding population. Bettridge *et al.* (2003) estimated the size of this population at 12,312 (95% CI 8,688–15,954) whales in 2004–05, which is consistent with previous population estimates of approximately 10,000–11,000 whales (Stevick *et al.,* 2003; Smith *et al.,* 1999) and the increasing trend for the West Indies DPS (Bettridge *et al.,* 2015). However, we retain the value predicted by Roberts *et al.* (2016) for appropriate comparison with the number of exposures predicted in the U.S. EEZ.

The current SARs abundance estimate for *Kogia* spp. is substantially higher than that provided by Roberts *et al.* (2016). However, the data from which the SARs estimate is derived was not made available to Roberts *et al.* (Roberts *et al.,* 2015h), and those more recent surveys reported observing substantially greater numbers of *Kogia* spp. than did earlier surveys (43 sightings, more than the combined total of 31 reported from all surveys from 1992–2014 considered by Roberts *et al.* (2016)) (NMFS, 2011). A 2013 NOAA survey, also not available to the model authors, reported 68 sightings of *Kogia* spp. (NMFS, 2013a). In addition, the SARs report an increase in *Kogia* spp. strandings (92 from 2001–05; 187 from 2007–11) (Waring *et al.,* 2007; 2013). A simultaneous increase in at-sea observations and strandings suggests increased abundance of *Kogia* spp., though NMFS has not conducted any trend analysis (Waring *et al.,* 2013). Therefore, we believe the most appropriate abundance estimate for use here is that currently reported by NMFS in the SARs. In fact, Waring *et al.* (2013) suggest that because this estimate was corrected for perception bias but not availability bias, the true estimate could be two to four times larger.

Biologically Important Areas—Several biologically important areas for some marine mammal species are recognized in the survey areas in the mid- and south Atlantic. Critical habitat is designated for the North Atlantic right whale within the southeast United States (81 FR 4838; January 27, 2016). Critical habitat is defined by section 3 of the ESA as (1) the specific areas within the geographical area occupied by the species, at the time it is listed, on which are found those physical or biological features (a) essential to the conservation of the species and (b) which may require special management considerations or protection; and (2) specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination by the Secretary that such areas are essential for the conservation of the species. Critical habitat for the right whale in the southeast United States (*i.e.,* Unit 2) encompasses calving habitat and is designated on the basis of the following essential features: (1) Calm sea surface conditions of Force 4 or less on the Beaufort Wind Scale; (2) sea surface temperatures from a minimum of 7° C, and never more than 17° C; and (3) water depths of 6 to 28 m, where these features simultaneously co-occur over contiguous areas of at least 231 nmi^2 of ocean waters during the months of November through April. When these features are available, they are selected by right whale cows and calves in dynamic combinations that are suitable for calving, nursing, and rearing, and which vary, within the ranges specified, depending on factors such as weather and age of the calves.

The area associated with such features includes nearshore and offshore waters of the southeastern United States, extending from Cape Fear, North Carolina south to 28° N. The specific area designated as Unit 2 of critical habitat, as defined by regulation (81 FR 4838; January 27, 2016), is demarcated by rhumb lines connecting the specific points identified in 50 CFR 226.203(b)(2), as shown in Figure 2.

There is no critical habitat designated for any other species within the survey area.

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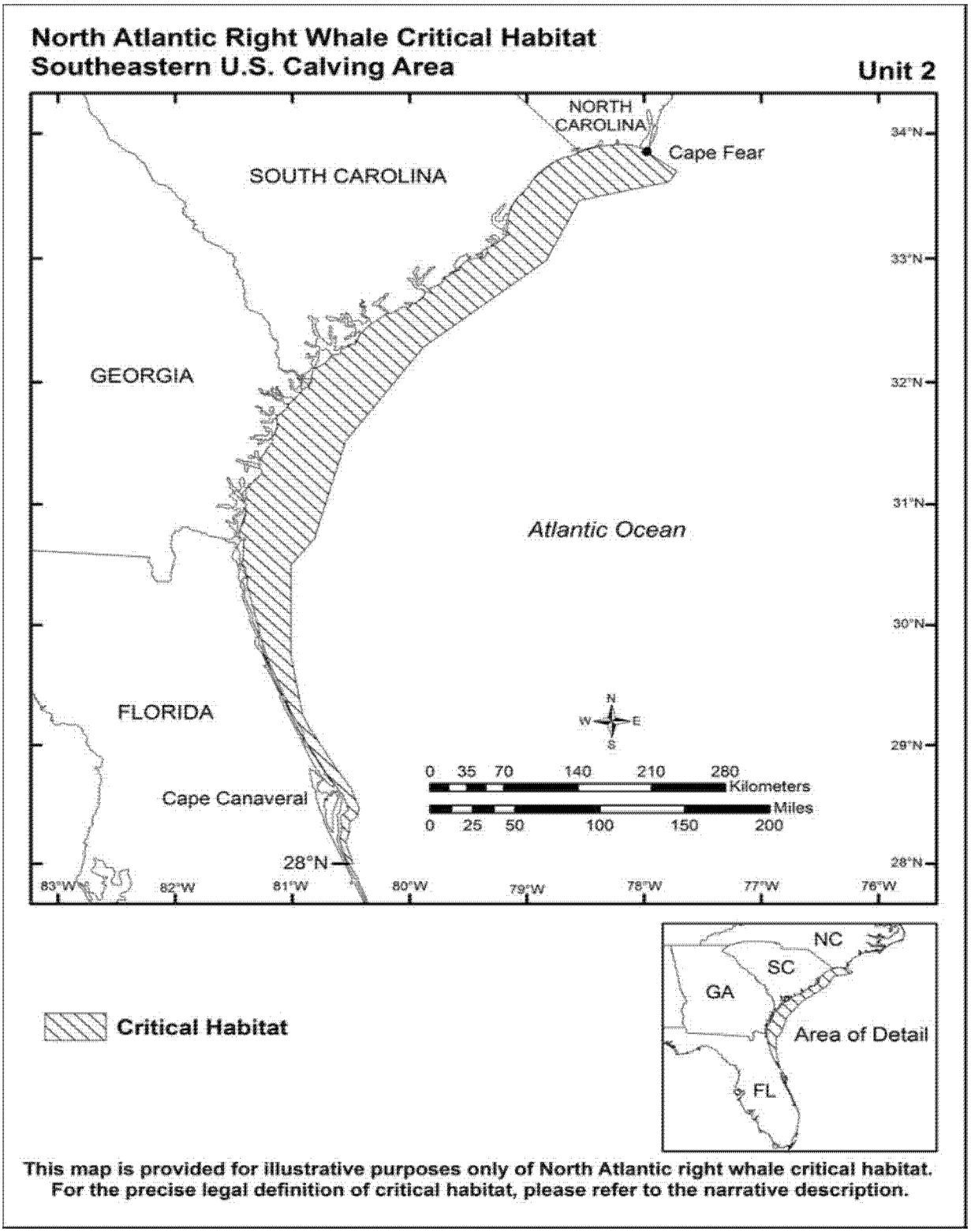

Figure 2. North Atlantic Right Whale Critical Habitat, Southeast United States.

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Biologically important areas for North Atlantic right whales in the mid- and south Atlantic were further described by LaBrecque *et al.* (2015). The authors describe an area of importance for reproduction that somewhat expands the boundaries of the critical habitat designation, including waters out to the 25-m isobath from Cape Canaveral to Cape Lookout from mid-November to mid-April, on the basis of habitat analyses (Good, 2008; Keller *et al.,* 2012) and sightings data (*e.g.,* Keller *et al.,* 2006; Schulte and Taylor, 2012) indicating that sea surface temperatures between 13° to 15° C and water depths between 10–20 m are critical parameters for calving. Right whales leave northern feeding grounds in November and December to migrate along the continental shelf to the calving grounds or to unknown winter areas before returning to northern areas by late spring. Right whales are known to travel along the continental shelf, but it is unknown whether they use the entire shelf area or are restricted to nearshore waters (Schick *et al.,* 2009; Whitt *et al.,* 2013). LaBrecque *et al.* (2015) define an important area for migratory behavior on the basis of aerial and vessel-based survey data, photo-identification data, radio-tracking data, and expert judgment.

As noted by LaBrecque *et al.* (2015), additional cetacean species are known to have strong links to bathymetric features, although there is currently insufficient information to specifically identify these areas. For example, pilot whales and Risso's dolphins aggregate at the shelf break in the survey area. These and other locations predicted as areas of high abundance (Roberts *et al.,* 2016) form the basis of spatiotemporal restrictions on survey effort as described under ''Mitigation.'' In addition, other data indicate potential areas of importance that are not yet fully described. Risch *et al.* (2014) describe minke whale presence offshore of the shelf break (evidenced by passive acoustic recorders), which may be indicative of a migratory area, while other data provides evidence that sei whales aggregate near meandering frontal eddies over the continental shelf in the Mid-Atlantic Bight (Newhall *et al.,* 2012).

Unusual Mortality Events (UME)—A UME is defined under the MMPA as ''a stranding that is unexpected; involves a significant die-off of any marine mammal population; and demands immediate response.'' From 1991 to the present, there have been approximately twelve formally recognized UMEs affecting marine mammals in the survey area and involving species under NMFS's jurisdiction. A recently ended UME involved bottlenose dolphins. Three UMEs are ongoing and under investigation. These involve humpback whales, North Atlantic right whales, and minke whales. Specific information for each ongoing UME is provided below. There is currently no direct connection between the three UMEs, as there is no evident cause of stranding or death that is common across the three species involved in the different UMEs. Additionally, strandings across the three species are not clustering in space or time.

Since January 2016, elevated humpback whale mortalities have occurred along the Atlantic coast from Maine through Florida (though there are only two records to date south of North Carolina). As of October 2018, partial or full necropsy examinations have been conducted on approximately half of the 84 known cases. Of the cases examined, approximately half had evidence of human interaction (ship strike or entanglement). Some of these investigated mortalities showed blunt force trauma or pre-mortem propeller wounds indicative of vessel strike, indicating a strike rate above the annual long-term average; however, these findings of pre-mortem vessel strike are not consistent across all of the whales examined and more research is needed. NOAA is consulting with researchers that are conducting studies on the humpback whale populations, and these efforts may provide information on changes in whale distribution and habitat use that could provide additional insight into how these vessel interactions occurred. Three previous UMEs involving humpback whales have occurred since 2000, in 2003, 2005, and 2006. More information is available at *www.fisheries.noaa.gov/national/marine-life-distress/2016-2018-humpback-whale-unusual-mortality-event-along-atlantic-coast* (accessed October 17, 2018).

Since January 2017, elevated minke whale strandings have occurred along the Atlantic coast from Maine through South Carolina, with highest numbers in Massachusetts, Maine, and New York. As of October 2018, partial or full necropsy examinations have been conducted on more than 60 percent of the 54 known cases. Preliminary findings in several of the whales have shown evidence of human interactions or infectious disease. These findings are not consistent across all of the whales examined, so more research is needed. As part of the UME investigation process, NOAA is assembling an independent team of scientists to coordinate with the Working Group on Marine Mammal Unusual Mortality Events to review the data collected, sample stranded whales, and determine the next steps for the investigation. More information is available at: *www.fisheries.noaa.gov/national/marine-life-distress/2017-2018-minke-whale-unusual-mortality-event-along-atlantic-coast* (accessed October 17, 2018).

Elevated North Atlantic right whale mortalities began in June 2017, primarily in Canada. To date, there are a total of 20 confirmed dead stranded whales (12 in Canada; 8 in the United States), and 5 live whale entanglements in Canada have been documented. Full necropsy examinations have been conducted on 13 of the cases, with results currently available for seven of these that occurred in Canada (Daoust *et al.,* 2017). Results indicate that two whales died from entanglement in fishing gear and, for four whales, necropsy findings were compatible with acute death due to trauma (although it is uncertain whether they were struck pre- or post-mortem) (Daoust *et al.,* 2017). Several investigated cases are undetermined due to advanced decomposition. Overall, findings to date confirm that vessel strikes and fishing gear entanglement continue to be the key threats to recovery of North Atlantic right whales. In response, the Canadian government has enacted fishery closures to help reduce future entanglements and has modified fixed gear fisheries, as well as implementing temporary mandatory vessel speed restrictions in a portion of the Gulf of St. Lawrence. NOAA is cooperating with Canadian government officials as they investigate the incidents in Canadian waters. A previous UME involving right whales occurred in 1996. More information is available at: *www.fisheries.noaa.gov/national/marine-life-distress/2017-2018-north-atlantic-right-whale-unusual-mortality-event* (accessed October 17, 2018).

Beginning in July 2013, elevated strandings of bottlenose dolphins were observed along the Atlantic coast from New York to Florida. The investigation was closed in 2015, with the UME ultimately being attributed to cetacean morbillivirus (though additional contributory factors are under investigation; *www.fisheries.noaa.gov/national/marine-life-distress/2013-2015-bottlenose-dolphin-unusual-mortality-event-mid-atlantic*; accessed July 2, 2018). Dolphin strandings during 2013–15 were greater than six times higher than the annual average from 2007–12, with the most strandings reported from Virginia, North Carolina, and Florida. A

total of approximately 1,650 bottlenose dolphins stranded from June 2013 to March 2015 and, additionally, a small number of individuals of several other cetacean species stranded during the UME and tested positive for morbillivirus (humpback whale, fin whale, minke whale, pygmy sperm whale, and striped dolphin). Only one offshore ecotype dolphin has been identified, meaning that over 99 percent of affected dolphins were of the coastal ecotype (D. Fauquier; pers. comm.). Research, to include analyses of stranding samples and post-UME monitoring and modeling of surviving populations, will continue in order to better understand the impacts of the UME on the affected stocks. Notably, an earlier major UME in 1987–88 was also caused by morbillivirus. Over 740 stranded dolphins were recovered during that event.

Additional recent UMEs include various localized events with undetermined cause involving bottlenose dolphins (*e.g.,* South Carolina in 2011; Virginia in 2009) and an event affecting common dolphins and Atlantic white-sided dolphins from North Carolina to New Jersey (2008; undetermined). For more information on UMEs, please visit: *www.fisheries.noaa.gov/national/marine-life-distress/marine-mammal-unusual-mortality-events.*

Take Reduction Planning—Take reduction plans are designed to help recover and prevent the depletion of strategic marine mammal stocks that interact with certain U.S. commercial fisheries, as required by Section 118 of the MMPA. The immediate goal of a take reduction plan is to reduce, within six months of its implementation, the mortality and serious injury of marine mammals incidental to commercial fishing to less than the potential biological removal level. The long-term goal is to reduce, within five years of its implementation, the mortality and serious injury of marine mammals incidental to commercial fishing to insignificant levels, approaching a zero serious injury and mortality rate, taking into account the economics of the fishery, the availability of existing technology, and existing state or regional fishery management plans. Take reduction teams are convened to develop these plans.

There are several take reduction plans in place for marine mammals in the survey areas of the mid- and south Atlantic. We described these here briefly in order to fully describe, in conjunction with referenced material, the baseline conditions for the affected marine mammal stocks. The Atlantic Large Whale Take Reduction Plan (ALWTRP) was implemented in 1997 to reduce injuries and deaths of large whales due to incidental entanglement in fishing gear. The ALWTRP is an evolving plan that changes as NMFS learns more about why whales become entangled and how fishing practices might be modified to reduce the risk of entanglement. It has several components, including restrictions on where and how gear can be set and requirements for entangling gears (*i.e.,* trap/pot and gillnet gears). The ALWTRP addresses those species most affected by fishing gear entanglements, *i.e.,* North Atlantic right whale, humpback whale, fin whale, and minke whale. Annual human-caused mortality exceeds PBR for the North Atlantic right whale and certain other ESA-listed whale species. More information is available online at: *www.greateratlantic.fisheries.noaa.gov/protected/whaletrp/.*

NMFS implemented a Harbor Porpoise Take Reduction Plan (HPTRP) to reduce interactions between harbor porpoise and commercial gillnet gear in both New England and the mid-Atlantic. The HPTRP has several components including restrictions on where, when, and how gear can be set, and in some areas requires the use of acoustic deterrent devices. More information is available online at: *www.greateratlantic.fisheries.noaa.gov/protected/porptrp/.*

The Atlantic Trawl Gear Take Reduction Team was developed to address the incidental mortality and serious injury of pilot whales, common dolphins, and white-sided dolphins incidental to Atlantic trawl fisheries. More information is available online at: *www.greateratlantic.fisheries.noaa.gov/Protected/mmp/atgtrp/.* Separately, NMFS established a Pelagic Longline Take Reduction Plan (PLTRP) to address the incidental mortality and serious injury of pilot whales in the mid-Atlantic region of the Atlantic pelagic longline fishery. The PLTRP includes a special research area, gear modifications, outreach material, observer coverage, and captains' communications. Pilot whales incur substantial incidental mortality and serious injury due to commercial fishing, and therefore are of particular concern. More information is available online at: *www.nmfs.noaa.gov/pr/interactions/trt/pl-trt.html.*

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). NMFS (2018) describes generalized hearing ranges for these marine mammal hearing groups. Generalized hearing ranges were chosen based on the approximately 65 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. Pinniped functional hearing is not discussed here, as no pinnipeds are expected to be affected by the specified activity. The functional groups and the associated frequencies are indicated below (note that these frequency ranges correspond to the range for the composite group, with the entire range not necessarily reflecting the capabilities of every species within that group):

- Low-frequency cetaceans (mysticetes): Generalized hearing is estimated to occur between approximately 7 Hz and 35 kHz;
- Mid-frequency cetaceans (larger toothed whales, beaked whales, and most delphinids): Generalized hearing is estimated to occur between approximately 150 Hz and 160 kHz;
- High-frequency cetaceans (porpoises, river dolphins, and members of the genera *Kogia* and *Cephalorhynchus;* including two members of the genus *Lagenorhynchus,* on the basis of recent echolocation data and genetic data): Generalized hearing is estimated to occur between approximately 275 Hz and 160 kHz.

For more detail concerning these groups and associated frequency ranges, please see NMFS (2018) for a review of available information. Thirty-four marine mammal species, all cetaceans, have the reasonable potential to co-occur with the survey activities. Please refer to Table 2. Of the species that may

be present, seven are classified as low-frequency cetaceans (*i.e.,* all mysticete species), 24 are classified as mid-frequency cetaceans (*i.e.,* all delphinid and ziphiid species and the sperm whale), and three are classified as high-frequency cetaceans (*i.e.,* harbor porpoise and *Kogia* spp.).

Potential Effects of the Specified Activities on Marine Mammals and Their Habitat

In our Notice of Proposed IHAs, this section included a comprehensive summary and discussion of the ways that components of the specified activity may impact marine mammals and their habitat, including general background information on sound and specific discussion of potential effects to marine mammals from noise produced through use of airgun arrays. We do not repeat that discussion here, instead referring the reader to the Notice of Proposed IHAs. However, we do provide a more thorough discussion regarding potential impacts to marine mammal habitat via effects to prey species, as well as discussion of important new information regarding potential impacts to prey species produced since publication of our notice. The ''Estimated Take'' section later in this document includes a quantitative analysis of the number of individuals that are expected to be taken by this activity. The ''Negligible Impact Analyses and Determinations'' section will include an analysis of how these specific activities will impact marine mammals and will consider the content of this section, the ''Estimated Take'' section, and the ''Mitigation'' section, to draw conclusions regarding the likely impacts of these activities on the reproductive success or survivorship of individuals and from that on the affected marine mammal populations.

Description of Active Acoustic Sound Sources

In our Notice of Proposed IHAs, this section contained a brief technical background on sound, the characteristics of certain sound types, and on metrics used in the proposal inasmuch as the information is relevant to the specified activity and to a discussion of the potential effects of the specified activity on marine mammals found later in this document. Here, we summarize key information relating to terminology used in this notice.

Amplitude (or ''loudness'') of sound is typically described using the relative unit of the decibel (dB). A sound pressure level (SPL) in dB is described as the ratio between a measured pressure and a reference pressure (for underwater sound, this is 1 microPascal (μPa)). The source level (SL) represents the SPL referenced at a distance of 1 m from the source (referenced to 1 μPa), while the received level is the SPL at the listener's position (referenced to 1 μPa).

Root mean square (rms) is the quadratic mean sound pressure over the duration of an impulse. This measurement is often used in the context of discussing behavioral effects, in part because behavioral effects, which often result from auditory cues, may be better expressed through averaged units than by peak pressures. Sound exposure level (SEL; represented as dB re 1 μPa^2–s) represents the total energy contained within a pulse, and considers both intensity and duration of exposure. Peak sound pressure (also referred to as zero-to-peak sound pressure or 0–p) is the maximum instantaneous sound pressure measurable in the water at a specified distance from the source, and is represented in the same units as the rms sound pressure. Another common metric is peak-to-peak sound pressure (pk–pk), which is the algebraic difference between the peak positive and peak negative sound pressures. Peak-to-peak pressure is typically approximately 6 dB higher than peak pressure (Southall *et al.,* 2007).

As described in more detail in our Notice of Proposed IHAs, airgun arrays are in a general sense considered to be omnidirectional sources of pulsed noise. Pulsed sound sources (as compared with non-pulsed sources) produce signals that are brief (typically considered to be less than one second), broadband, atonal transients (ANSI, 1986, 2005; Harris, 1998; NIOSH, 1998; ISO, 2003) and occur either as isolated events or repeated in some succession. Pulsed sounds are all characterized by a relatively rapid rise from ambient pressure to a maximal pressure value followed by a rapid decay period that may include a period of diminishing, oscillating maximal and minimal pressures, and generally have an increased capacity to induce physical injury as compared with sounds that lack these features. Airguns produce sound with energy in a frequency range from about 10–2,000 Hz, with most energy radiated at frequencies below 200 Hz. Although the amplitude of the acoustic wave emitted from the source is equal in all directions (*i.e.,* omnidirectional), airgun arrays do possess some directionality due to different phase delays between guns in different directions. Airgun arrays are typically tuned to maximize functionality for data acquisition purposes, meaning that sound transmitted in horizontal directions and at higher frequencies is minimized to the extent possible.

Anticipated Effects on Marine Mammal Habitat

We received numerous public comments regarding potential effects to marine mammal habitat, including to prey species, including some comments pointing out additional relevant literature and/or claiming that we had not adequately considered potential impacts to prey species. While we disagree that we had not adequately considered potential impacts to marine mammal habitat, particularly with regard to marine mammal prey, in response to public comment we did consider additional literature regarding potential impacts to prey species, as well as some new literature made available since publication of our Notice of Proposed IHAs (*e.g.,* McCauley *et al.,* 2017). Portions of this information were described in responses to comments above. We provide a revised summary of our review of available literature regarding impacts to prey species here (please see our Notice of Proposed IHAs for our discussions of potential effects to other aspects of marine mammal habitat, including acoustic habitat). Our overall conclusions regarding potential impacts of the specified activities on marine mammal habitat are unchanged. As stated in our Notice of Proposed IHAs, our review of the available information and the specific nature of the activities considered herein suggest that the activities associated with the planned actions are not likely to have more than short-term adverse effects on any prey habitat or populations of prey species or on the quality of acoustic habitat. 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. Information supporting this conclusion is summarized below.

Effects to Prey—As stated above, here we provide an updated and more detailed discussion of the available information regarding potential effects to prey, as well as additional support for our conclusion.

Sound may affect marine mammals through impacts on the abundance, behavior, or distribution of prey species (*e.g.,* crustaceans, cephalopods, fish, zooplankton). Marine mammal prey varies by species, season, and location and, for some, is not well documented. Here, we describe studies regarding the effects of noise on known marine mammal prey.

Fish utilize the soundscape (see our Notice of Proposed IHAs for discussion of this concept) and components of sound in their environment to perform important functions such as foraging, predator avoidance, mating, and spawning (*e.g.,* Zelick *et al.,* 1999; Fay, 2009). Depending on their hearing anatomy and peripheral sensory structures, which vary among species, fishes hear sounds using pressure and particle motion sensitivity capabilities and detect the motion of surrounding water (Fay *et al.,* 2008). The potential effects of airgun noise on fishes depends on the overlapping frequency range, distance from the sound source, water depth of exposure, and species-specific hearing sensitivity, anatomy, and physiology. Key impacts to fishes may include behavioral responses, hearing damage, barotrauma (pressure-related injuries), and mortality.

Fish react to sounds which are especially strong and/or intermittent low-frequency sounds, and behavioral responses such as flight or avoidance are the most likely effects. Short duration, sharp sounds can cause overt or subtle changes in fish behavior and local distribution. The reaction of fish to airguns depends on the physiological state of the fish, past exposures, motivation (*e.g.,* feeding, spawning, migration), and other environmental factors. Hastings and Popper (2005) identified several studies that suggest fish may relocate to avoid certain areas of sound energy. Several studies have demonstrated that airgun sounds might affect the distribution and behavior of some fishes, potentially impacting foraging opportunities or increasing energetic costs (*e.g.,* Fewtrell and McCauley, 2012; Pearson *et al.,* 1992; Skalski *et al.,* 1992; Santulli *et al.,* 1999). One recent study found a 78 percent decline in snapper-grouper complex species abundance during evening hours at a reef habitat site off central North Carolina following an airgun survey (Paxton *et al.,* 2017). During the days prior to the survey passing, fish use of this habitat was highest during the same hours.

However, our review shows that the bulk of studies indicate no or slight reaction to noise (*e.g.,* Miller and Cripps, 2013; Dalen and Knutsen, 1987; Pena *et al.,* 2013; Chapman and Hawkins, 1969; Wardle *et al.,* 2001; Sara *et al.,* 2007; Jorgenson and Gyselman, 2009; Blaxter *et al.,* 1981; Cott *et al.,* 2012; Boeger *et al.,* 2006), and that, most commonly, while there are likely to be impacts to fish as a result of noise from nearby airguns, such effects will be temporary. For example, investigators reported significant, short-term declines in commercial fishing catch rate of gadid fishes during and for up to five days after seismic survey operations, but the catch rate subsequently returned to normal (Engas *et al.,* 1996; Engas and Lokkeborg, 2002); other studies have reported similar findings (Hassel *et al.,* 2004). Skalski *et al.* (1992) also found a reduction in catch rates—for rockfish (*Sebastes* spp.) in response to controlled airgun exposure—but suggested that the mechanism underlying the decline was not dispersal but rather decreased responsiveness to baited hooks associated with an alarm behavioral response. A companion study showed that alarm and startle responses were not sustained following the removal of the sound source (Pearson *et al.,* 1992); therefore, Skalski *et al.* (1992) suggested that the effects on fish abundance may be transitory, primarily occurring during the sound exposure itself. In some cases, effects on catch rates are variable within a study, which may be more broadly representative of temporary displacement of fish in response to airgun noise (*i.e.,* catch rates may increase in some locations and decrease in others) than any long-term damage to the fish themselves (Streever *et al.,* 2016).

While the findings of Paxton *et al.* (2017) may be interpreted as a significant shift in distribution that could compromise life history behaviors—as some commenters have done—we interpret these findings as corroborating prior studies indicating that typically a startle response or short-term displacement should be expected. In fact, the evening hours during which the decline in fish habitat use were recorded (via video recording) occurred on the same day that the airgun survey passed, and no subsequent data is presented to support an inference that the response was long-lasting. Additionally, given that the finding is based on video images, the lack of recorded fish presence does not support a conclusion that the fish actually moved away from the site or suffered any serious impairment. Other studies have been inconclusive regarding the abundance effects of airgun noise (Thomson *et al.,* 2014).

SPLs of sufficient strength have been known to cause injury to fish and fish mortality and, in some studies, fish auditory systems have been damaged by airgun noise (McCauley *et al.,* 2003; Popper *et al.,* 2005; Song *et al.,* 2008). (No mortality occurred to fish in any of these studies.) While experiencing a TTS, fish may be more susceptible to fitness impacts resulting from effects to communication, predator/prey detection, etc. (Popper *et al.,* 2014). However, in most fish species, hair cells in the ear continuously regenerate and loss of auditory function likely is restored when damaged cells are replaced with new cells (Smith, 2016). Halvorsen *et al.* (2012a) showed that a TTS of 4–6 dB was recoverable within 24 hours for one species. Impacts would be most severe when the individual fish is close to the source and when the duration of exposure is long—neither condition should be expected in relation to the specified activities.

Injury caused by barotrauma can range from slight to severe and can cause death, and is most likely for fish with swim bladders. Barotrauma injuries have been documented during controlled exposure to impact pile driving (an impulsive noise source, as are airguns) (Halvorsen *et al.,* 2012b; Casper *et al.,* 2013). For geophysical surveys, the sound source is constantly moving, and most fish would likely avoid the sound source prior to receiving sound of sufficient intensity to cause physiological or anatomical damage.

Invertebrates appear to be able to detect sounds (Pumphrey, 1950; Frings and Frings, 1967) and are most sensitive to low-frequency sounds (Packard *et al.,* 1990; Budelmann and Williamson, 1994; Lovell *et al.,* 2005; Mooney *et al.,* 2010). Available data suggest that cephalopods are capable of sensing the particle motion of sounds and detect low frequencies up to 1–1.5 kHz, depending on the species, and so are likely to detect airgun noise (Kaifu *et al.,* 2008; Hu *et al.,* 2009; Mooney *et al.,* 2010; Samson *et al.,* 2014). Cephalopods have a specialized sensory organ inside the head called a statocyst that may help an animal determine its position in space (orientation) and maintain balance (Budelmann, 1992). Packard *et al.* (1990) showed that cephalopods were sensitive to particle motion, not sound pressure, and Mooney *et al.* (2010) demonstrated that squid statocysts act as an accelerometer through which particle motion of the sound field can be detected. Auditory injuries (lesions occurring on the statocyst sensory hair cells) have been reported upon controlled exposure to low-frequency sounds, suggesting that cephalopods are particularly sensitive to low-frequency sound (Andre *et al.,* 2011; Sole *et al.,* 2013); however, these controlled exposures involved long exposure to sounds dissimilar to airgun pulses (*i.e.,* 2 hours of continuous exposure to 1-second sweeps, 50–400 Hz). Behavioral responses, such as inking and jetting, have also been reported upon exposure to low-

frequency sound (McCauley *et al.,* 2000b; Samson *et al.,* 2014).

Impacts to benthic communities from impulsive sound generated by active acoustic sound sources are not well documented. There are no published data that indicate whether threshold shift injuries or effects of auditory masking occur in benthic invertebrates, and there are little data to suggest whether sounds from seismic surveys would have any substantial impact on invertebrate behavior (Hawkins *et al.,* 2014), though some studies have indicated no short-term or long-term effects of airgun exposure (*e.g.,* Andriguetto-Filho *et al.,* 2005; Payne *et al.,* 2007; 2008; Boudreau *et al.,* 2009). Exposure to airgun signals was found to significantly increase mortality in scallops, in addition to causing significant changes in behavioral patterns and disruption of hemolymph chemistry during exposure (Day *et al.,* 2017). However, the implications of this finding are not straightforward, as the authors state that the observed levels of mortality were not beyond naturally occurring rates. Fitzgibbon *et al.* (2017) found significant changes to hemolymph cell counts in spiny lobsters subjected to repeated airgun signals, with the effects lasting up to a year post-exposure. However, despite the high levels of exposure, direct mortality was not observed. Further, in reference to the study, Day *et al.* (2016) stated that ''[s]eismic surveys appear to be unlikely to result in immediate large scale mortality [. . .] and, on their own, do not appear to result in any degree of mortality'' and that ''[e]arly stage lobster embryos showed no effect from air gun exposure, indicating that at this point in life history, they are resilient to exposure and subsequent recruitment should be unaffected.''

There is little information concerning potential impacts of noise on zooplankton populations. However, one recent study (McCauley *et al.,* 2017) investigated zooplankton abundance, diversity, and mortality before and after exposure to airgun noise, finding that the exposure resulted in significant depletion for more than half the taxa present and that there were two to three times more dead zooplankton after airgun exposure compared with controls for all taxa. The majority of taxa present were copepods and cladocerans; for these taxa, the range within which effects on abundance were detected was up to approximately 1.2 km. In order to have significant impacts on *r*-selected species such as plankton, the spatial or temporal scale of impact must be large in comparison with the ecosystem concerned (McCauley *et al.,* 2017). It is also possible that the findings reflect avoidance by zooplankton rather than mortality (McCauley *et al.,* 2017). Therefore, the large scale of effect observed here is of concern—particularly where repeated noise exposure is expected—and further study is warranted.

A modeling exercise was conducted as a follow-up to the McCauley *et al.* (2017) study, in order to assess the potential for impacts on ocean ecosystem dynamics and zooplankton population dynamics (Richardson *et al.,* 2017). Richardson *et al.* (2017) found that for copepods with a short life cycle in a high-energy environment, a full-scale airgun survey would impact copepod abundance up to three days following the end of the survey, suggesting that effects such as those found by McCauley *et al.* (2017) would not be expected to be detectable downstream of the survey areas, either spatially or temporally. However, these findings are relevant for zooplankton with rapid reproductive cycles in areas where there is a high natural replenishment rate resulting from new water masses moving in, and the findings may not apply in lower-energy environments or for zooplankton with longer life-cycles. In fact, the study found that by turning off the current, as may reflect lower-energy environments, the time to recovery for the modelled population extended from several days to several weeks.

In the absence of further validation of the McCauley *et al.* (2017) findings, if we assume a worst-case likelihood of severe impacts to zooplankton within approximately 1 km of the acoustic source, the large spatial scale and expected wide dispersal of survey vessels does not lead us to expect any meaningful follow-on effects to the prey base for odontocete predators (the region is not an important feeding area for taxa that feed directly on zooplankton, *i.e.,* mysticetes). While the large scale of effect observed by McCauley *et al.* (2017) may be of concern, NMFS concludes that these findings indicate a need for more study, particularly where repeated noise exposure is expected—a condition unlikely to occur in relation to the time period in which the surveys considered for the five IHAs will take place.

A recent review article concluded that, while laboratory results provide scientific evidence for high-intensity and low-frequency sound-induced physical trauma and other negative effects on some fish and invertebrates, the sound exposure scenarios in some cases are not realistic to those encountered by marine organisms during routine seismic operations (Carroll *et al.,* 2017). The review finds that there has been no evidence of reduced catch or abundance following seismic activities for invertebrates, and that there is conflicting evidence for fish with catch observed to increase, decrease, or remain the same. Further, where there is evidence for decreased catch rates in response to airgun noise, these findings provide no information about the underlying biological cause of catch rate reduction (Carroll *et al.,* 2017).

As addressed earlier in ''Comments and Responses,'' some members of the public made strong assertions regarding the likely effects of airgun survey noise on marine mammal prey. These assertions included, for example, that the specified activities would harm fish and invertebrate species over the long-term, cause reductions in recruitment and effects to behavior that may reduce reproductive potential and foraging success and increase the risk of predation, and induce changes in community composition via such population-level impacts. We have addressed these claims both in our comment responses and in our review of the available literature, above. We also reviewed available information regarding populations of representative prey stocks in the northern Gulf of Mexico (GOM), which is the only U.S. location where marine seismic surveys are a routinely occurring activity. While we recognize the need for caution in assuming correlation between the ongoing survey activity in the GOM and the health of assessed stocks there, we believe this information has some value in informing the likelihood of population-level effects to prey species and, therefore, the likelihood that the specified activities would negatively impact marine mammal populations via effects to prey. We note that the information reported below is in context of managed commercial and recreational fishery exploitation, in addition to any other impacts (*e.g.,* noise) on the stocks. The species listed below are known prey species for marine mammals and represent groups with different life histories and patterns of habitat use.

- Red snapper (*Lutjanus campechanus*): Red snapper are bottom-dwelling fish generally found at approximately 10–190 m deep that typically live near hard structures on the continental shelf that have moderate to high relief (for example, coral reefs, artificial reefs, rocks, ledges, and caves), sloping soft-bottom areas, and limestone deposits. Larval snapper swim freely within the water column. Increases in total and spawning stock biomass are

predicted beginning in about 1990 (Cass-Calay *et al.,* 2015). Regional estimates suggest that recruitment in the west has generally increased since the 1980s, and has recently been above average, while recruitment in the east peaked in the mid-2000s, and has since declined. However, the most recent assessment suggests a less significant decline (to moderate levels) (Cass-Calay *et al.,* 2015).

• Yellowfin tuna (*Thunnus albacares*): Yellowfin tuna are highly migratory, living in deep pelagic waters, and spawn in the GOM from May to August. However, we note that a single stock is currently assumed for the entire Atlantic, with additional spawning grounds in the Gulf of Guinea, Caribbean Sea, and off Cabo Verde. The most recent assessment indicates that spawning stock biomass for yellowfin tuna is stable or increasing somewhat and that, overall, the stock is near levels that produce the maximum sustainable yield (ICCAT, 2016).

• King mackerel (*Scomberomorus cavalla*): King mackerel are a coastal pelagic species, found in open waters near the coast in waters from approximately 35–180 m deep. King mackerel migrate in response to changes in water temperature, and spawn in shelf waters from May through October. Estimates of recruitment demonstrate normal cyclical patterns over the past 50 years, with a period of higher recruitment most recently (1990–2007) (SEDAR, 2014). Long-term spawning stock biomass patterns indicate that the spawning stock has been either rebuilding or remained relatively consistent over the last 20 years, with nothing indicating that the stock has declined in these recent decades (SEDAR, 2014).

In summary, impacts of the specified activities will likely be limited to behavioral responses, the majority of prey species will be capable of moving out of the project area during surveys, a rapid return to normal recruitment, distribution, and behavior for prey species is anticipated, and, overall, impacts to prey species will be minor and temporary. Prey species exposed to sound might move away from the sound source, experience TTS, experience masking of biologically relevant sounds, or show no obvious direct effects. Mortality from decompression injuries is possible in close proximity to a sound, but only limited data on mortality in response to airgun noise exposure are available (Hawkins *et al.,* 2014). The most likely impacts for most prey species in a given survey area would be temporary avoidance of the area. Surveys using towed airgun arrays move through an area relatively quickly, limiting exposure to multiple impulsive sounds. In all cases, sound levels would return to ambient once a survey moves out of the area or ends and the noise source is shut down and, when exposure to sound ends, behavioral and/or physiological responses are expected to end relatively quickly (McCauley *et al.,* 2000b). The duration of fish avoidance of a given area after survey effort stops is unknown, but a rapid return to normal recruitment, distribution, and behavior is anticipated. While the potential for disruption of spawning aggregations or schools of important prey species can be meaningful on a local scale, the mobile and temporary nature of most surveys and the likelihood of temporary avoidance behavior suggest that impacts would be minor.

Based on the information discussed herein, we reaffirm our conclusion that impacts of the specified activities 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 information regarding the number of incidental takes authorized, which informs both NMFS's consideration of ''small numbers'' and the negligible impact determinations.

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).

Anticipated takes would primarily be by Level B harassment, as use of the acoustic sources (*i.e.,* airgun arrays) can result in disruption of behavioral patterns for individual marine mammals. There is also some potential for auditory injury (Level A harassment) to result for low- and high-frequency species due to the size of the predicted auditory injury zones for those species. We do not expect auditory injury to occur for mid-frequency species, as discussed in greater detail below. The required mitigation and monitoring measures are expected to minimize the severity of such taking to the extent practicable. It is unlikely that lethal takes would occur even in the absence of the mitigation and monitoring measures, and no such takes are anticipated or authorized. Below we describe how the authorized take was estimated using acoustic thresholds, sound field modeling, and marine mammal density data.

Acoustic Thresholds

NMFS uses acoustic thresholds that identify the received level of underwater sound above which exposed marine mammals generally would be reasonably expected to exhibit disruption of behavioral patterns (equated to Level B harassment) or to incur PTS of some degree (equated to Level A harassment).

Level B Harassment—Although available data are consistent with the basic concept that louder sounds evoke more significant behavioral responses than softer sounds, defining precise sound levels that will potentially disrupt behavioral patterns is difficult because responses depend on the context in which the animal receives the sound, including an animal's behavioral mode when it hears sounds (*e.g.,* feeding, resting, or migrating), prior experience, and biological factors (*e.g.,* age and sex). Some species, such as beaked whales, are known to be more highly sensitive to certain anthropogenic sounds than other species. Other contextual factors, such as signal characteristics, distance from the source, duration of exposure, and signal to noise ratio, may also help determine response to a given received level of sound. Therefore, levels at which responses occur are not necessarily consistent and can be difficult to predict (Southall *et al.,* 2007; Ellison *et al.,* 2012; Bain and Williams, 2006).

However, based on the practical need to use a relatively simple threshold based on available information that is both predictable and measurable for most activities, NMFS has historically used a generalized acoustic threshold based on received level to estimate the onset of Level B harassment. These thresholds are 160 dB rms (intermittent sources, which include impulsive sources) and 120 dB rms (continuous sources). Airguns are impulsive sound sources; therefore, the 160 dB rms threshold is appropriate for use in evaluating effects from the specified activities.

Level A Harassment—NMFS's *Technical Guidance for Assessing the Effects of Anthropogenic Sound on*

Marine Mammal Hearing (NMFS, 2018) identifies dual criteria to assess the potential for auditory injury (Level A harassment) to occur for different marine mammal groups (based on hearing sensitivity) as a result of exposure to noise. The technical guidance identifies the received levels, or thresholds, above which individual marine mammals are predicted to experience changes in their hearing sensitivity for all underwater anthropogenic sound sources, and reflects the best available science on the potential for noise to affect auditory sensitivity by:

- Dividing sound sources into two groups (*i.e.,* impulsive and non-impulsive) based on their potential to affect hearing sensitivity;
- Choosing metrics that best address the impacts of noise on hearing sensitivity, *i.e.,* peak sound pressure level (peak SPL) (reflects the physical properties of impulsive sound sources to affect hearing sensitivity) and cumulative sound exposure level (cSEL) (accounts for not only level of exposure but also duration of exposure); and
- Dividing marine mammals into hearing groups and developing auditory weighting functions based on the science supporting that not all marine mammals hear and use sound in the same manner.

The premise of the dual criteria approach is that, while there is no definitive answer to the question of which acoustic metric is most appropriate for assessing the potential for injury, both the received level and duration of received signals are important to an understanding of the potential for auditory injury. Therefore, peak SPL is used to define a pressure criterion above which auditory injury is predicted to occur, regardless of exposure duration (*i.e.,* any single exposure at or above this level is considered to cause auditory injury), and cSEL is used to account for the total energy received over the duration of sound exposure (*i.e.,* both received level and duration of exposure) (Southall *et al.,* 2007; NMFS, 2018). As a general principle, whichever criterion is exceeded first (*i.e.,* results in the largest isopleth) would be used as the effective injury criterion (*i.e.,* the more precautionary of the criteria). Note that cSEL acoustic threshold levels incorporate marine mammal auditory weighting functions, while peak pressure thresholds do not (*i.e.,* flat or unweighted). Weighting functions for each hearing group (*e.g.,* low-, mid-, and high-frequency cetaceans) are described in NMFS (2018).

NMFS (2018) recommends 24 hours as a maximum accumulation period relative to cSEL thresholds. These thresholds were developed by compiling and synthesizing the best available science, and are provided in Table 3 below. The references, analysis, and methodology used in the development of the thresholds are described in NMFS (2018), and more information is available online at: *www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-acoustic-technical-guidance.*

TABLE 3—EXPOSURE CRITERIA FOR AUDITORY INJURY FOR IMPULSIVE SOURCES

Hearing group	Peak pressure [1] (dB)	Cumulative sound exposure level [2] (dB)
Low-frequency cetaceans	219	183
Mid-frequency cetaceans	230	185
High-frequency cetaceans	202	155

[1] Referenced to 1 μPa; unweighted within generalized hearing range.
[2] Referenced to 1 μPa^2s; weighted according to appropriate auditory weighting function.

NMFS considers these updated thresholds and associated weighting functions to be the best available information for assessing whether exposure to specific activities is likely to result in changes in marine mammal hearing sensitivity.

Sound Field Modeling

BOEM's PEIS (BOEM, 2014a) provides information related to estimation of the sound fields that would be generated by potential geophysical survey activity on the mid- and south Atlantic OCS. We provide a brief summary of that modeling effort here; for more information, please see our Notice of Proposed IHAs. For full detail, please see Appendix D of BOEM's PEIS (Zykov and Carr, 2014 in BOEM, 2014a). The acoustic modeling generated a three-dimensional acoustic propagation field as a function of source characteristics and physical properties of the ocean for later integration with marine mammal density information in an animal movement model to estimate potential acoustic exposures.

The authors selected 15 modeling sites throughout BOEM's mid-Atlantic and south Atlantic OCS planning areas for use in modeling predicted sound fields resulting from use of the airgun array. The water depth at the sites varied from 30–5,400 m. Two types of bottom composition were considered: Sand and clay, their selection depending on the water depth at the source. Twelve possible sound speed profiles for the water column were used to cover the variation of the sound velocity distribution in the water with location and season. Twenty-one distinct propagation scenarios resulted from considering different sound speed profiles at some of the modeling sites. Two acoustic propagation models were employed to estimate the acoustic field radiated by the sound sources. A version of JASCO Applied Science's Marine Operations Noise Model (MONM), based on the Range-dependent Acoustic Model (RAM) parabolic-equations model, MONM–RAM, was used to estimate the SELs for low-frequency sources (below 2 kHz) such as an airgun array. For more information on sound propagation model types, please see, *e.g.,* Etter (2013). The model takes into account the geoacoustic properties of the sea bottom, vertical sound speed profile in the water column, range-dependent bathymetry, and the directivity of the source. The directional source levels for the airgun array were modeled using the Airgun Array Source Model (AASM) based on the specifications of the source such as the arrangement and volume of the guns, firing pressure, and depth below the sea surface. The modeled directional source levels were used as the input for the acoustic propagation model. For background information on major factors affecting underwater sound propagation, please see Zykov and Carr (2014).

The modeling used a 5,400 in^3 airgun array as a representative example. The array has dimensions of 16 x 15 m and consists of 18 air guns placed in three identical strings of six air guns each (please see Figure D–6 of Zykov and

Carr (2014)). The volume of individual air guns ranges from 105–660 in^3. Firing pressure for all elements is 2,000 psi. The depth below the sea surface for the array was set at 6.5 m. Please see Table 1 for a comparison to the airgun arrays planned for use by the applicant companies. Horizontal third-octave band directionality plots resulting from source modeling are shown in Figure D–8 of Zykov and Carr (2014). The estimated received levels are expressed in terms of the SEL metric over the duration of a single source pulse. For the purposes of this study, the SEL results were converted to the rms SPL metric using a range dependent conversion coefficient.

Four depth regions were classified based on bathymetry: Shallow continental shelf (<60 m); continental shelf (60–150 m); continental slope (150–1,000 m); and deep ocean (>1,000 m). The modeling results show that the largest threshold radii are typically associated with sites in intermediate water depths (250 and 900 m). Low frequencies propagate relatively poorly in shallow water (*i.e.,* water depths on the same order as or less than the wavelength). At intermediate water depths, this stripping of low-frequency sound no longer occurs, and longer-range propagation can be enhanced by the channeling of sound caused by reflection from the surface and seafloor (depending on the nature of the sound speed profile and sediment type). Table 4 shows scenario-specific modeling results for distances to the 160 dB level; results presented are for the 95 percent range to threshold.

TABLE 4—MODELING SCENARIOS AND SITE-SPECIFIC MODELED THRESHOLD RADII FROM BOEM'S PEIS

Scenario No.	Site No.[1]	Water depth (m)	Season	Bottom type	Threshold radii (m)[2]
1	1	5,390	Winter	Clay	4,969
2	2	2,560	Winter	Clay	5,184
3	3	880	Winter	Sand	8,104
4	4	249	Winter	Sand	8,725
5	5	288	Winter	Sand	8,896
6	1	5,390	Spring	Clay	4,989
7	6	3,200	Spring	Clay	5,026
8	3	880	Spring	Sand	8,056
9	7	251	Spring	Sand	8,593
10	8	249	Spring	Sand	8,615
11	1	5,390	Summer	Clay	4,973
12	6	3,200	Summer	Clay	5,013
13	3	880	Summer	Sand	8,095
14	9	275	Summer	Sand	9,122
15	10	4,300	Fall	Clay	5,121
16	11	3,010	Fall	Clay	5,098
17	12	4,890	Fall	Clay	4,959
18	13	3,580	Fall	Clay	5,069
19	3	880	Fall	Sand	8,083
20	14	100	Fall	Sand	8,531
21	15	51	Fall	Sand	8,384
Mean					6,838

Adapted from Tables D–21 and D–22 of Zykov and Carr (2014).
[1] Please see Figure D–35 of Zykov and Carr (2014) for site locations.
[2] Threshold radii to 160 dB (rms) SPL, 95 percent range.

We provide this description of the modeling performed for BOEM's PEIS as a general point of reference for the surveys, and also because three of the applicant companies—TGS, CGG, and Western—directly used these results to inform their exposure modeling, rather than performing separate sound field modeling. As described by BOEM (2014a), the modeled array was selected to be representative of the large airgun arrays likely to be used by geophysical exploration companies in the mid- and south Atlantic OCS. Therefore, we use the BOEM (2014a) results as a reasonable proxy for those three companies (please see ''Detailed Description of Activities'' for further description of the acoustic sources planned for use by these three companies). ION and Spectrum elected to perform separate sound field modeling efforts, and these are described below.

ION—ION provided information related to estimation of the sound fields that would be generated by their geophysical survey activity on the mid- and south Atlantic OCS. We provide a brief summary of that modeling effort here; for more information, please see our Notice of Proposed IHAs. For full detail, please see Appendix A of ION's application (Li, 2014; referred to hereafter as Appendix A of ION's application). ION plans to use a 36-element airgun array with a 6,420 in^3 total firing volume (please see ''Detailed Description of Activities'' for further description of ION's acoustic source). The modeling assumed that ION would operate from July to December. Sixteen representative sites were selected along survey track lines planned by ION for use in modeling predicted sound fields resulting from use of the airgun array (see Figure 2 in Appendix A of ION's application for site locations). Two acoustic propagation models were employed to estimate the acoustic field radiated by the sound sources. As was described above for BOEM's PEIS, the acoustic signature of the airgun array was predicted using AASM and MONM was used to calculate the sound propagation and acoustic field near each defined site. The modeling process follows generally that described previously for BOEM's PEIS. Key differences are the characteristics of the acoustic source (see Table 1), locations of the modeled sites, and the use of a restricted set of sound velocity profiles (*e.g.,* fall and winter). Site-specific modeling results for distances to the 160 dB rms level were presented in Table 8 of our Notice of Proposed IHAs and are not reprinted here; mean result for the

95 percent range to threshold was 5,836 m.

Spectrum—Spectrum provided information related to estimation of the sound fields that would be generated by their geophysical survey activity on the mid- and south Atlantic OCS. We provide a brief summary of that modeling effort here; for more information, please see our Notice of Proposed IHAs. For full detail, please see Appendix A of Spectrum's application (Frankel *et al.,* 2015; referred to hereafter as Appendix A of Spectrum's application). Spectrum plans to use a 32-element airgun array with a 4,920 in^3 total firing volume (please see ''Detailed Description of Activities'' for further description of Spectrum's acoustic source). Array characteristics were input into the GUNDALF model to calculate the source level and predict the array signature. The directivity pattern of the airgun array was calculated using the beamforming module in the CASS-GRAB acoustic propagation model. These models provided source input information for the range-dependent acoustic model (RAM), which was then used to predict acoustic propagation and estimate the resulting sound field. The RAM model creates frequency-specific, three-dimensional directivity patterns (sound field) based upon the size and location of each airgun in the array. As described previously, physical characteristics of the underwater environment (*e.g.,* sound velocity profile, bathymetry, substrate composition) are critical to understanding acoustic propagation; 16 modeling locations were selected that span the acoustic conditions of the survey area. Spectrum elected to use sound velocity profiles for winter and spring and assumed that half of the survey would occur in winter and half in spring. Site-specific modeling results for distances to the 160 dB rms level were presented in Table 9 of our Notice of Proposed IHAs and are not reprinted here; mean result for the 95 percent range to threshold was 9,775 m.

Marine Mammal Density Information

The best available scientific information was considered in conducting marine mammal exposure estimates (the basis for estimating take). Historically, distance sampling methodology (Buckland *et al.,* 2001) has been applied to visual line-transect survey data to estimate abundance within large geographic strata (*e.g.,* Fulling *et al.,* 2003; Mullin and Fulling, 2004; Palka, 2006). Design-based surveys that apply such sampling techniques produce stratified abundance estimates and do not provide information at appropriate spatiotemporal scales for assessing environmental risk of a planned survey. To address this issue of scale, efforts were developed to relate animal observations and environmental correlates such as sea surface temperature in order to develop predictive models used to produce fine-scale maps of habitat suitability (*e.g.,* Waring *et al.,* 2001; Hamazaki, 2002; Best *et al.,* 2012). However, these studies generally produce relative estimates that cannot be directly used to quantify potential exposures of marine mammals to sound, for example. A more recent approach known as density surface modeling couples traditional distance sampling with multivariate regression modeling to produce density maps predicted from fine-scale environmental covariates (*e.g.,* DoN, 2007; Becker *et al.,* 2014; Roberts *et al.,* 2016).

At the time the applications were initially developed, the best available information concerning marine mammal densities in the survey area was the U.S. Navy's Navy Operating Area (OPAREA) Density Estimates (NODEs) (DoN, 2007). These habitat-based cetacean density models utilized vessel-based and aerial survey data collected by NMFS from 1998–2005 during broad-scale abundance studies. Modeling methodology is detailed in DoN (2007). A more advanced cetacean density modeling effort, described in Roberts *et al.* (2016), was ongoing during initial development of the applications, and the model outputs were made available to the applicant companies. All information relating to this effort was made publicly available in March 2016.

Roberts *et al.* (2016) provided several key improvements with respect to the NODEs effort, by incorporating additional aerial and shipboard survey data from NMFS and from other organizations collected over the period 1992–2014, incorporating 60 percent more shipboard and 500 percent more aerial survey hours than did NODEs; controlling for the influence of sea state, group size, availability bias, and perception bias on the probability of making a sighting; and modeling density from an expanded set of eight physiographic and 16 dynamic oceanographic and biological covariates. There are multiple reasons why marine mammals may be undetected by observers. Animals are missed because they are underwater (availability bias) or because they are available to be seen, but are missed by observers (perception and detection biases) (*e.g.,* Marsh and Sinclair, 1989). Negative bias on perception or detection of an available animal may result from environmental conditions, limitations inherent to the observation platform, or observer ability. Therefore, failure to correct for these biases may lead to underestimates of cetacean abundance (*e.g.,* NMFS's SAR estimates fail to correct for availability bias). Use of additional data was used to improve detection functions for taxa that were rarely sighted in specific survey platform configurations. The degree of underestimation would likely be particularly high for species that exhibit long dive times or are cryptic, such as sperm whales or beaked whales. In summary, consideration of additional survey data and an improved modeling strategy allowed for an increased number of taxa modeled and better spatiotemporal resolutions of the resulting predictions. In general, we consider the models produced by Roberts *et al.* (2016) to be the best available source of data regarding cetacean density in the Atlantic. More information, including the model results and supplementary information for each model, is available at *seamap.env.duke.edu/models/Duke-EC-GOM-2015/.*

Aerial and shipboard survey data produced by the Atlantic Marine Assessment Program for Protected Species (AMAPPS) program provides an additional source of information regarding marine mammal presence in the survey areas. These surveys represent a collaborative effort between NMFS, BOEM, and the Navy. Although the cetacean density models described above do include survey data from 2010–14, the AMAPPS data for those years was not made available to the model authors. Future model updates will incorporate these data, but currently the AMAPPS data comprise a separate source of information (*e.g.,* NMFS, 2010a, 2011, 2012, 2013a, 2014, 2015a).

Cetacean density predictions provided by the Roberts *et al.* (2016) models are in most cases limited to the U.S. EEZ. However, the planned survey areas extend beyond the EEZ out to 350 nmi. Because specific modeling results were not available for this region at the time the exposure estimates were developed, the Roberts *et al.* (2016) model predictions were extrapolated out to the additional area (described in further detail below). Newer modeling products regarding cetacean densities in areas of the western North Atlantic beyond the EEZ became available (Mannocci *et al.,* 2017) following development of the exposure estimates; however, this information was not reasonably available to the applicants in

developing their applications or to NMFS in preparing the Notice of Proposed IHAs. Therefore, we retain use of the extrapolated density values from Roberts *et al.* (2016) in estimating potential exposures in the region beyond the EEZ; this approach remains reasonably representative of cetacean densities in the portion of the specific geographic region outside the EEZ.

North Atlantic Right Whale—Following publication of our Notice of Proposed IHAs, we became aware of an effort by Roberts *et al.* to update certain density models, including for the North Atlantic right whale. In contrast to other new information that was not reasonably available to us in developing the exposure estimates discussed herein (*e.g.,* Mannocci *et al.,* 2017 and additional Roberts *et al.* model revisions (discussed below)), we determined that the revised North Atlantic right whale models represent a significant improvement to the available information. These updates greatly expanded the dataset used to derive density outputs, especially within the action area, as they incorporated both AMAPPs data as well as data from aerial surveys conducted by several organizations in the southeast United States. By including these additional data sources, the number of right whale sightings used to inform the models within the action area increased by over 2,500 sightings (approximately 40 sightings in the 2015 model versus approximately 2,560 sightings in the 2017 model) (Roberts *et al.,* 2017). In addition, the updated models incorporated several improvements to minimize known biases and used an improved seasonal definition that more closely aligns with right whale biology. Importantly, the updated model outputs showed a strong relationship between right whale abundance in the action area and distance to shore out to approximately 80 km (Roberts *et al.,* 2017)—the same relationship was indicated as being out to approximately 50 km by the previous model version (Roberts *et al.,* 2016). As a result of these significant model improvements and in context of the significant concern regarding North Atlantic right whale status, we determined it necessary to produce revised exposure estimates for the North Atlantic right whale (described in further detail below). As stated by the authors, their goal in updating the right whale model was to re-examine all aspects of the model and make as many improvements as possible. This updated model represents the best available scientific information regarding North Atlantic right whale density and distribution.

We note that, in addition to the models for North Atlantic right whales, Roberts *et al.* (2017) presented updated models for 10 additional taxa (fin, humpback, minke, sei, and sperm whales; separate models for Cuvier's, Mesoplodont, and unidentified beaked whales; pilot whales; and harbor porpoise). While these models incorporate several improvements (additional data (although mostly outside of the action area), new seasonal definitions, updates to better correct for known biases), we evaluated the model outputs as being generally similar to those produced by Roberts *et al.* (2016). Thus, while the Roberts *et al.* (2017) models for these additional species likely represent minor improvements over the Roberts *et al.* (2016) models for these species, they are unlikely to result in meaningful differences if used in an exposure analysis. That is, we consider both the Roberts *et al.* (2016) and Roberts *et al.* (2017) model outputs the best available density estimates for these additional species, and estimates of exposure based on the outputs of one model are unlikely to be meaningfully different than estimates based on outputs from the other. Therefore, because these revised models were not available to us at the time of initial development of the exposure estimates and do not represent a significant improvement in the state of available scientific information, as do the updated right whale models, we did not request these updated models from the authors and retain use of the 2015 model version for these taxa.

Description of Exposure Estimates

Here, we provide applicant-specific descriptions of the processes employed to estimate potential exposures of marine mammals to given levels of received sound. The discussions provided here are specific to estimated exposures at or above the criterion for Level B harassment (*i.e.,* 160 dB rms); we provide a separate discussion below regarding our consideration of potential Level A harassment. We provide a brief summary of the exposure modeling process performed for BOEM's PEIS as a point of reference; for more information, please see our Notice of Proposed IHAs. For full detail, see Appendix E of the PEIS (BOEM, 2014a).

This description builds on the description of sound field modeling provided earlier in this section and in Appendix D of BOEM's PEIS. As described previously, 21 distinct acoustic propagation regions were defined. Reflecting seasonal differences in sound velocity profiles, these regions were specific to each season. Using the NODEs data, the average density of each species was then numerically determined for each region. However, the NODEs models do not provide outputs for the extended continental shelf areas seaward of the EEZ; therefore, known density information at the edge of the area modeled by NODEs was extrapolated to the remainder of the study area.

The results of the acoustic modeling exercise (*i.e.,* estimated 3D sound field) and the region-specific density estimates were then input into MAI's Acoustic Integration Model (AIM). AIM is a software package developed to predict the exposure of receivers (*e.g.,* an animal) to any stimulus propagating through space and time through use of a four-dimensional, individual-based, Monte Carlo-based statistical model. Within the model, simulated marine animals (*i.e.,* animats) may be programmed to behave in specific ways on the basis of measured field data. An animat movement engine controls the geographic and vertical movements (*e.g.,* speed and direction) of sound sources and animats through four dimensions (time and space) according to user inputs.

Species-specific animats were created with programmed behavioral parameters describing dive depth, surfacing and dive durations, swimming speed, course change, and behavioral aversions (*e.g.,* water too shallow). The programmed animats were then randomly distributed over a given bounded simulation area. Because the exact positions of sound sources and animals are not known in advance for proposed activities, multiple runs of realistic predictions are used to provide statistical validity to the simulated scenarios. Each species-specific simulation is seeded with a given density of animats. A separate simulation was created and run for each combination of location, movement pattern, and marine mammal species.

A model run consists of a user-specified number of steps forward in time, in which each animat is moved according to the rules describing its behavior. For each time step of the model run, the received sound levels at each animat (*i.e.,* each marine mammal) are calculated. AIM returns the movement patterns of the animats, and the received sound levels are calculated separately using the given acoustic propagation predictions at different locations. At the end of each time step, an animat ''evaluates'' its environment, including its 3D location, the time, and any received sound level.

Animat positions relative to the acoustic source (*i.e.,* range, bearing, and depth) were used to extract received level estimates from the acoustic propagation modeling results. The source levels, and therefore subsequently the received levels, include the embedded corrections for signal pulse length and M-weighting. M-weighting is a type of frequency weighting curve intended to reflect the differential potential for sound to affect marine mammals based on their sensitivity to the particular frequencies produced (Southall *et al.,* 2007). Please see Appendix D of BOEM's PEIS for further description of the application of M-weighting filters. For each bearing, distance, and depth from the source, the received level values were expressed as SPLs (rms) with units of dB re 1μ Pa. These are then converted back to intensity and summed over the duration of the exercise to generate an integrated energy level, expressed in terms of dB re 1 μPa^2-sec or dB SEL. The number of animats per species that exceeded a given criterion (*e.g.,* 160 dB rms) may then be determined, and these results scaled according to the relationship of model-to-real world densities per species. That is, the exposure results are corrected using the actual species- and region-specific density derived from the density model outputs (as described above) to give real-world estimates of exposure to sound exceeding a given received level.

As noted previously, the NODEs models (DoN, 2007) provided the best available information at the time of initial development for these applications. Outputs of the cetacean density models described by Roberts *et al.* (2016) were subsequently made available to the applicant companies, which, with the exception of CGG, had previously submitted applications. Two applicants (TGS and Western) elected to consider the new information and produced revised applications accordingly. CGG used the Roberts *et al.* (2016) models in developing their application. Two applicants (Spectrum and ION) declined to use the Roberts *et al.* (2016) density models. However, we worked with MAI—which performed the initial exposure modeling provided in the Spectrum and ION applications—to produce revised exposure estimates utilizing the outputs of the Roberts *et al.* (2016) density models.

In order to revise the exposure estimates for Spectrum and ION, we first extracted appropriate density estimates from the Roberts *et al.* (2016) model outputs. Because both Spectrum and ION used modeling processes conceptually similar to that described above for BOEM's PEIS, these density estimates would replace those previously derived from the NODEs models in rescaling the exposure estimation results from those derived from animal movement modeling using a user-specified density. The steps involved in calculating mean marine mammal densities over the 21 modeling areas used in both BOEM's PEIS and the applications were described in our Notice of Proposed IHAs, and are not repeated here. As was the case for the NODEs model outputs, the Roberts *et al.* (2016) model outputs are restricted to the U.S. EEZ. Therefore, we similarly extended the edge densities to cover the area outside of the data extent. This process was also described in our Notice of Proposed IHAs, and is not repeated here.

Spectrum—Spectrum's sound field estimation process was previously described, and their exposure modeling process is substantially similar to that described above for BOEM's PEIS. Spectrum's exposure modeling process was described in full in our Notice of Proposed IHAs; please see that document for more detail. As described previously, Spectrum limited their analysis to winter and spring seasons and therefore used only ten of the 21 seasonal propagation acoustic regions. Half of the survey activity was assumed to occur in winter and half in spring.

In summary, the original exposure results were obtained using AIM to model source and animat movements, with received SEL for each animat predicted at a 30-second time step. This predicted SEL history was used to determine the maximum SPL (rms or peak) and cSEL for each animat, and the number of exposures exceeding relevant criteria recorded. The number of exposures are summed for all animats to get the number of exposures for each species, with that summed value then scaled by the ratio of real-world density to the model density value. The final scaling value was the ratio of the length of the modeled survey line to the length of survey line in each modeling region. The exposure estimates provided in Spectrum's application were based on the NODEs model outputs. In order to make use of the best available information (*i.e.,* Roberts *et al.* (2016)), we extracted species- and region-specific density values as described above. These were provided to MAI in order to rescale the original exposure results produced using the seeded animat density; revised exposure estimates are shown in Table 6.

As stated above, Spectrum notified NMFS on June 26, 2018, of a modification to their survey plan. Note that analysis corresponding with Spectrum's original survey plan is retained here, in ''Estimated Take.'' Please see ''Spectrum Survey Plan Modification'' for further information and for revised (and authorized) take numbers (Table 17) relating to Spectrum's modified survey plan.

ION—ION's sound field estimation process was previously described, and their exposure modeling process is substantially similar to that described above for BOEM's PEIS (and for Spectrum). ION's exposure modeling process was described in full in our Notice of Proposed IHAs; please see that document for more detail. The same acoustic propagation regions described for BOEM's PEIS were used by ION for exposure modeling; however, ION limited their analysis to summer and fall seasons and therefore used only 11 of the 21 regions. Whichever season returned the higher number of estimated exposures for a given species was assumed to be the season in which the survey occurred, *i.e.,* ION's requested take authorization corresponds to the higher of the two seasonal species-specific exposure estimates.

In summary, the original exposure results were obtained using AIM to model source and animat movements, with received SEL for each animat predicted at a 30-second time step. This predicted SEL history was used to determine the maximum SPL (rms or peak) and cSEL for each animat, and the number of exposures exceeding relevant criteria recorded. The number of exposures are summed for all animats to get the number of exposures for each species, with that summed value then scaled by the ratio of real-world density to the model density value. The final scaling value was the ratio of the length of the modeled survey line to the length of survey line in each modeling region. As described above, the exposure estimates provided in ION's application were based on the NODEs model outputs. In order to make use of the best available information (*i.e.,* Roberts *et al.* (2016)), we extracted species- and region-specific density values as described above. These were provided to MAI in order to rescale the original exposure results produced using the seeded animat density; revised exposure estimates are shown in Table 6.

TGS—TGS did not conduct their own sound field modeling, instead relying on the sound field estimates provided by BOEM (2014a). For purposes of exposure modeling, TGS considered threshold radii for three depth bins: <880 m, 880–2,560 m, >2,560 m (note that there are no sound field modeling sites at depths between 880–2,560 m).

When considering the 21 modeling scenarios across the 15 sites, threshold radii shown in Table 4 break down evenly with 11 at depths ≤880 m (mean threshold radius of 8,473 m) and ten at depths ≥2,560 m (mean threshold radius of 5,040 m). Therefore, the overall mean for all scenarios of 6,838 m was used for estimating potential exposures for track lines occurring in water depths of 880–2,560 m.

Regarding marine mammal occurrence, TGS considered both the Roberts *et al.* (2016) density models as well as the AMAPPS data. TGS stated that there are aspects of the Roberts *et al.* (2016) methodology that limit the model outputs' applicability to estimating marine mammal exposures to underwater sound and determined it appropriate to develop their own density estimates for certain species using AMAPPS data.

As stated above, we believe the density models described by Roberts *et al.* (2016) provide the best available information at the time of our evaluation and recommend their use for species other than those expected to be extremely rare in a given area. However, TGS used the most recent observational data available in their alternative take estimation process conducted for seven of the affected species or groups. We acknowledge their concerns regarding use of predictive density models for species with relatively few observations in the survey area, *e.g.,* that model-derived density estimates must be applied cautiously on a species-by-species basis with the recognition that in some cases the out-of-bound predictions could produce unrealistic results (Becker *et al.,* 2014). Further, use of uniform (*i.e.,* stratified) density models assumes a given density over a large geographic range which may include areas where the species has rarely or never been observed. For the seven species or species groups that TGS applied their alternative approach to (described below), five are modeled in whole or part through use of stratified models. We also acknowledge (as do Roberts *et al.* (2016)) that predicted habitat may not be occupied at expected densities or that models may not agree in all cases with known occurrence patterns, and that there is uncertainty associated with predictive habitat modeling (*e.g.,* Becker *et al.,* 2010; Forney *et al.,* 2012). We determined that TGS' alternative approach (for seven species or species groups) is acceptable and, importantly, we recognize that there is no model or approach that is always the most appropriate and that there may be multiple approaches that may be considered acceptable (*e.g.,* Box, 1979). Further detailed discussion on these topics was provided in our Notice of Proposed IHAs, and is not repeated here.

In summary, TGS described the following issues in support of their development of an alternative approach for certain species:

- There are very few sightings of some species despite substantial survey effort;
- The modeling approach extrapolates based on habitat associations and assumes some species' occurrence in areas where they have never been or were rarely documented (despite substantial effort);
- In some cases, uniform density models spread densities of species with small sample sizes across large areas of the EEZ without regard to habitat, and;
- The most recent NOAA shipboard and aerial survey data (*i.e.,* AMAPPS) were not included in model development.

As a result of their general concerns regarding suitability of model outputs for exposure estimation, TGS developed a scheme related to the number of observations in the dataset available to Roberts *et al.* (2016) for use in developing the density models. Extremely rare species (*i.e.,* less than four sightings in the survey area) were considered to have a very low probability of encounter, and it was assumed that the species might be encountered once. Therefore, a single group of the species was considered as expected to be exposed to sound exceeding the 160 dB rms harassment criterion. We agree with this approach for rarely occurring species and adopted it for all applicants, as described below.

As described previously, marine mammal abundance has traditionally been estimated by applying distance sampling methodology (Buckland *et al.,* 2001) to visual line-transect survey data. Buckland *et al.* (2001) recommend a minimum sample size of 60–80 sightings to provide reasonably robust estimates of density and abundance to fit the mathematical detection function required for this estimation; smaller sample sizes result in higher variance and thus less confidence and less accurate estimates. While we agree that TGS' approach is a reasonable one, we also note that the Buckland *et al.* (2001) recommendation that sample size should generally be at least 60–80 should be considered as general guidance but not an absolute rule. Buckland *et al.* (2001) provide no theoretical proof for it and, in fact, it has not been followed as a rule in practice. Miller and Thomas (2015) provide an example where a detection function fitted to 30 sightings resulted in a detection function with low bias. NMFS's line-transect abundance estimates are in some cases based on many fewer sightings, *e.g.,* stock assessments based on Palka (2012). For species meeting the Buckland *et al.* guideline within the survey area, TGS used Roberts *et al.* (2016)'s model. For species with fewer sightings (but with greater than four sightings in the survey area), TGS used what they refer to as ''Line Transect Theory'' in conjunction with AMAPPS data to estimate species density within the assumed 160 dB rms zone of ensonification.

Nine species or species groups met TGS' requirement of having at least 60 sightings within the survey area in the dataset available to Roberts *et al.* (2016): Atlantic spotted dolphin, pilot whales, striped dolphin, beaked whales, bottlenose dolphin, Risso's dolphin, common dolphin, sperm whale, and humpback whale. The steps involved in the exposure estimation process for these species was described in full in our Notice of Proposed IHAs and is not repeated here.

Seven species or species groups met TGS' criterion for conducting exposure modeling, but did not have the recommended 60 sightings in the survey area: Minke whale, fin whale, *Kogia* spp., harbor porpoise, pantropical spotted dolphin, clymene dolphin, and rough-toothed dolphin. For these species, TGS did not feel use of the density models was appropriate and developed a method using the available data instead (*i.e.,* AMAPPS data as well as data considered by Roberts *et al.* (2016), excluding results of surveys conducted entirely outside of an area roughly coincident with the planned survey area); species-specific rationale is provided in section 6.3 of TGS' application. Please see section 6.3 of TGS' application for further details regarding the AMAPPS survey effort considered by TGS. Table 6–1 in TGS' application summarizes the AMAPPS data available for consideration by the authors. The steps involved in the exposure estimation process for these species was described in full in our Notice of Proposed IHAs and is not repeated here (see Table 6–4 in TGS' application for numerical process details).

TGS initially proposed use of a mitigation source (*i.e.,* 90-in^3 airgun) for line turns and transits not exceeding three hours and produced exposure estimates specific to use of the mitigation source. As described in ''Mitigation,'' we do not allow use of the mitigation source; therefore, exposure estimates specific to use of a mitigation

gun would not actually occur. In their application, TGS provided exposure estimates specific to use of the full-power array and to use of the mitigation gun for the seven species for which the alternative approach was followed, but not for the nine species whose exposure estimates are based on the Roberts *et al.* (2016) density models (for the latter group, only a combined total was provided). Therefore, in our Notice of Proposed IHAs, we did not include mitigation gun exposure estimates for the former group but did for the latter group, noting exposure estimates for those nine species were slightly overestimated. However, following publication of our Notice of Proposed IHAs, TGS provided a breakdown for these species according to full-power array versus mitigation source; therefore, we have removed the estimates associated with use of the mitigation source for all species. Take authorization numbers provided for TGS (Table 6) reflect this appropriate adjustment.

Western—Western's approach to estimating potential marine mammal exposures to underwater sound was identical to that described above for TGS; therefore, we do not provide a separate description for Western.

Western also initially proposed use of a mitigation source for line turns and transits not exceeding three hours and produced exposure estimates specific to use of the mitigation source. Like TGS, Western's application provided information specific to use of the full-power array versus the mitigation source for the seven species for which the alternative approach was followed, but not for the nine species whose exposure estimates are based on the Roberts *et al.* (2016) density models (for the latter group, only a combined total was provided). However, unlike TGS, Western did not provide additional information following publication of our Notice of Proposed IHAs. Therefore, mitigation gun exposure estimates are included in the total for the latter group, and exposure estimates for those nine species are slightly overestimated.

CGG—CGG used applicable results from BOEM's sound field modeling exercise in conjunction with the outputs of models described by Roberts *et al.* (2016) to inform their estimates of likely acoustic exposures. CGG's exposure modeling process was described in full in our Notice of Proposed IHAs; please see that document for more detail. Considering only the BOEM modeling sites that are in or near CGG's survey area provided a mean radial distance to the 160 dB rms criterion of 6,751 m (range 5,013–8,593 m). Taxon-specific model outputs, averaged over the six-month period planned for the survey (*i.e.,* July-December) where relevant, were used with the assumed ensonification zone to provide estimates of marine mammal exposures to noise above the 160 dB rms threshold. Similar to other applicants, CGG performed an interpolation analysis to estimate density values for the portion of planned survey area outside the EEZ.

North Atlantic Right Whale—As described above, given the current status of North Atlantic right whales, we re-evaluated available information subsequent to public review of our proposed IHAs. Finding that significant improvements were available to us, we determined it appropriate to re-estimate acoustic exposures specifically for right whales using the updated models. To do so, we relied on the sound field modeling results provided in BOEM's 2014 PEIS (see description above and Appendix D in BOEM (2014a)), as was previously done by TGS, CGG, and Western in their IHA applications. Using site- and season-specific radii to the 160 dB rms threshold (95 percent range, see Table 4 above or Table D–22 in BOEM (2014a)) and the total amount of trackline planned by each company within the acoustic modeling regions specified in BOEM's 2014 PEIS (see Appendix E, Table E–5 and Figures E–11 to E14 in BOEM (2014a)), we calculated monthly, region-specific ensonified areas for each company as if their entire survey tracklines were completed in each month. Then, using the updated 2017 density model outputs (Roberts *et al.,* 2017), we calculated average monthly regional right whale densities, which were then multiplied by the monthly ensonified areas. Finally, these data were averaged (annually or according to the planned operating window where appropriate) to estimate the average total exposure of North Atlantic right whales. In this way, we incorporated the seasonal variation in density of right whales since we do not know the exact distribution of survey effort within each company's operating window.

Importantly, in these calculations we took into account the time-area restrictions specified in ''Mitigation.'' For the year-round closure areas, data (*i.e.,* ensonified areas and North Atlantic right whale densities) were not used to formulate exposure estimates since surveys would be completely prohibited within these areas. In the seasonal restriction areas, only data from months when the areas are open were used in calculating the exposure estimates. The final resulting exposure estimates then are based on the best available information on North Atlantic right whale densities within the action area (Roberts *et al.,* 2017), fully take into account all time-area restrictions, and are specific to each company's tracklines and planned operating window (if specified). Take estimates shown in Table 6 for North Atlantic right whales reflect this analysis, and replace those previously estimated using different information and specified in our Notice of Proposed IHAs.

Time-Area Restrictions—Following review of public comments, we conducted an analysis of expected take avoided due to implementation of the time-area restrictions described in ''Mitigation.'' To do this, we took an approach related to that previously described for right whales. In brief, we started with the existing take estimates as described in our Notice of Proposed IHAs and then calculated the take that would be avoided due to the planned restrictions. We then subtracted this from the originally proposed take to get our final take estimates. As described below, we took a slightly different approach for the sperm whale as compared with other species in that we accounted for the seasonal restriction of Area #4 (the ''Hatteras and North'' restriction; see ''Mitigation''). We did this because the area was designed in part specifically to benefit sperm whales, and because density model outputs are provided at monthly resolution for sperm whales, whereas density model outputs are provided at only annual resolution for beaked whales and pilot whales (Area #4 was also designed specifically to benefit these species). Take avoided due to seasonal restrictions, versus year-round closures, cannot be calculated for species for which only annual density outputs are available. For those species with monthly data availability but for which the seasonal restriction was not designed, we determined that the analysis was unlikely to result in meaningful changes to the take estimates.

For sperm whales, we calculated the monthly density within each year-round closure area using the Roberts *et al.* (2016) model outputs and calculated the monthly ensonified area within each year-round closure for each company based on their planned tracklines and the radii to the 160 dB rms threshold. We then multiplied these monthly numbers by each other to estimate the monthly take avoided and, finally, computed the annual average of these avoided takes to estimate the overall take that would be avoided due to the year-round closures. For the seasonal

restrictions, only Area #4 (the ''Hatteras and North'' restriction; see ''Mitigation'') was accounted for since it is the only seasonal restriction designed specifically to protect sperm whales. While we considered accounting for the North Atlantic right whale seasonal restriction, we opted not to since it primarily protects shallower waters where sperm whales are less likely to be found, and the added complication of incorporating the restriction was unlikely to result in meaningful changes to the overall take estimates for sperm whales. To account for Area #4, we calculated the change in take due to the restriction in a similar fashion to the year-round closures above, except that instead of calculating the change in take based on an annual average, we calculated the difference between the average take for when the area is open and when the area is closed in order to calculate the overall change in take due to restricting surveys within this area. As before, for these calculations we took into account specific survey timing where relevant but otherwise assumed the surveys could happen at any time of the year. The combined year-round and seasonal avoided takes were then subtracted from the originally proposed take authorizations described in our Notice of Proposed IHAs to calculate the final take estimates for sperm whales.

For other species, a simpler approach was taken. First, we did not account for any seasonal restrictions, either because sufficient data is not available or because the seasonal restrictions' benefit in protecting species for which they were not specifically designed is unclear. Second, we did not recalculate density estimates specifically within the year-round closures, but instead relied on density estimates derived from the Roberts *et al.* (2016) model outputs for each acoustic modeling region used in BOEM's 2014 PEIS. Using these density estimates, we then followed the same procedure detailed above for sperm whales (multiplied monthly or seasonal densities by monthly or seasonal ensonified area, and compute annual or operating window average) to estimate the take that would be avoided due to the year-round closures. These avoided takes were then subtracted from the originally proposed take authorizations described in our Notice of Proposed IHAs to calculate the final take estimates.

Level A Harassment

All requests for IHAs described herein were received prior to NMFS's original 2016 technical guidance and, therefore, did not reflect consideration of the currently best available information regarding the potential for auditory injury. In our Notice of Proposed IHAs, we described a process by which we estimated expected takes by Level A harassment in reflection of both NMFS's technical guidance and the specific survey characteristics (*i.e.,* actual line-kms and specific airgun arrays planned for use) using modeled auditory injury exposure results found in BOEM's 2014 PEIS. The PEIS results were based on both the Southall *et al.* (2007) guidance (a precursor to NMFS's technical guidance) and the historical 180-dB rms criterion (which provides information relevant to a comparison to the likelihood of injurious exposure resulting from peak pressure). That process was described in our Notice of Proposed IHAs and is not repeated here. However, following review of public comments, we determined it appropriate to re-evaluate the analysis, as described below.

In our Notice of Proposed IHAs, we acknowledged that the Level A exposure estimates provided therein—based on adjustments made to the results provided in BOEM's PEIS—were a rough approximation of potential exposures, with multiple limitations in reflection of the available information or lack thereof. For example, specific trackline locations planned by the applicant companies may differ somewhat from those considered in BOEM's PEIS, although it is likely that all portions of the survey area are considered in the PEIS analysis. More importantly, the PEIS exposure estimates were based on outputs of the NODEs models (DoN, 2007) available for BOEM's analysis versus the density models subsequently provided by Roberts *et al.* (2016), which we believe represent the best available information for purposes of exposure estimation. In addition, we noted that we did not attempt to approximate the probability of marine mammal aversion or to incorporate the effects of mitigation on the likelihood of Level A harassment. Following review of public comments, we reconsidered the likelihood of potential auditory injury, specific to each hearing group (*i.e.,* low-frequency, mid-frequency, and high-frequency), and re-evaluated the specific Level A harassment estimates presented in our Notice of Proposed IHAs. Here, we provide a revised analysis of likely takes by Level A harassment.

Specifically, we determined that there is a low likelihood of take by Level A harassment for any species, and that this likelihood is primarily influenced by the specific hearing group. For mid- and high-frequency cetaceans, potential auditory injury would be expected to occur on the basis of instantaneous exposure to peak pressure output from an airgun array, leading to a relatively straightforward consideration of the Level A harassment zone as an areal subset of the Level B harassment zone and, therefore, takes by Level A harassment as a subset of the previously enumerated takes by Level B harassment. However, for mid-frequency cetaceans, additional considerations of the small calculated Level A harassment zone size in conjunction with the properties of sound fields produced by arrays in the near field versus far field lead to a logical conclusion that Level A harassment is so unlikely for species in this hearing group as to be discountable. For low-frequency cetaceans, consideration of the likely potential for auditory injury is not straightforward, as such exposure would occur on the basis of the accumulation of energy output over time by an airgun array. Additional factors, such as the relative motion of source and receiver and the implementation of mitigation lead us to conclude that a quantitative evaluation of such potential, in light of the available information, does not make sense. Our evaluations for all three hearing groups are detailed below.

As part of the exposure estimation process described in our Notice of Proposed IHAs, we calculated expected injury zones specific to each applicant's array for each hearing group relative to injury criteria for both the cSEL and peak pressure metrics. The results of this process, shown in Table 5, remain valid and were used to inform the revised estimates of take by Level A harassment described herein. For the cSEL metric, in order to incorporate the technical guidance's weighting functions over an array's full acoustic band, we obtained unweighted spectrum data (modeled in 1 Hz bands) for a reasonably equivalent acoustic source (*i.e.,* a 36-airgun array with total volume of 6,600 in^3). Using these data, we made adjustments (dB) to the unweighted spectrum levels, by frequency, according to the weighting functions for each relevant marine mammal hearing group. We then converted these adjusted/weighted spectrum levels to pressures (micropascals) in order to integrate them over the entire broadband spectrum, resulting in broadband weighted source levels by hearing group that could be directly incorporated within NMFS's User Spreadsheet (*i.e.,* override the Spreadsheet's more simple weighting factor adjustment).

When NMFS (2016) was published, in recognition of the fact that appropriate

isopleth distances could be more technically challenging to predict because of the duration component in the new thresholds, NMFS developed a User Spreadsheet that includes tools to help predict a simple isopleth that can be used in conjunction with marine mammal density to help predict exposures. For mobile sources, such as the surveys considered here, the User Spreadsheet predicts the closest distance at which a stationary animal would not incur PTS if the sound source traveled by the animal in a straight line at a constant speed (the ''safe distance'' methodology discussed below). For more information about the User Spreadsheet, please see *www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-acoustic-technical-guidance*.

Using the User Spreadsheet's ''safe distance'' methodology for mobile sources (described by Sivle *et al.,* 2014) with the hearing group-specific weighted source levels, and inputs assuming spherical spreading propagation, a source velocity of 4.5 kn, shot intervals specified by the applicants, and pulse duration of 100 ms, we then calculated potential radial distances to auditory injury zones relative to the cSEL metric. We also calculated potential radial distances to auditory injury zones on the basis of maximum peak pressure using values provided by the applicants (Table 1) and assuming a simple model of spherical spreading propagation. We note that our Notice of Proposed IHAs contained an error. On page 26254 of that notice, we stated that the range of distances for injury zones relative to the cSEL metric was 80–4,766 m. The correct range is 80–951 m; results are shown in Table 5.

TABLE 5—ESTIMATED AUDITORY INJURY ZONES [1]

Hearing group	Metric	Spectrum	ION	TGS	Western	CGG
Low-frequency	cSEL	757	951	380	80	757
	peak	224	79	63	71	50
Mid-frequency	cSEL	0	0	0	0	0
	peak	63	22	18	20	14
High-frequency	cSEL	1	8	1	0	1
	peak	1,585	562	447	501	355
Estimated near-field [2]		417	233	142	80	141

[1] Radial isopleth distances presented in meters.
[2] See discussion of ''near-field'' below.

Based on our analysis of expected injury zones (Table 5), accumulation of energy is considered to be the predominant source of potential auditory injury for low-frequency cetaceans in all cases, while instantaneous exposure to peak pressure received levels is considered to be the predominant source of potential injury for both mid- and high-frequency cetaceans in all cases. Please note that discussion in this section and estimates of take by Level A harassment provided in Table 6 for Spectrum relate to Spectrum's original survey plan. Please see ''Spectrum Survey Plan Modification'' for additional discussion of Level A harassment reflecting Spectrum's modified survey plan.

Mid-Frequency Cetaceans—For all mid-frequency cetaceans, following re-evaluation of the available scientific literature regarding the auditory sensitivity of mid-frequency cetaceans and the properties of airgun array sound fields, we do not expect any reasonable potential for Level A harassment to occur. For these species, the only potential injury zones (for all applicants) would be based on the peak pressure metric (Table 5). However, the estimated zone sizes for the 230 dB peak threshold for mid-frequency cetaceans range from only 14 m to 63 m. While in a theoretical modeling scenario it is possible for animats to engage with such small assumed zones around a notional point source and, subsequently, for these interactions to scale to predictions of real-world exposures given a sufficient number of predicted 24-hr survey days in confluence with sufficiently high predicted real-world animal densities—*i.e.,* the modeling process that resulted in the predicted exposure estimates for mid-frequency cetaceans in BOEM's PEIS—this is not a realistic outcome. The source level of the array is a theoretical definition assuming a point source and measurement in the far-field of the source (MacGillivray, 2006). As described by Caldwell and Dragoset (2000), an array is not a point source, but one that spans a small area. In the far-field, individual elements in arrays will effectively work as one source because individual pressure peaks will have coalesced into one relatively broad pulse. The array can then be considered a ''point source.'' For distances within the near-field, *i.e.,* approximately 2–3 times the array dimensions, pressure peaks from individual elements do not arrive simultaneously because the observation point is not equidistant from each element. The effect is destructive interference of the outputs of each element, so that peak pressures in the near-field will be significantly lower than the output of the largest individual element. Here, the 230 dB peak isopleth distances would in all cases be expected to be within the near-field of the arrays where the definition of source level breaks down. Therefore, actual locations within these distances (*i.e.,* 14–63 m) of the array center where the sound level exceeds 230 dB peak SPL would not necessarily exist. In general, Caldwell and Dragoset (2000) suggest that the near-field for airgun arrays is considered to extend out to approximately 250 m.

In order to provide quantitative support for this theoretical argument, we calculated expected maximum distances at which the near-field would transition to the far-field (Table 5). For a specific array one can estimate the distance at which the near-field transitions to the far-field by:

$$D = \frac{L^2}{4\lambda}$$

with the condition that $D >> \lambda$, and where D is the distance, L is the longest dimension of the array, and λ is the wavelength of the signal (Lurton, 2002). Given that λ can be defined by:

$$\lambda = \frac{v}{f}$$

where f is the frequency of the sound signal and v is the speed of the sound in the medium of interest, one can rewrite the equation for D as:

$$D = \frac{fL^2}{4v}$$

and calculate D directly given a particular frequency and known speed of sound (here assumed to be 1,500

meters per second in water, although this varies with environmental conditions).

To determine the closest distance to the arrays at which the source level predictions in Table 1 are valid (*i.e.,* maximum extent of the near-field), we calculated *D* based on an assumed frequency of 1 kHz. A frequency of 1 kHz is commonly used in near-field/far-field calculations for airgun arrays (Zykov and Carr, 2014; MacGillivray, 2006; NSF and USGS, 2011), and based on representative airgun spectrum data and field measurements of an airgun array used on the R/V *Marcus G. Langseth,* nearly all (greater than 95 percent) of the energy from airgun arrays is below 1 kHz (Tolstoy *et al.,* 2009). Thus, using 1 kHz as the upper cut-off for calculating the maximum extent of the near-field should reasonably represent the near-field extent in field conditions.

If the largest distance to the peak sound pressure level threshold was equal to or less than the longest dimension of the array (*i.e.,* under the array), or within the near-field, then received levels that meet or exceed the threshold in most cases are not expected to occur. This is because within the near-field and within the dimensions of the array, the source levels specified in Table 1 are overestimated and not applicable. In fact, until one reaches a distance of approximately three or four times the near-field distance the average intensity of sound at any given distance from the array is still less than that based on calculations that assume a directional point source (Lurton, 2002). For example, an airgun array used on the R/V *Marcus G. Langseth* has an approximate diagonal of 29 m, resulting in a near-field distance of 140 m at 1 kHz (NSF and USGS, 2011). Field measurements of this array indicate that the source behaves like multiple discrete sources, rather than a directional point source, beginning at approximately 400 m (deep site) to 1 km (shallow site) from the center of the array (Tolstoy *et al.,* 2009), distances that are actually greater than four times the calculated 140-m near-field distance. Within these distances, the recorded received levels were always lower than would be predicted based on calculations that assume a directional point source, and increasingly so as one moves closer towards the array (Tolstoy *et al.,* 2009). Given this, relying on the calculated distances (Table 5) as the distances at which we expect to be in the near-field is a conservative approach since even beyond this distance the acoustic modeling still overestimates the actual received level.

Within the near-field, in order to explicitly evaluate the likelihood of exceeding any particular acoustic threshold, one would need to consider the exact position of the animal, its relationship to individual array elements, and how the individual acoustic sources propagate and their acoustic fields interact. Given that within the near-field and dimensions of the array source levels would be below those in Table 1, we believe exceedance of the peak pressure threshold would only be possible under highly unlikely circumstances.

Therefore, we expect the potential for Level A harassment of mid-frequency cetaceans to be de minimis, even before the likely moderating effects of aversion and/or other compensatory behaviors (*e.g.,* Nachtigall *et al.,* 2018) are considered. We do not believe that Level A harassment is a likely outcome for any mid-frequency cetacean and do not authorize any Level A harassment for these species.

Low-Frequency Cetaceans—For low-frequency cetaceans, we previously adjusted the BOEM PEIS estimates of potential Level A harassment to account for NMFS's technical acoustic guidance, as described in our Notice of Proposed IHAs. This process resulted in few estimated Level A harassment exposures for low-frequency cetaceans, *i.e.,* 2–22 such exposures for humpback whales and 0–1 such exposures for minke whales, depending on array specifics, and zero exposures for right whales and fin whales (see Table 11 in our Notice of Proposed IHAs). The potential injury zones are relatively large for low-frequency cetaceans (up to 951 m; Table 5); therefore, we expect that some Level A harassment may occur for the most commonly occurring low-frequency cetacean species (*i.e.,* humpback, fin, and minke whales). However, we also note that injury on the basis of accumulation of energy is not a straightforward consideration of calculated zone size, as is consideration of injury on the basis of instantaneous peak pressure exposure. For example, observation of a whale at the distance calculated as being the ''injury zone'' using the cSEL criterion does not necessarily mean that the animal has in fact incurred auditory injury. Rather, the animal would have to be at the calculated distance (or closer) as the mobile source approaches, passes, and recedes from the exposed animal, being exposed to and accumulating energy from airgun pulses the entire time, as is implied by the name of the ''safe distance'' methodology by which such zone distances are calculated.

Therefore, while we do believe that some limited Level A harassment of low-frequency cetaceans is likely unavoidable, despite the required mitigation measures (including ramp-up, shutdown upon detection within a 500-m exclusion zone for most mysticetes and shutdown upon detection of North Atlantic right whales within an expanded 1.5-km exclusion zone; see ''Mitigation''), we do not believe that the process followed in estimating potential Level A harassment in our Notice of Proposed IHAs is the most appropriate method. Further, upon re-evaluation of the results of that process, we do not have confidence in those results, which suggest that Level A harassment is likely for humpback whales but not for fin whales. Upon reconsideration of the available information, we note that the original information from BOEM's PEIS includes prediction of zero incidents of Level A harassment for fin whales while predicting non-zero results for all other mysticete species (see Table E–4 in BOEM (2014a))—a puzzling result that underlies the lack of predicted Level A harassment for fin whales in our Notice of Proposed IHAs. Therefore, we apply a simplified approach intended to acknowledge that there would likely be some minimal, yet difficult to accurately quantify, Level A harassment of certain mysticete species. As a result of the planned mitigation, including a seasonal restriction (or alternate methods of equivalent impact avoidance) and an expanded right whale exclusion zone of 1.5 km (intended to practicably avoid or minimize interaction with North Atlantic right whales; see ''Mitigation''), we do not expect any reasonable potential for Level A harassment of North Atlantic right whales (consistent with the predictions of our original analysis). Any likely potential for the occurrence of Level A harassment is further minimized by likely aversion. For example, Ellison *et al.* (2016) demonstrated that animal movement models where no aversion probability was used overestimated the potential for high levels of exposure required for PTS by about five times.

In order to account for the minimal likelihood of Level A harassment occurring for low-frequency cetaceans, we assume that in most cases during the course of conducting the survey at least one group of each species could incur auditory injury for all applicants other than Western. (As shown in Table 5, the calculated injury zone for Western is only 80 m. It is extremely unlikely that injury could occur given such a small

calculated zone, especially in context of a required 500-m exclusion zone.) We acknowledge that application of group size to estimation of take is more appropriate for take resulting from instantaneous exposure than it is for take resulting from the accumulation of energy, as any given group may disperse to some degree in a way that could lead to differing accumulation among individuals of the group. However, given the low likelihood of take by Level A harassment, small group sizes typical of mysticetes, and the likelihood that these individuals will remain within close distance of one another during the exposure, we believe that use of group size is appropriate in this context.

For applicants other than Western, we consider both the size of the calculated potential injury zone and the total amount of planned survey effort. Spectrum, CGG, and ION have larger calculated potential injury zones, *i.e.,* larger than the required 500-m exclusion zone (Table 5). However, ION has significantly less total survey effort (approximately half of what is planned by Spectrum and CGG; Table 1). TGS has a significantly smaller calculated injury zone, *i.e.,* smaller than the required 500-m exclusion zone. However, at 380 m, the zone is sufficiently large that a whale could potentially occur within the zone without being observed in time to implement shutdown, and TGS's planned survey effort is substantially larger (approximately twice as large as that planned by Spectrum and CGG). Therefore, TGS' lower likelihood of causing injury is offset to some degree by their substantially greater survey effort. Finally, on the basis of expected taking by Level B harassment (Table 6), we see that the location and timing of CGG's planned survey effort results in significantly less potential interaction with humpback whales than for Spectrum and TGS.

In summary, we conclude there is sufficiently reasonable potential for Level A harassment (even considering the likely effects of aversion) that it is appropriate to authorize take by Level A harassment for a minimum of one average size group of each relevant species (*i.e.,* humpback, minke, and fin whales) for Spectrum, TGS, ION, and CGG. For Spectrum, in consideration of the calculated injury zone and level of planned effort, we increase this to two groups of each relevant species. For TGS, in consideration of the level of planned survey effort and despite the smaller calculated injury zone, we also increase this to two groups of each relevant species. For CGG, in consideration of the calculated injury zone and level of planned effort, we increase this to two groups for minke whales and fin whales only, given the lower potential for interaction with humpback whales. For ION, given the lower level of planned survey effort, we maintain the take authorization at one group of each relevant species. As a point of reference, we note that BOEM's PEIS analysis of potential takes by Level A harassment estimated that no more than 5.9 humpback whales could experience auditory injury in any given year for all surveys combined, despite a greater amount of assumed activity. Estimates were much less for all other species (see Table E–4 of BOEM (2014a)). As noted above, please see ''Spectrum Survey Plan Modification'' for additional discussion of Level A harassment reflecting Spectrum's modified survey plan, including Table 17, providing revised (and authorized) levels of take by Level A harassment for Spectrum.

Average group size was determined by considering observational data from AMAPPS survey effort (*e.g.,* NMFS, 2010a, 2011, 2012, 2013a, 2014, 2015a). Average group sizes were as follows: Fin whale, 1.3 whales; humpback whale, 1.4 whales; minke whale, 1.2 whales. Therefore, we assume an average group size of two whales for each species. These take authorizations, which are subtracted from the estimates for take by Level B harassment to avoid double-counting, are shown in Table 6.

High-Frequency Cetaceans—For high-frequency cetaceans (*i.e., Kogia* spp. and harbor porpoise), injury zones are based on instantaneous exposure to peak pressure and are larger than the expected near-field in all cases (*i.e.,* 355–1,585 m). Therefore, we assume that Level A harassment is likely for some individuals of these species. In order to avoid consistency issues that may result when estimates of Level A harassment are based off of the results of a separate analysis that was founded in part on use of different density inputs, as was the case for the estimates of Level A harassment described in our Notice of Proposed IHAs, we simplified the analysis through use of the existing estimates of Level B harassment for each applicant. Under the assumption that some of these estimated exposures would in fact result in Level A harassment versus Level B harassment, we used applicant-specific calculated Level A and Level B harassment zones to generate estimates of the portion of estimated Level B harassment incidents that would be expected to be Level A harassment instead. For example, radial isopleth distances for Spectrum's calculated harassment zones are 1,585 m for Level A harassment and a mean of 9,775 m for Level B harassment, which we use to calculate relative area. On this basis, we assume that approximately 2.6 percent of estimated Level B harassment incidents would potentially be Level A harassment instead (for Spectrum). These final estimates, shown in Table 6, were then subtracted from the total take by Level B harassment. As noted for low-frequency cetaceans, we recognize that the effects of aversion would likely reduce these already low levels of Level A harassment.

We recognize that the Level A exposure estimates provided here are a rough approximation of actual exposures; however, our intention is to use the information available to us, in reflection of available science regarding the potential for auditory injury, to acknowledge the potential for such outcomes in a way that is a reasonable approximation. Our revised analysis of potential Level A harassment, as reflected in Table 6, accomplishes this goal. As described in our Notice of Proposed IHAs, we note here that four of the five applicant companies (excepting Spectrum) declined to request authorization of take by Level A harassment. These four applicants claim, in summary, that injurious exposures will not occur largely due to the effectiveness of planned mitigation. While we agree that Level A harassment is unlikely for mid-frequency cetaceans, and that only limited injurious exposure is likely for low-frequency cetaceans, we do not find this assertion persuasive in all cases. Therefore, we are authorizing limited take by Level A harassment, as displayed in Table 6.

Rare Species

Certain species potentially present in the survey areas are expected to be encountered only extremely rarely, if at all. Although Roberts *et al.* (2016) provide density models for these species (with the exception of the pygmy killer whale), due to the small numbers of sightings that underlie these models' predictions we believe it appropriate to account for the small likelihood that these species would be encountered by assuming that these species might be encountered once by a given survey, and that Level A harassment would not occur for these species. With the exception of the northern bottlenose whale, none of these species should be considered cryptic (*i.e.,* difficult to observe when present) versus rare (*i.e.,* not likely to be present). Average group size was determined by considering known sightings in the western North

Atlantic (CETAP, 1982; Hansen *et al,* 1994; NMFS, 2010a, 2011, 2012, 2013a, 2014, 2015a; Waring *et al.,* 2007, 2015). We provided discussion for each of these species in our Notice of Proposed IHAs, and do not repeat the discussion here. For each of these species—sei, Bryde's, and blue whales; the northern bottlenose whale; killer whale, false killer whale, pygmy killer whale, and melon-headed whale; and spinner, Fraser's, and Atlantic white-sided dolphins—we authorize take equivalent to one group of each species per applicant (Table 6).

Table 6 provides the authorized numbers of take by Level A and Level B harassment for each applicant. The numbers of authorized take reflect the expected exposure numbers provided in Table 10 of our Notice of Proposed IHAs, as derived by various methods described above, and additionally include take numbers for rare species that reflect the approach described above for average group size. In summary, the exposure estimates provided in Table 10 of our Notice of Proposed IHAs have been changed in reflection of the following: (1) Revised exposure estimates for North Atlantic right whales using Roberts *et al.* (2017); (2) removed exposure estimates specific to use of the disallowed mitigation source as necessary for certain species (TGS only); (3) removed estimated take avoided as a result of implementation of planned time-area restrictions; and (4) revised analysis of potential Level A harassment.

As described previously, for most species these estimated exposure levels apply to a generic western North Atlantic stock defined by NMFS for management purposes. For the humpback and sei whale, any takes are assumed to occur to individuals of the species occurring in the specific geographic region (which may or may not be individuals from the Gulf of Maine and Nova Scotia stocks, respectively). For bottlenose dolphins, NMFS defines an offshore stock and multiple coastal stocks of dolphins, and we are not able to quantitatively determine the extent to which the estimated exposures may accrue to the oceanic versus various coastal stocks. However, because of the spatial distribution of planned survey effort and our prescribed mitigation, we assume that almost all incidents of take for bottlenose dolphins would accrue to the offshore stock.

TABLE 6—NUMBERS OF POTENTIAL INSTANCES OF INCIDENTAL TAKE AUTHORIZED

Common name	Spectrum [1]		TGS		ION		Western		CGG	
	Level A	Level B	Level A	Level B	Level A	Level B	Level A	Level B	Level A	Level B
North Atlantic right whale	0	6	0	9	0	2	0	4	0	2
Humpback whale	4	41	4	56	2	5	0	49	2	5
Minke whale	4	419	4	208	2	10	0	100	4	124
Bryde's whale	0	2	0	2	0	2	0	2	0	2
Sei whale	0	2	0	2	0	2	0	2	0	2
Fin whale	4	333	4	1,140	2	3	0	537	4	45
Blue whale	0	1	0	1	0	1	0	1	0	1
Sperm whale	0	1,077	0	3,579	0	16	0	1,941	0	1,304
Kogia spp.	5	200	5	1,216	[2] 2	28	3	569	[2] 2	238
Beaked whales	0	3,357	0	12,072	0	490	0	4,960	0	3,511
Northern bottlenose whale	0	4	0	4	0	4	0	4	0	4
Rough-toothed dolphin	0	201	0	261	0	[1] 14	0	123	0	177
Common bottlenose dolphin	0	37,562	0	40,595	0	2,599	0	23,600	0	9,063
Clymene dolphin	0	6,459	0	821	0	252	0	391	0	6,382
Atlantic spotted dolphin	0	16,926	0	41,222	0	568	0	18,724	0	6,596
Pantropical spotted dolphin	0	1,632	0	1,470	0	78	0	690	0	1,566
Spinner dolphin	0	91	0	91	0	91	0	91	0	91
Striped dolphin	0	8,022	0	23,418	0	162	0	8,845	0	6,328
Common dolphin	0	11,087	0	52,728	0	372	0	20,683	0	6,026
Fraser's dolphin	0	204	0	204	0	204	0	204	0	204
Atlantic white-sided dolphin	0	48	0	48	0	48	0	48	0	48
Risso's dolphin	0	755	0	3,241	0	90	0	1,608	0	809
Melon-headed whale	0	50	0	50	0	50	0	50	0	50
Pygmy killer whale	0	6	0	6	0	6	0	6	0	6
False killer whale	0	28	0	28	0	28	0	28	0	28
Killer whale	0	7	0	7	0	7	0	7	0	7
Pilot whales	0	2,765	0	8,902	0	199	0	4,682	0	1,964
Harbor porpoise	16	611	[2] 3	322	[2] 3	18	[2] 3	152	[2] 3	27

[1] Take numbers provided for Spectrum reflect Spectrum's original survey plan and are retained here in reference to the negligible impact and small numbers analyses provided later in this document for Spectrum. For revised (and authorized) take numbers for Spectrum reflecting their modified survey plan, please see ''Spectrum Survey Plan Modification.''

[2] Exposure estimate increased to account for average group size observed during AMAPPS survey effort. For ION, estimated Level A harassment of *Kogia* spp. and harbor porpoise was zero and, for CGG, estimated Level A harassment of harbor porpoise was zero. We assume as a precaution that one group (as estimated from AMAPPS data) may incur Level A harassment.

Mitigation

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.'' (While section 101(a)(5)(D) refers to ''least practicable impact,'' we hereafter use the term ''least practicable adverse impact,'' the term as it appears in section 101(a)(5)(A). Given the provision in which the language appears, and its similarity to the parallel provision in section 101(a)(5)(A), we believe that ''least practicable impact'' in section 101(a)(5)(D) similarly is referring to the requirement to prescribe the means of effecting the least practicable *adverse* impact, and we interpret the term in that manner.) Consideration of the availability of marine mammal species or stocks for taking for subsistence uses pertains only to Alaska, and is therefore not relevant here. NMFS does not have a regulatory definition for ''least practicable adverse impact.''

In *Conservation Council for Hawaii* v. *National Marine Fisheries Service,* 97 F. Supp.3d 1210, 1229 (D. Haw. 2015), the Court stated that NMFS ''appear[s] to think [it] satisf[ies] the statutory 'least practicable adverse impact' requirement with a 'negligible impact' finding.'' More recently, expressing similar concerns in a challenge to an incidental take rule for U.S. Navy Operation of Surveillance Towed Array Sensor System Low Frequency Active Sonar (SURTASS LFA) (77 FR 50290), the Ninth Circuit Court of Appeals in *Natural Resources Defense Council (NRDC)* v. *Pritzker,* 828 F.3d 1125, 1134 (9th Cir. 2016), stated, ''[c]ompliance with the 'negligible impact' requirement does not mean there [is] compliance with the 'least practicable adverse impact' standard.'' As the Ninth Circuit noted in its opinion, however, the Court was interpreting the statute without the benefit of NMFS's formal interpretation. We state here explicitly that NMFS is in full agreement that the ''negligible impact'' and ''least practicable adverse impact'' requirements are distinct, even though both statutory standards refer to species and stocks. With that in mind, we provide further explanation of our interpretation of least practicable adverse impact, and explain what distinguishes it from the negligible impact standard. This discussion is consistent with, and expands upon, previous rules we have issued (such as the Navy Gulf of Alaska rule (82 FR 19530; April 27, 2017)).

Before NMFS can issue an incidental take authorization under sections 101(a)(5)(A) or (D) of the MMPA, it must make a finding that the taking will have a ''negligible impact'' on the affected ''species or stocks'' of marine mammals. NMFS's and U.S. Fish and Wildlife Service's implementing regulations for section 101(a)(5) both define ''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 and 50 CFR 18.27(c)). Recruitment (*i.e.,* reproduction) and survival rates are used to determine population growth rates [1] and, therefore are considered in evaluating population level impacts.

Not every population-level impact violates the negligible impact requirement. The negligible impact standard does not require a finding that the anticipated take will have ''no effect'' on population numbers or growth rates. The statutory standard does not require that the same recovery rate be maintained, rather that no significant effect on annual rates of recruitment or survival occurs. The key factor is the significance of the level of impact on rates of recruitment or survival. See 54 FR 40338, 40341–42 (September 29, 1989).

While some level of impact on population numbers or growth rates of a species or stock may occur and still satisfy the negligible impact requirement—even without consideration of mitigation—the least practicable adverse impact provision separately requires NMFS to prescribe means of effecting the least practicable adverse impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance. 50 CFR 216.102(b). These are typically identified as mitigation measures.[2]

The negligible impact and least practicable adverse impact standards in the MMPA both call for evaluation at the level of the ''species or stock.'' The MMPA does not define the term ''species.'' However, Merriam-Webster Dictionary defines ''species'' to include ''related organisms or *populations* potentially capable of interbreeding.'' See *www.merriam-webster.com/dictionary/species* (emphasis added). The MMPA defines ''stock'' as a group of marine mammals of the same species or smaller taxa in a common spatial arrangement that interbreed when mature. 16 U.S.C. 1362(11). The definition of ''population'' is ''a group of interbreeding organisms that represents the level of organization at which speciation begins.'' *www.merriam-webster.com/dictionary/population.* The definition of ''population'' is strikingly similar to the MMPA's definition of ''stock,'' with both involving groups of individuals that belong to the same species and located in a manner that allows for interbreeding. In fact, the term ''stock'' in the MMPA is interchangeable with the statutory term ''population stock.'' 16 U.S.C. 1362(11). Thus, the MMPA terms ''species'' and ''stock'' both relate to populations, and it is therefore appropriate to view both the negligible impact standard and the least practicable adverse impact standard, both of which call for evaluation at the level of the species or stock, as having a population-level focus.

This interpretation is consistent with Congress's statutory findings for enacting the MMPA, nearly all of which are most applicable at the species or stock (*i.e.,* population) level. See 16 U.S.C. 1361 (finding that it is species and population stocks that are or may be in danger of extinction or depletion; that it is species and population stocks that should not diminish beyond being significant functioning elements of their ecosystems; and that it is species and population stocks that should not be permitted to diminish below their optimum sustainable population level). Annual rates of recruitment (*i.e.,* reproduction) and survival are the key biological metrics used in the evaluation of population-level impacts, and accordingly these same metrics are also used in the evaluation of population level impacts for the least practicable adverse impact standard.

Recognizing this common focus of the least practicable adverse impact and negligible impact provisions on the ''species or stock'' does not mean we conflate the two standards; despite some common statutory language, we recognize the two provisions are different and have different functions. First, a negligible impact finding is required before NMFS can issue an incidental take authorization. Although it is acceptable to use the mitigation measures to reach a negligible impact finding (see 50 CFR 216.104(c)), no amount of mitigation can enable NMFS

[1] A growth rate can be positive, negative, or flat.

[2] For purposes of this discussion we omit reference to the language in the standard for least practicable adverse impact that says we also must mitigate for subsistence impacts because they are not at issue in these actions.

to issue an incidental take authorization for an activity that still would not meet the negligible impact standard. Moreover, even where NMFS can reach a negligible impact finding—which we emphasize does allow for the possibility of some ''negligible'' population-level impact—the agency must still prescribe measures that will effect the least practicable amount of adverse impact upon the affected species or stock.

Section 101(a)(5)(D)(ii)(I) (like section 101(a)(5)(A)(i)(II)) requires NMFS to issue, in conjunction with its authorization, binding—and enforceable—restrictions setting forth how the activity must be conducted, thus ensuring the activity has the ''least practicable adverse impact'' on the affected species or stocks. In situations where mitigation is specifically needed to reach a negligible impact determination, section 101(a)(5)(D)(ii)(I) also provides a mechanism for ensuring compliance with the ''negligible impact'' requirement. Finally, we reiterate that the least practicable adverse impact standard also requires consideration of measures for marine mammal habitat, with particular attention to rookeries, mating grounds, and other areas of similar significance, and for subsistence impacts; whereas the negligible impact standard is concerned solely with conclusions about the impact of an activity on annual rates of recruitment and survival.[3]

In *NRDC* v. *Pritzker,* the Court stated, ''[t]he statute is properly read to mean that even if population levels are not threatened *significantly,* still the agency must adopt mitigation measures aimed at protecting *marine mammals* to the greatest extent practicable in light of military readiness needs.'' *Id.* at 1134 (emphases added). This statement is consistent with our understanding stated above that even when the effects of an action satisfy the negligible impact standard (*i.e.,* in the Court's words, ''population levels are not threatened significantly''), still the agency must prescribe mitigation under the least practicable adverse impact standard. However, as the statute indicates, the focus of both standards is ultimately the impact on the affected ''species or stock,'' and not solely focused on or directed at the impact on individual marine mammals.

We have carefully reviewed and considered the Ninth Circuit's opinion in *NRDC* v. *Pritzker* in its entirety. While the Court's reference to ''marine mammals'' rather than ''marine mammal species or stocks'' in the italicized language above might be construed as a holding that the least practicable adverse impact standard applies at the individual ''marine mammal'' level, *i.e.,* that NMFS must require mitigation to minimize impacts to each individual marine mammal unless impracticable, we believe such an interpretation reflects an incomplete appreciation of the Court's holding. In our view, the opinion as a whole turned on the Court's determination that NMFS had not given separate and independent meaning to the least practicable adverse impact standard apart from the negligible impact standard, and further, that the Court's use of the term ''marine mammals'' was not addressing the question of whether the standard applies to individual animals as opposed to the species or stock as a whole. We recognize that while consideration of mitigation can play a role in a negligible impact determination, consideration of mitigation measures extends beyond that analysis. In evaluating what mitigation measures are appropriate, NMFS considers the potential impacts of the specified activity, the availability of measures to minimize those potential impacts, and the practicability of implementing those measures, as we describe below.

Given the *NRDC* v. *Pritzker* decision, we discuss here how we determine whether a measure or set of measures meets the ''least practicable adverse impact'' standard. Our separate analysis of whether the take anticipated to result from applicants' activities satisfies the ''negligible impact'' standard appears in the section ''Negligible Impact Analyses and Determinations'' below.

Our evaluation of potential mitigation measures includes consideration of two primary factors:

(1) The manner in which, and the degree to which, implementation of the potential measure(s) is expected to reduce adverse impacts to marine mammal species or stocks, their habitat, and their availability for subsistence uses (when relevant). This analysis considers such things as the nature of the potential adverse impact (such as likelihood, scope, and range), the likelihood that the measure will be effective if implemented, and the likelihood of successful implementation.

(2) The practicability of the measure for applicant implementation. Practicability of implementation may consider such things as cost, impact on operations, personnel safety, and practicality of implementation.

While the language of the least practicable adverse impact standard calls for minimizing impacts to affected species or stocks, we recognize that the reduction of impacts to those species or stocks accrues through the application of mitigation measures that limit impacts to individual animals. Accordingly, NMFS's analysis focuses on measures designed to avoid or minimize impacts on marine mammals from activities that are likely to increase the probability or severity of population-level effects.

While complete information on impacts to species or stocks from a specified activity is not available for every activity type, and additional information would help NMFS better understand how specific disturbance events affect the fitness of individuals of certain species, there have been significant improvements in understanding the process by which disturbance effects are translated to the population. With recent scientific advancements (both marine mammal energetic research and the development of energetic frameworks), the relative likelihood or degree of impacts on species or stocks may typically be predicted given a detailed understanding of the activity, the environment, and the affected species or stocks. This same information is used in the development of mitigation measures and helps us understand how mitigation measures contribute to lessening effects to species or stocks. We also acknowledge that there is always the potential that new information, or a new recommendation that we had not previously considered, becomes available and necessitates re-evaluation of mitigation measures (which may be addressed through adaptive management) to see if further reductions of population impacts are possible and practicable.

In the evaluation of specific measures, the details of the specified activity will necessarily inform each of the two primary factors discussed above (expected reduction of impacts and practicability), and will be carefully considered to determine the types of mitigation that are appropriate under the least practicable adverse impact standard. Analysis of how a potential mitigation measure may reduce adverse impacts on a marine mammal stock or species and practicability of implementation are not issues that can be meaningfully evaluated through a yes/no lens. The manner in which, and the degree to which, implementation of a measure is expected to reduce impacts, as well as its practicability, can vary widely. For example, a time-area

[3] Mitigation may also be appropriate to ensure compliance with the ''small numbers'' language in MMPA sections 101(a)(5)(A) and (D).

restriction could be of very high value for decreasing population-level impacts (*e.g.,* avoiding disturbance of feeding females in an area of established biological importance) or it could be of lower value (*e.g.,* decreased disturbance in an area of high productivity but of less firmly established biological importance). Regarding practicability, a measure might involve operational restrictions that completely impede the operator's ability to acquire necessary data (higher impact), or it could mean additional incremental delays that increase operational costs but still allow the activity to be conducted (lower impact). A responsible evaluation of ''least practicable adverse impact'' will consider the factors along these realistic scales. Expected effects of the activity and of the mitigation as well as status of the stock all weigh into these considerations. Accordingly, the greater the likelihood that a measure will contribute to reducing the probability or severity of adverse impacts to the species or stock or their habitat, the greater the weight that measure is given when considered in combination with practicability to determine the appropriateness of the mitigation measure, and vice versa. We discuss consideration of these factors in greater detail below.

1. Reduction of Adverse Impacts to Marine Mammal Species or Stocks and Their Habitat [4]

The emphasis given to a measure's ability to reduce the impacts on a species or stock considers the degree, likelihood, and context of the anticipated reduction of impacts to individuals as well as the status of the species or stock.

The ultimate impact on any individual from a disturbance event (which informs the likelihood of adverse species- or stock-level effects) is dependent on the circumstances and associated contextual factors, such as duration of exposure to stressors. Though any required mitigation needs to be evaluated in the context of the specific activity and the species or stocks affected, measures with the following types of goals are expected to reduce the likelihood or severity of adverse species- or stock-level impacts: Avoiding or minimizing injury or mortality; limiting interruption of known feeding, breeding, mother/calf, or resting behaviors; minimizing the abandonment of important habitat (temporally and spatially); minimizing the number of individuals subjected to these types of disruptions; and limiting degradation of habitat. Mitigating these types of effects is intended to reduce the likelihood that the activity will result in energetic or other types of impacts that are more likely to result in reduced reproductive success or survivorship. It is also important to consider the degree of impacts that are expected in the absence of mitigation in order to assess the added value of any potential measures. Finally, because the least practicable adverse impact standard gives NMFS the discretion to weigh a variety of factors when determining what should be included as appropriate mitigation measures and because the focus is on reducing impacts at the species or stock level, it does not compel mitigation for every kind of individual take, even when practicable for implementation by the applicant.

The status of the species or stock is also relevant in evaluating the appropriateness of potential mitigation measures in the context of least practicable adverse impact. The following are examples of factors that may (either alone, or in combination) result in greater emphasis on the importance of a mitigation measure in reducing impacts on a species or stock: The stock is known to be decreasing or status is unknown, but believed to be declining; the known annual mortality (from any source) is approaching or exceeding the PBR level; the affected species or stock is a small, resident population; or the stock is involved in a UME or has other known vulnerabilities.

Habitat mitigation, particularly as it relates to rookeries, mating grounds, and areas of similar significance, is also relevant to achieving the standard and can include measures such as reducing impacts of the activity on known prey utilized in the activity area or reducing impacts on physical habitat. As with species- or stock-related mitigation, the emphasis given to a measure's ability to reduce impacts on a species or stock's habitat considers the degree, likelihood, and context of the anticipated reduction of impacts to habitat. Because habitat value is informed by marine mammal presence and use, in some cases there may be overlap in measures for the species or stock and for use of habitat.

We consider available information indicating the likelihood of any measure to accomplish its objective. If evidence shows that a measure has not typically been effective or successful, then either that measure should be modified or the potential value of the measure to reduce effects is lowered.

2. Practicability

Factors considered may include those such as cost, impact on operations, personnel safety, and practicality of implementation.

In carrying out the MMPA's mandate for these five IHAs, we apply the previously described context-specific balance between the manner in which and the degree to which measures are expected to reduce impacts to the affected species or stocks and their habitat and practicability for the applicant. The effects of concern (*i.e.,* those with the potential to adversely impact species or stocks and their habitat), addressed previously in the ''Potential Effects of the Specified Activity on Marine Mammals and Their Habitat'' section, include auditory injury, severe behavioral reactions, disruptions of critical behaviors, and to a lesser degree, masking and impacts on acoustic habitat (see discussion of this concept in the ''Anticipated Effects on Marine Mammal Habitat'' section in the Notice of Proposed IHAs). Here, we focus on measures with proven or reasonably presumed ability to avoid or reduce the intensity of acute exposures that have potential to result in these anticipated effects with an understanding of the drawbacks or costs of these requirements, as well as time-area restrictions that would avoid or reduce both acute and chronic impacts. To the extent of the information available to us, we considered practicability concerns, as well as potential undesired consequences of the measures, *e.g.,* extended periods using the acoustic source due to the need to reshoot lines. We also recognize that instantaneous protocols, such as shutdown requirements, are not capable of avoiding all acute effects, and are not suitable for avoiding many cumulative or chronic effects and do not provide targeted protection in areas of greatest importance for marine mammals. Therefore, in addition to a basic suite of seismic mitigation protocols, we also consider measures that may or may not be appropriate for other activities (*e.g.,* time-area restrictions specific to the surveys discussed herein) but that are warranted here given the spatial scope of these specified activities, potential for population-level effects and/or high magnitude of take for certain species in the absence of such mitigation (see ''Negligible Impact Analyses and

[4] We recognize the least practicable adverse impact standard requires consideration of measures that will address minimizing impacts on the availability of the species or stocks for subsistence uses where relevant. Because subsistence uses are not implicated for this action we do not discuss them. However, a similar framework would apply for evaluating those measures, taking into account the MMPA's directive that we make a finding of no unmitigable adverse impact on the availability of the species or stocks for taking for subsistence, and the relevant implementing regulations.

Determinations''), and the information we have regarding habitat for certain species.

In order to satisfy the MMPA's least practicable adverse impact standard, we evaluated a suite of basic mitigation protocols that are required regardless of the status of a stock. Additional or enhanced protections are required for species whose stocks are in poor health and/or are subject to some significant additional stressor that lessens that stock's ability to weather the effects of the specified activities without worsening its status. We reviewed the applicants' proposals, the requirements specified in BOEM's PEIS, seismic mitigation protocols required or recommended elsewhere (*e.g.,* HESS, 1999; DOC, 2013; IBAMA, 2005; Kyhn *et al.,* 2011; JNCC, 2017; DEWHA, 2008; BOEM, 2016a; DFO, 2008; GHFS, 2015; MMOA, 2015; Nowacek *et al.,* 2013; Nowacek and Southall, 2016), and the available scientific literature. We also considered recommendations given in a number of review articles (*e.g.,* Weir and Dolman, 2007; Compton *et al.,* 2008; Parsons *et al.,* 2009; Wright and Cosentino, 2015; Stone, 2015b). Certain changes from the mitigation measures described in our Notice of Proposed IHAs were made on the basis of additional information and following review of public comments. The required suite of mitigation measures differs in some cases from the measures proposed by the applicants and/or those specified by BOEM in their PEIS and Record of Decision (ROD) in order to reflect what we believe to be the most appropriate suite of measures to satisfy the requirements of the MMPA.

First, we summarize notable changes made to the mitigation requirements as a result of review of public comments and then describe mitigation prescribed in the issued IHAs. For additional detail regarding mitigation considerations, including expected efficacy and/or practicability, or descriptions of mitigation considered but not required, please see our Notice of Proposed IHAs.

Here we provide a single description of required mitigation measures, as we require the same measures of all applicants.

Changes From the Notice of Proposed IHAs

Here we summarize substantive changes to mitigation requirements from our Notice of Proposed IHAs. All changes were made on the basis of review of public comments received, including from applicants, and/or review of new information.

Time-Area Restrictions

• We spatially expanded the proposed time-area restriction for North Atlantic right whales. Our proposed restriction area was comprised of an area containing three distinct areas: (1) A 20-nmi coastal strip throughout the specific geographic region; (2) designated Seasonal Management Areas; and (3) designated critical habitat. This combined area was then buffered by 10 km, resulting in an approximate 47-km standoff distance. We received numerous public comments expressing concern regarding the adequacy of this measure and, more generally, regarding the status of the North Atlantic right whale. Also, since publication of the Notice of Proposed IHAs, the status of this population has worsened, including declaration of an ongoing UME. Given this, we considered newly available information (*e.g.,* Roberts *et al.,* 2017; Davis *et al.,* 2017) and re-evaluated the restriction. This is described in more detail under ''Comments and Responses'' as well as later in this section. Following this review, we expanded the restriction to 80 km from shore, with the same 10-km buffer, for a total 90-km restriction. As was proposed, the restriction would be in effect from November through April.

However, in lieu of this requirement, applicants may alternatively develop and submit a monitoring and mitigation plan for NMFS's approval that would be sufficient to achieve comparable protection for North Atlantic right whales. If approved, applicants would be required to maintain a minimum coastal standoff distance of 47 km from November through April while operating in adherence with the approved plan from 47 through 80 km offshore. (Note that the 80 km distance is assumed to represent to a reasonable extent right whale occurrence on the migratory pathway; therefore, under an approved plan the 10-km buffer would not be relevant.)

• We shifted the timing of the ''Hatteras and North'' time-area restriction (Area #4 in Figure 4 and Table 7; described as Area #5 in our Notice of Proposed IHAs), developed primarily to benefit beaked whales, sperm whales, and pilot whales, but also to provide seasonal protection to a notable biodiversity hotspot. The timing of this restriction, proposed as July through September (Roberts *et al.,* 2015n), is shifted to January through March on the basis of new information (Stanistreet *et al.,* 2018), as described in more detail later in this section. The restriction area remains the same.

• We eliminated the proposed (former) Area #1, which was delineated in an effort to reduce likely acoustic exposures for the species for three applicants only, as opposed to a more meaningful reduction of impacts in important habitat and/or for species expected to be more sensitive to disturbance from airgun noise. As was stated in our Notice of Proposed IHAs, ''Although there are no relevant considerations with regard to population context or specific stressors that lead us to develop mitigation focused on Atlantic spotted dolphins [. . .] we believe it appropriate to delineate a time-area restriction for the sole purpose of reducing likely acoustic exposures for the species [for three companies].'' We received comments on this proposed restriction from several commenters who provided compelling rationale to eliminate the measure. As was stated in our Notice of Proposed IHAs, Atlantic spotted dolphins display a bifurcated distribution, with a portion of the stock inhabiting the continental shelf south of Cape Hatteras inside the 200-m isobath and a portion of the stock off the shelf and north of the Gulf Stream (north of Cape Hatteras). Our proposed restriction—located in the southern, on-shelf portion of the range, which we believe to be more predictable habitat for the species—was not likely to have the intended effect, as a seasonal restriction would not necessarily reduce acoustic exposures for a species that is not known to migrate in and out of the restriction area, and because a relatively small portion of overall survey effort was planned for this area. Implementation of this restriction would also likely have meaningful practicability implications for applicants with survey lines in the area, as they would need to plan for both the seasonal restriction for spotted dolphin (proposed as July through September) as well as the right whale restriction, which overlaps the proposed spotted dolphin area and would be in effect from November through April. Therefore, the proposal would not likely provide commensurate benefit to the species to offset these concerns.

Shutdown Requirements

• In our Notice of Proposed IHAs, we proposed an exception to the general shutdown requirements for certain species of dolphins in certain circumstances. Specifically, we proposed that the exception to the shutdown requirement would apply if the animals are traveling, including approaching the vessel. Our rationale in proposing this specific exception was to avoid the perceived subjective decision-

making associated with an exception based on a determination that dolphins were approaching voluntarily, while still protecting dolphins from disturbance of potentially important behaviors such as feeding or socialization, as might be indicated by the presence of dolphins engaged in behavior other than traveling (*e.g.,* milling). Although the ''bow-riding'' dolphin exception was similarly criticized when presented for public comment in BOEM's draft PEIS, we agree that our proposal (*i.e.,* based on ''traveling'' versus ''stationary'' dolphins in relation to the vessel's movement) was unclear and that it would not likely result in an improvement with regard to clarity of protected species observer (PSO) decision-making. Therefore, this proposal was properly considered impracticable, while not offering meaningfully commensurate biological benefit. While we are careful to note that we do not fully understand the reasons for and potential effects of dolphin interaction with vessels, including working survey vessels, we also understand that dolphins are unlikely to incur any degree of threshold shift due to their relative lack of sensitivity to the frequency content in an airgun signal (as well as because of potential coping mechanisms). We also recognize that, although dolphins do in fact react to airgun noise in ways that may be considered take (Barkaszi *et al.,* 2012), there is a lack of notable adverse dolphin reactions to airgun noise despite a large body of observational data. Therefore, the removal of the conditional shutdown measure for small delphinids is warranted in consideration of the available information regarding the effectiveness of such measures in mitigating impacts to small delphinids and the practicability of such measures. No shutdown is required for these species.

- We proposed a number of expanded shutdown requirements on the basis of detections of certain species deemed particularly sensitive (*e.g.,* beaked whales) or of particular circumstances deemed to warrant the expanded shutdown requirement (*e.g.,* whales with calves). These were all conditioned upon observation or detection of these species or circumstances at any distance from the vessel. We received several comments challenging the value of expanded shutdown requirements at all and, while we disagree with these comments, we agree that some reasonable distance limit should be placed on these requirements in order to better focus the observational effort of PSOs and to avoid the potential for numerous shutdowns based on uncertain detections at great distance. Therefore, as described in greater detail later in this section, we limit such expanded shutdown zones for relevant species or circumstances to 1.5 km.
- We eliminated a proposed requirement for shutdowns upon observation of a diving sperm whale at any distance centered on the forward track of the source vessel. We received several comments indicating that this proposed requirement was unclear in terms of how it was to be implemented, and that the benefit to the species was poorly demonstrated. We agree with these comments.
- We eliminated a proposed requirement for shutdowns upon detection of fin whales at any distance (proposed for TGS only). As stated in our Notice of Proposed IHAs, this requirement was proposed only on the basis of a high predicted amount of exposures. Following review of this requirement, we recognize that it would not be effective in achieving the stated goal of reducing the overall amount of takes, as any observed fin whale would still be within the Level B harassment zone and thus taken. Therefore, this measure serves no meaningful purpose while imposing an additional practicability burden on TGS.
- We clarify that the proposed requirement to shut down upon observation of an aggregation of marine mammals applies only to large whales (*i.e.,* baleen whales and sperm whales), as was our intent. Several commenters interpreted the requirement as applying to all marine mammals and noted that this would require a significant increase in shutdowns as a result of the prevalence of observations of dolphins in groups exceeding five (most dolphin species have average group sizes larger than five). It has been common practice in prior issued IHAs for similar activities to require such a measure for whale species; however, we inadvertently omitted this key detail in describing the proposed measure. Also, we remove the language regarding ''traveling,'' which had been proposed in a similar context as was discussed above for small delphinids and which we have determined to be a poorly defined condition.

Monitoring

- We require that at least two acoustic PSOs have prior experience (minimum 90 days) working in that role, on the basis of discussion with experts who emphasized the critical importance of experience for acoustic PSOs (*e.g.,* Thode *et al.,* 2017; pers. comm., D. Epperson, BSEE). Our proposal required that only one acoustic PSO have prior experience.

Below, we describe mitigation requirements in detail.

Mitigation-Related Monitoring

Monitoring by independent, dedicated, trained marine mammal observers is required. Note that, although we discuss requirements related only to observation of marine mammals, we hereafter use the generic term ''protected species observer'' (PSO). Independent observers are employed by a third-party observer provider; vessel crew may not serve as PSOs. Dedicated observers are those who have no tasks other than to conduct observational effort, record observational data, and communicate with and instruct the survey operator (*i.e.,* vessel captain and crew) with regard to the presence of marine mammals and mitigation requirements. Communication with the operator may include brief alerts regarding maritime hazards. Trained PSOs have successfully completed an approved PSO training course (see ''Monitoring and Reporting''), and experienced PSOs have additionally gained a minimum of 90 days at-sea experience working as a PSO during a deep penetration seismic survey, with no more than 18 months having elapsed since the conclusion of the relevant at-sea experience. Training and experience is specific to either visual or acoustic PSO duties. An experienced visual PSO must have completed approved, relevant training and must have gained the requisite experience working as a visual PSO. An experienced acoustic PSO must have completed a passive acoustic monitoring (PAM) operator training course and must have gained the requisite experience working as an acoustic PSO. Hereafter, we also refer to acoustic PSOs as PAM operators.

NMFS expects to provide informal approval for specific training courses as needed to approve PSO staffing plans. NMFS does not plan to formally administer any training program or to sanction any specific provider, but will approve courses that meet the curriculum and trainer requirements specified herein (see ''Monitoring and Reporting''). We expect to provide such approvals in context of the need to ensure that PSOs have the necessary training to carry out their duties competently while also approving applicant staffing plans quickly. In order for PSOs to be approved, NMFS must review and approve PSO resumes accompanied by a relevant training course information packet that includes

the name and qualifications (*i.e.,* experience, training completed, or educational background) of the instructor(s), the course outline or syllabus, and course reference material as well as a document stating the PSO's successful completion of the course. Although NMFS must affirm PSO approvals, third-party observer providers and/or companies seeking PSO staffing should expect that observers having satisfactorily completed approved training and with the requisite experience (if required) will be quickly approved. A PSO may be trained and/or experienced as both a visual PSO and PAM operator and may perform either duty, pursuant to scheduling requirements. PSO watch schedules shall be devised in consideration of the following restrictions: (1) A maximum of two consecutive hours on watch followed by a break of at least one hour between watches for visual PSOs (periods typical of observation for research purposes and as used for airgun surveys in certain circumstances (Broker *et al.,* 2015)); (2) a maximum of four consecutive hours on watch followed by a break of at least two consecutive hours between watches for PAM operators; and (3) a maximum of 12 hours observation per 24-hour period. Further information regarding PSO requirements may be found in the ''Monitoring and Reporting'' section, later in this document.

During survey operations (*e.g.,* any day on which use of the acoustic source is planned to occur; whenever the acoustic source is in the water, whether activated or not), a minimum of two PSOs must be on duty and conducting visual observations at all times during daylight hours (*i.e.,* from 30 minutes prior to sunrise through 30 minutes following sunset) and 30 minutes prior to and during nighttime ramp-ups of the airgun array (see ''Ramp-ups'' below). PSOs should use NOAA's solar calculator (*www.esrl.noaa.gov/gmd/grad/solcalc/*) to determine sunrise and sunset times at their specific location. We recognize that certain daytime conditions (*e.g.,* fog, heavy rain) may reduce or eliminate effectiveness of visual observations; however, on-duty PSOs shall remain alert for marine mammal observational cues and/or a change in conditions.

All source vessels must carry a minimum of one experienced visual PSO, who shall be designated as the lead PSO, coordinate duty schedules and roles, and serve as primary point of contact for the operator. However, while it is desirable for all PSOs to be qualified through experience, we are also mindful of the need to expand the workforce by allowing opportunity for newly trained PSOs to gain experience. Therefore, the lead PSO shall devise the duty schedule such that experienced PSOs are on duty with trained PSOs (*i.e.,* those PSOs with appropriate training but who have not yet gained relevant experience) to the maximum extent practicable in order to provide necessary mentorship.

With regard to specific observational protocols, we largely follow those described in Appendix C of BOEM's PEIS (BOEM, 2014a). The lead PSO shall determine the most appropriate observation posts that will not interfere with navigation or operation of the vessel while affording an optimal, elevated view of the sea surface; these should be the highest elevation available on each vessel, with the maximum viewable range from the bow to 90 degrees to port or starboard of the vessel. PSOs shall coordinate to ensure 360° visual coverage around the vessel, and shall conduct visual observations using binoculars and the naked eye while free from distractions and in a consistent, systematic, and diligent manner. All source vessels must be equipped with pedestal-mounted ''bigeye'' binoculars that will be available for PSO use. Within these broad outlines, the lead PSO and PSO team will have discretion to determine the most appropriate vessel- and survey-specific system for implementing effective marine mammal observational effort. Any observations of marine mammals by crew members aboard any vessel associated with the survey, including chase vessels, should be relayed to the source vessel and to the PSO team.

All source vessels must use a towed PAM system for potential detection of marine mammals. The system must be monitored at all times during use of the acoustic source, and acoustic monitoring must begin at least 30 minutes prior to ramp-up. PAM operators must be independent, and all source vessels shall carry a minimum of two experienced PAM operators. PAM operators shall communicate all detections to visual PSOs, when visual PSOs are on duty, including any determination by the PSO regarding species identification, distance and bearing and the degree of confidence in the determination. Further detail regarding PAM system requirements may be found in the ''Monitoring and Reporting'' section, later in this document. The effectiveness of PAM depends to a certain extent on the equipment and methods used and competency of the PAM operator, but no established standards are currently in place.

Visual monitoring must begin at least 30 minutes prior to ramp-up (described below) and must continue until one hour after use of the acoustic source ceases or until 30 minutes past sunset. If any marine mammal is observed at any distance from the vessel, a PSO would record the observation and monitor the animal's position (including latitude/longitude of the vessel and relative bearing and estimated distance to the animal) until the animal dives or moves out of visual range of the observer. A PSO would continue to observe the area to watch for the animal to resurface or for additional animals that may surface in the area. Visual PSOs shall communicate all observations to PAM operators, including any determination by the PSO regarding species identification, distance, and bearing and the degree of confidence in the determination.

As noted previously, all source vessels must carry a minimum of one experienced visual PSO and two experienced PAM operators. The observer designated as lead PSO (including the full team of visual PSOs and PAM operators) must have experience as a visual PSO. The applicant may determine how many additional PSOs are required to adequately fulfill the requirements specified here. To summarize, these requirements are: (1) 24-hour acoustic monitoring during use of the acoustic source; (2) visual monitoring during use of the acoustic source by two PSOs during all daylight hours, with one visual PSO on-duty during nighttime ramp-ups; (3) maximum of two consecutive hours on watch followed by a minimum of one hour off watch for visual PSOs and a maximum of four consecutive hours on watch followed by a minimum of two consecutive hours off watch for PAM operators; and (4) maximum of 12 hours of observational effort per 24-hour period for any PSO, regardless of duties.

PAM Malfunction—Emulating sensible protocols described by the New Zealand Department of Conservation for airgun surveys conducted in New Zealand waters (DOC, 2013), survey activity may continue for brief periods of time when the PAM system malfunctions or is damaged. Activity may continue for 30 minutes without PAM while the PAM operator diagnoses the issue. If the diagnosis indicates that the PAM system must be repaired to solve the problem, operations may continue for an additional two hours without acoustic monitoring under the following conditions:

- Daylight hours and sea state is less than or equal to Beaufort sea state (BSS) 4;
- No marine mammals (excluding delphinids; see below) detected solely by PAM in the exclusion zone (see below) in the previous two hours;
- NMFS is notified via email as soon as practicable with the time and location in which operations began without an active PAM system; and
- Operations with an active acoustic source, but without an operating PAM system, do not exceed a cumulative total of four hours in any 24-hour period.

Exclusion Zone and Buffer Zone

An exclusion zone is a defined area within which occurrence of a marine mammal triggers mitigation action intended to reduce potential for certain outcomes, *e.g.,* auditory injury, more severe disruption of behavioral patterns. The PSOs shall establish and monitor a 500-m exclusion zone and additional 500-m buffer zone (total 1,000 m) during the pre-clearance period (see below) and a 500-m exclusion zone during the ramp-up and operational periods. PSOs should focus their observational effort within this 1-km zone, although animals observed at greater distances should be recorded and mitigation action taken as necessary (see below). These zones shall be based upon radial distance from any element of the airgun array (rather than being based on the center of the array or around the vessel itself). During use of the acoustic source, occurrence of marine mammals within the buffer zone (but outside the exclusion zone) should be communicated to the operator to prepare for the potential shutdown of the acoustic source. Use of the buffer zone in relation to ramp-up is discussed below under ''Ramp-up.'' Further detail regarding the exclusion zone and shutdown requirements is given under ''Exclusion Zone and Shutdown Requirements.''

Ramp-Up

Ramp-up of an acoustic source is intended to provide a gradual increase in sound levels, enabling animals to move away from the source if the signal is sufficiently aversive prior to its reaching full intensity. We infer on the basis of behavioral avoidance studies and observations that this measure results in some reduced potential for auditory injury and/or more severe behavioral reactions. Although this measure is not proven and some arguments have been made that use of ramp-up may not have the desired effect of aversion (which is itself a potentially negative impact but assumed to be better than the alternative), ramp-up remains a relatively low-cost, common-sense component of standard mitigation for airgun surveys. Ramp-up is most likely to be effective for more sensitive species (*e.g.,* beaked whales) with known behavioral responses at greater distances from an acoustic source (*e.g.,* Tyack *et al.,* 2011; DeRuiter *et al.,* 2013; Miller *et al.,* 2015).

The ramp-up procedure involves a step-wise increase in the number of airguns firing and total array volume until all operational airguns are activated and the full volume is achieved. Ramp-up is required at all times as part of the activation of the acoustic source (including source tests; see ''Miscellaneous Protocols'' for more detail) and may occur at times of poor visibility, assuming appropriate acoustic monitoring with no detections in the 30 minutes prior to beginning ramp-up. Acoustic source activation should only occur at night where operational planning cannot reasonably avoid such circumstances. For example, a nighttime initial ramp-up following port departure is reasonably avoidable and may not occur. Ramp-up may occur at night following acoustic source deactivation due to line turn or mechanical difficulty. The operator must notify a designated PSO of the planned start of ramp-up as agreed-upon with the lead PSO; the notification time should be at least 60 minutes prior to the planned ramp-up. A designated PSO must be notified again immediately prior to initiating ramp-up procedures and the operator must receive confirmation from the PSO to proceed.

Ramp-up procedures follow the recommendations of IAGC (2015). Ramp-up would begin by activating a single airgun (*i.e.,* array element) of the smallest volume in the array. Ramp-up continues in stages by doubling the number of active elements at the commencement of each stage, with each stage of approximately the same duration. Total duration should not be less than approximately 20 minutes but maximum duration is not prescribed and will vary depending on the total number of stages. Von Benda-Beckmann *et al.* (2013), in a study of the effectiveness of ramp-up for sonar, found that extending the duration of ramp-up did not have a corresponding effect on mitigation benefit. There will generally be one stage in which doubling the number of elements is not possible because the total number is not even. This should be the last stage of the ramp-up sequence. The operator must provide information to the PSO documenting that appropriate procedures were followed. Ramp-ups should be scheduled so as to minimize the time spent with the source activated prior to reaching the designated run-in. This approach is intended to ensure a perceptible increase in sound output per increment while employing increments that produce similar degrees of increase at each step.

PSOs must monitor a 1,000-m zone (or to the distance visible if less than 1,000 m) for a minimum of 30 minutes prior to ramp-up (*i.e.,* pre-clearance). The pre-clearance period may occur during any vessel activity (*i.e.,* transit, line turn). Ramp-up must be planned to occur during periods of good visibility when possible; operators may not target the period just after visual PSOs have gone off duty. Following deactivation of the source for reasons other than mitigation, the operator must communicate the near-term operational plan to the lead PSO with justification for any planned nighttime ramp-up. Any suspected patterns of abuse must be reported by the lead PSO to be investigated by NMFS. Ramp-up may not be initiated if any marine mammal is within the designated 1,000-m zone. If a marine mammal is observed within the zone during the pre-clearance period, ramp-up may not begin until the animal(s) has been observed exiting the zone or until an additional time period has elapsed with no further sightings (*i.e.,* 15 minutes for small odontocetes and 30 minutes for all other species). PSOs will monitor the 500-m exclusion zone during ramp-up, and ramp-up must cease and the source shut down upon observation of marine mammals within or approaching the zone.

Exclusion Zone and Shutdown Requirements

The PSOs must establish a minimum exclusion zone with a 500-m radius as a perimeter around the outer extent of the airgun array (rather than being delineated around the center of the array or the vessel itself). If a marine mammal (other than the small delphinid species discussed below) appears within or enters this zone, the acoustic source must be shut down (*i.e.,* power to the acoustic source must be immediately turned off). If a marine mammal is detected acoustically, the acoustic source must be shut down, unless the PAM operator is confident that the animal detected is outside the exclusion zone or that the detected species is not subject to the shutdown requirement (see below).

The 500-m radial distance of the standard exclusion zone is expected to contain sound levels exceeding peak pressure injury criteria for all hearing groups other than, potentially, high-frequency cetaceans, while also

providing a consistent, reasonably observable zone within which PSOs would typically be able to conduct effective observational effort. Although significantly greater distances may be observed from an elevated platform under good conditions, we believe that 500 m is likely regularly attainable for PSOs using the naked eye during typical conditions. In addition, an exclusion zone is expected to be helpful in avoiding more severe behavioral responses. Behavioral response to an acoustic stimulus is determined not only by received level but by context (*e.g.,* activity state) including, importantly, proximity to the source (*e.g.,* Southall *et al.,* 2007; Ellison *et al.,* 2012; DeRuiter *et al.,* 2013). In prescribing an exclusion zone, we seek not only to avoid most potential auditory injury but also to reduce the likely severity of the behavioral response at a given received level of sound.

As discussed in our Notice of Proposed IHAs, use of monitoring and shutdown measures within defined exclusion zone distances is inherently an essentially instantaneous proposition—a rule or set of rules that requires mitigation action upon detection of an animal. This indicates that defining an exclusion zone on the basis of cSEL thresholds, which require that an animal accumulate some level of sound energy exposure over some period of time (*e.g.,* 24 hours), has questionable relevance as a standard protocol for mobile sources, given the relative motion of the source and the animals. A PSO aboard a mobile source will typically have no ability to monitor an animal's position relative to the acoustic source over relevant time periods for purposes of understanding whether auditory injury is likely to occur on the basis of cumulative sound exposure and, therefore, whether action should be taken to avoid such potential.

Cumulative SEL thresholds are more relevant for purposes of modeling the potential for auditory injury than they are for dictating real-time mitigation, though they can be informative (especially in a relative sense). We recognize the importance of the accumulation of sound energy to an understanding of the potential for auditory injury and that it is likely that, at least for low-frequency cetaceans, some potential auditory injury is likely impossible to fully avoid and should be considered for authorization.

Considering both the dual-metric thresholds described previously (and shown in Table 3) and hearing group-specific marine mammal auditory weighting functions in the context of the airgun sources considered here, auditory injury zones indicated by the peak pressure metric are expected to be predominant for both mid- and high-frequency cetaceans, while zones indicated by cSEL criteria are expected to be predominant for low-frequency cetaceans. Assuming source levels provided by the applicants and indicated in Table 1 and spherical spreading propagation, distances for exceedance of group-specific peak injury thresholds were calculated and are shown in Table 5.

Consideration of auditory injury zones based on cSEL criteria are dependent on the animal's generalized hearing range and how that overlaps with the frequencies produced by the sound source of interest in relation to marine mammal auditory weighting functions (NMFS, 2018). As noted above, these are expected to be predominant for low-frequency cetaceans because their most susceptible hearing range overlaps the low frequencies produced by airguns, while the modeling indicates that zones based on peak pressure criteria dominate for mid- and high-frequency cetaceans. As described in detail in our Notice of Proposed IHAs, we obtained unweighted spectrum data (modeled in 1 Hz bands) for a reasonably equivalent acoustic source (*i.e.,* a 36-airgun array with total volume of 6,600 in^3) in order to evaluate notional zone sizes and to incorporate NMFS's technical guidance weighting functions over an airgun array's full acoustic band. Using NMFS's associated User Spreadsheet with hearing group-specific weighted source levels, and inputs assuming spherical spreading propagation, a source velocity of 4.5 kn, shot intervals specified by the applicants, and pulse duration of 100 ms, we calculated potential radial distances to auditory injury zones (shown in Table 5).

Therefore, our 500-m exclusion zone contains the entirety of any potential injury zone for mid-frequency cetaceans (realistically, there is no such zone, as discussed above in ''Estimated Take''), while the zones within which injury could occur may be larger for high-frequency cetaceans (on the basis of peak pressure and depending on the specific array) and for low-frequency cetaceans (on the basis of cumulative sound exposure). Only three species of high-frequency cetacean could occur in the planned survey areas: The harbor porpoise and two species of the Family Kogiidae. Harbor porpoise are expected to occur rarely and only in the northern portion of the survey area. However, we require an extended shutdown measure for *Kogia* spp. to address these potential injury concerns (described later in this section).

In summary, our goal in prescribing a standard exclusion zone distance is to (1) encompass zones for most species within which auditory injury could occur on the basis of instantaneous exposure; (2) provide protection from the potential for more severe behavioral reactions (*e.g.,* panic, antipredator response) for marine mammals at relatively close range to the acoustic source; (3) enable more effective implementation of required mitigation by providing consistency and ease of implementation for PSOs, who need to monitor and implement the exclusion zone; and (4) to define a distance within which detection probabilities are reasonably high for most species under typical conditions. Our use of 500 m as the zone is not based directly on any quantitative understanding of the range at which auditory injury would be entirely precluded or any range specifically related to disruption of behavioral patterns. Rather, we believe it is a reasonable combination of factors. This zone has been proven as a feasible measure through past implementation by operators in the Gulf of Mexico (GOM; as regulated by BOEM pursuant to the Outer Continental Shelf Lands Act (OCSLA) (43 U.S.C. 1331–1356)). In summary, a practicable criterion such as this has the advantage of familiarity and simplicity while still providing in most cases a zone larger than relevant auditory injury zones, given realistic movement of source and receiver. Increased shutdowns, without a firm idea of the outcome the measure seeks to avoid, simply displace survey activity in time and increase the total duration of acoustic influence as well as total sound energy in the water (due to additional ramp-up and overlap where data acquisition was interrupted).

Dolphin Exception—The shutdown requirement described above is in place for all marine mammals, with the exception of small delphinids. As defined here, the small delphinid group is intended to encompass those members of the Family Delphinidae most likely to voluntarily approach the source vessel for purposes of interacting with the vessel and/or airgun array (*e.g.,* bow-riding). This exception to the shutdown requirement applies solely to specific genera of small dolphins—*Steno, Tursiops, Stenella, Delphinus, Lagenorhynchus,* and *Lagenodelphis* (see Table 2)—and applies under all circumstances, regardless of what the perception of the animal(s) behavior or intent may be. Variations of this measure that include exceptions based on animal behavior—including that

described in our Notice of Proposed IHAs, in which an exception was proposed to be applied only to ''traveling'' dolphins—have been proposed by both NMFS and BOEM and have been criticized, in part due to the subjective on-the-spot decision-making this scheme would require of PSOs. If the mitigation requirements are not sufficiently clear and objective, the outcome may be differential implementation across surveys as informed by individual PSOs' experience, background, and/or training. The exception described here is based on several factors: The lack of evidence of or presumed potential for the types of effects to these species of small delphinid that our shutdown requirement for other species seeks to avoid, the uncertainty and subjectivity introduced by such a decision framework, and the practicability concern presented by the operational impacts. Despite a large volume of observational effort during airgun surveys, including in locations where dolphin shutdowns have not previously been required (*i.e.,* the U.S. GOM and United Kingdom (UK) waters), we are not aware of accounts of notable adverse dolphin reactions to airgun noise (Stone, 2015a; Barkaszi *et al.,* 2012) other than one isolated incident (Gray and Van Waerebeek, 2011). Dolphins have a relatively high threshold for the onset of auditory injury (*i.e.,* PTS) and more severe adverse behavioral responses seem less likely given the evidence of purposeful approach and/or maintenance of proximity to vessels with operating airguns.

The best available scientific evidence indicates that auditory injury as a result of airgun sources is extremely unlikely for mid-frequency cetaceans, primarily due to a relative lack of sensitivity and susceptibility to noise-induced hearing loss at the frequency range output by airguns (*i.e.,* most sound below 500 Hz) as shown by the mid-frequency cetacean auditory weighting function (NMFS, 2018). Criteria for TTS in mid-frequency cetaceans for impulsive sounds were derived by experimental measurement of TTS in beluga whales exposed to pulses from a seismic watergun; dolphins exposed to the same stimuli in this study did not display TTS (Finneran *et al.,* 2002). Moreover, when the experimental watergun signal was weighted appropriately for mid-frequency cetaceans, less energy was filtered than would be the case for an airgun signal. More recently, Finneran *et al.* (2015) exposed bottlenose dolphins to repeated pulses from an airgun and measured no TTS.

We caution that, while dolphins are observed voluntarily approaching source vessels (*e.g.,* bow-riding or interacting with towed gear), the reasons for the behavior are unknown. In context of an active airgun array, the behavior cannot be assumed to be harmless. Although bow-riding comprises approximately 30 percent of behavioral observations in the GOM, there is a much lower incidence of the behavior when the acoustic source is active (Barkaszi *et al.,* 2012), and this finding was replicated by Stone (2015a) for surveys occurring in UK waters. There appears to be evidence of aversive behavior by dolphins during firing of airguns. Barkaszi *et al.* (2012) found that the median closest distance of approach to the acoustic source was at significantly greater distances during times of full-power source operation when compared to silence, while Stone (2015a) and Stone and Tasker (2006) reported that behavioral responses, including avoidance and changes in swimming or surfacing behavior, were evident for dolphins during firing of large arrays. Goold and Fish (1998) described a ''general pattern of localized disturbance'' for dolphins in the vicinity of an airgun survey. However, while these general findings—typically, dolphins will display increased distance from the acoustic source, decreased prevalence of ''bow-riding'' activities, and increases in surface-active behaviors—are indicative of adverse or aversive responses that may rise to the level of ''take'' (as defined by the MMPA), they are not indicative of any response of a severity such that the need to avoid it outweighs the impact on practicability for the industry and operators.

Additionally, increased shutdowns resulting from such a measure would require source vessels to revisit the missed track line to reacquire data, resulting in an overall increase in the total sound energy input to the marine environment and an increase in the total duration over which the survey is active in a given area. Therefore, the removal of such measures for small delphinids is warranted in consideration of the available information regarding the effectiveness of such measures in mitigating impacts to small delphinids and the practicability of such measures.

Although other mid-frequency hearing specialists (*e.g.,* large delphinids) are considered no more likely to incur auditory injury than are small delphinids, they are more typically deep divers, meaning that there is some increased potential for more severe effects from a behavioral reaction, as discussed in greater detail in ''Comments and Responses.'' Therefore, we anticipate benefit from a shutdown requirement for large delphinids in that it is likely to preclude more severe behavioral reactions for any such animals in close proximity to the source vessel as well as any potential for physiological effects.

At the same time, large delphinids are much less likely to approach vessels. Therefore, a shutdown requirement for large delphinids would not have similar impacts as a small delphinid shutdown in terms of either practicability for the applicant or corollary increase in sound energy output and time on the water.

Other Shutdown Requirements—Shutdown of the acoustic source is also required in the event of certain other observations beyond the standard 500-m exclusion zone. In our Notice of Proposed IHAs, we proposed to condition these shutdowns upon detection of the relevant species or circumstances at any distance. Following review of public comments, we determined it appropriate to limit such shutdown requirements to within a reasonable detection radius of 1.5 km. This maintains the intent of the measures as originally proposed, *i.e.,* to provide for additional real-time protection by limiting the intensity and duration of acoustic exposures for certain species or in certain circumstances, while reducing the area over which PSOs must maintain observational effort. As for normal shutdowns within the standard 500-m exclusion zone, shutdowns at extended distance should be made on the basis of confirmed detections (visual or acoustic) within the zone.

We determined an appropriate distance on the basis of available information regarding detection functions for relevant species, but note that, while based on quantitative data, the distance is an approximate limit that is merely intended to encompass the region within which we would expect a relatively high degree of success in sighting certain species while also improving PSO efficacy by removing the potential that a PSO might interpret these requirements as demanding a focus on areas further from the vessel. For each modeled taxon, Roberts *et al.* (2016) fitted detection functions that modeled the detectability of the taxon according to distance from the trackline and other covariates (*i.e.,* the probability of detecting an animal given its distance from the transect). These functions were based on nearly 1.1 million linear km of line-transect survey effort conducted from 1992–2014, with surveys arranged in aerial and shipboard hierarchies and further grouped according to similarity

of observation protocol and platform. Where a taxon was sighted infrequently, a detection function was fit to pooled sightings of suitable proxy species. For example, for the North Atlantic right whale and shipboard binocular surveys (*i.e.,* the relevant combination of platform and protocol), a detection function was fit using pooled sightings of right whales and other mysticete species (Roberts *et al.,* 2015p). The resulting detection function shows a slightly more than 20 percent probability of detecting right whales at 2 km, with a mean effective strip half-width (ESHW) (which provides a measure of how far animals are seen from the transect line; Buckland *et al.,* 2001) of 1,309 m (Roberts *et al.,* 2015p). Similarly, Barlow *et al.* (2011) reported mean ESHWs for various mysticete species ranging from approximately 1.5–2 km. The detection function used in modeling density for beaked whales provided a mean ESHW of 1,587 m (Roberts *et al.,* 2015l). Therefore, we set the shutdown radius for special circumstances (described below) at 1.5 km.

Comments disagreeing with our proposal to require shutdowns upon certain detections at any distance also suggested that the measures did not have commensurate benefit for the relevant species. However, it must be noted that any such observations would still be within range of where behavioral disturbance of some form and degree would be likely to occur (Table 4). While visual PSOs should focus observational effort within the vicinity of the acoustic source and vessel, this does not preclude them from periodic scanning of the remainder of the visible area or from noting observations at greater distances, and there is no reason to believe that such periodic scans by professional PSOs would hamper the ability to maintain observation of areas closer to the source and vessel. Circumstances justifying shutdown at extended distance (*i.e.,* within 1.5 km) include:

• Upon detection of a right whale. Recent data concerning the North Atlantic right whale, one of the most endangered whale species (Best *et al.,* 2001), indicate uncertainty regarding the population's recovery and a possibility of decline (see discussion under ''Description of Marine Mammals in the Area of the Specified Activities''). We believe it appropriate to eliminate potential effects to individual right whales to the extent possible;

• Upon visual observation of a large whale (*i.e.,* sperm whale or any baleen whale) with calf, with ''calf'' defined as an animal less than two-thirds the body size of an adult observed to be in close association with an adult. Groups of whales are likely to be more susceptible to disturbance when calves are present (*e.g.,* Bauer *et al.,* 1993), and disturbance of cow-calf pairs could potentially result in separation of vulnerable calves from adults. Separation, if it occurred, could be exacerbated by airgun signals masking communication between adults and the separated calf (Videsen *et al.,* 2017). Absent separation, airgun signals can disrupt or mask vocalizations essential to mother-calf interactions. Given the consequences of potential loss of calves in the context of ongoing UMEs for multiple mysticete species, as well as the functional sensitivity of the mysticete whales to frequencies associated with airgun survey activity, we believe this measure is warranted;

• Upon detection of a beaked whale or *Kogia* spp. These species are behaviorally sensitive deep divers and it is possible that disturbance could provoke a severe behavioral response leading to injury (*e.g.,* Wursig *et al.,* 1998; Cox *et al.,* 2006). We recognize that there are generally low detection probabilities for beaked whales and *Kogia* spp., meaning that many animals of these species may go undetected. Barlow (1999) estimates such probabilities at 0.23 to 0.45 for Cuvier's and Mesoplodont beaked whales, respectively. However, Barlow and Gisiner (2006) predict a roughly 24–48 percent reduction in the probability of detecting beaked whales during seismic mitigation monitoring efforts as compared with typical research survey efforts, and Moore and Barlow (2013) noted a decrease in $g(0)$ for Cuvier's beaked whales from 0.23 at BSS 0 (calm) to 0.024 at BSS 5. Similar detection probabilities have been noted for *Kogia* spp., though they typically travel in smaller groups and are less vocal, thus making detection more difficult (Barlow and Forney, 2007). As discussed previously in this document (see ''Estimated Take''), there are high levels of predicted exposures for beaked whales in particular. Additionally for high-frequency cetaceans such as *Kogia* spp., auditory injury zones relative to peak pressure thresholds may range from approximately 350–1,550 m from the acoustic source, depending on the specific array characteristics (NMFS, 2018); and

• Upon visual observation of an aggregation (defined as six or more animals) of large whales of any species. Under these circumstances, we assume that the animals are engaged in some important behavior (*e.g.,* feeding, socializing) that should not be disturbed.

Shutdown Implementation Protocols—Any PSO on duty has the authority to delay the start of survey operations or to call for shutdown of the acoustic source. When shutdown is called for by a PSO, the acoustic source must be immediately deactivated and any dispute resolved only following deactivation. The operator must establish and maintain clear lines of communication directly between PSOs on duty and crew controlling the acoustic source to ensure that shutdown commands are conveyed swiftly while allowing PSOs to maintain watch; hand-held UHF radios are recommended. When both visual PSOs and PAM operators are on duty, all detections must be immediately communicated to the remainder of the on-duty team for potential verification of visual observations by the PAM operator or of acoustic detections by visual PSOs and initiation of dialogue as necessary. When there is certainty regarding the need for mitigation action on the basis of either visual or acoustic detection alone, the relevant PSO(s) must call for such action immediately.

Upon implementation of shutdown, the source may be reactivated after the animal(s) has been observed exiting the exclusion zone or following a 30-minute clearance period with no further detection of the animal(s). For harbor porpoise—the only small odontocete for which shutdown is required—this clearance period is limited to 15 minutes.

If the acoustic source is shut down for reasons other than mitigation (*e.g.,* mechanical difficulty) for brief periods (*i.e.,* less than 30 minutes), it may be activated again without ramp-up if PSOs have maintained constant visual and acoustic observation and no visual detections of any marine mammal have occurred within the exclusion zone and no acoustic detections have occurred. We define ''brief periods'' in keeping with other clearance watch periods and to avoid unnecessary complexity in protocols for PSOs. For any longer shutdown (*e.g.,* during line turns), pre-clearance watch and ramp-up are required. For any shutdown at night or in periods of poor visibility (*e.g.,* BSS 4 or greater), ramp-up is required but if the shutdown period was brief and constant observation maintained, pre-clearance watch is not required.

Power-Down

Power-down, as defined here, refers to reducing the array to a single element as a substitute for full shutdown. Use of a single airgun as a ''mitigation source,''

e.g., during extended line turns, is not allowed. In a power-down scenario, it is assumed that reducing the size of the array to a single element reduces the ensonified area such that an observed animal is outside of any area within which injury or more severe behavioral reactions could occur. Here, power-down is not allowed for any reason (*e.g.,* to avoid pre-clearance and/or ramp-up).

Miscellaneous Protocols

The acoustic source must be deactivated when not acquiring data or preparing to acquire data, except as necessary for testing. Unnecessary use of the acoustic source should be avoided. Firing of the acoustic source at any volume above the stated production volume is not authorized for these IHAs; the operator must provide information to the lead PSO at regular intervals confirming the firing volume. Notified operational capacity (not including redundant backup airguns) must not be exceeded during the survey, except where unavoidable for source testing and calibration purposes. All occasions where activated source volume exceeds notified operational capacity must be noticed to the PSO(s) on duty and fully documented for reporting. The lead PSO must be granted access to relevant instrumentation documenting acoustic source power and/or operational volume.

Testing of the acoustic source involving all elements requires normal mitigation protocols (*e.g.,* ramp-up). Testing limited to individual source elements or strings does not require ramp-up but does require pre-clearance.

Restriction Areas

Below we provide discussion of various time-area restrictions. Because the purpose of these areas is to reduce the likelihood of exposing animals within the designated areas to noise from airgun surveys that is likely to result in harassment, we require that source vessels maintain minimum standoff distances (*i.e.,* buffers) from the areas. Sound propagation modeling results provided for a notional large airgun array in BOEM's PEIS indicate that a 10 km distance would likely contain received levels of sound exceeding 160 dB rms under a wide variety of conditions (*e.g.,* 21 scenarios encompassing four depth regimes, four seasons, two bottom types). See Appendix D of BOEM's PEIS for more detail. The 95 percent ranges (*i.e.,* the radius of a circle encompassing 95 percent of grid points equal to or greater than the 160 dB threshold value) provided in Table D–22 of BOEM's PEIS range from 4,959–9,122 m, with mean of 6,838 m. We adopt a standard 10-km buffer distance to avoid ensonification above 160 dB rms of restricted areas under most circumstances.

Coastal Restriction—No survey effort may occur within 30 km of the coast. The intent of this restriction is to provide additional protection for coastal stocks of bottlenose dolphin, all of which are designated as depleted under the MMPA. This designation for all current coastal stocks is retained from the originally delineated single coastal migratory stock, which was revised to recognize the existence of multiple stocks in 2002 (Waring *et al.,* 2016). The prior single coastal stock was designated as depleted because it was determined to be below the optimum sustainable population level (*i.e.,* the number of animals that will result in the maximum productivity of the population, keeping in mind the carrying capacity of their ecosystem) (Waring *et al.,* 2001). Already designated as depleted, a UME affected bottlenose dolphins along the Atlantic coast, from New York to Florida, from 2013–15. Genetic analyses performed to date indicate that 99 percent of dolphins impacted were of the coastal ecotype, which may be expected to typically occur within 20 km of the coast. As described above, a 10 km buffer is provided to encompass the area within which sound exceeding 160 dB rms would reasonably be expected to occur. Further discussion of this UME is provided under ''Description of Marine Mammals in the Area of the Specified Activity.''

North Atlantic Right Whale—From November through April, no survey effort may occur within 90 km of the coast. In our Notice of Proposed IHAs, we proposed a similar restriction out to 47 km. The proposed 47-km seasonal restriction of survey effort was intended to avoid ensonification by levels of sound expected to result in behavioral harassment of particular areas of expected importance for North Atlantic right whales, including designated critical habitat, vessel speed limit seasonal management areas (SMAs), a coastal strip containing SMAs, and vessel speed limit dynamic management areas (DMAs). This area was expected to provide substantial protection of right whales within the migratory corridor and calving and nursery grounds. However, following review of comments received from the Marine Mammal Commission, as well as other public comments received and as a result of the continued deterioration of the status of this population (described previously in ''Description of Marine Mammals in the Area of the Specified Activity''), we considered new information regarding predicted right whale distribution (*e.g.,* Roberts *et al.,* 2017; Davis *et al.,* 2017) and re-evaluated the proposed right whale time-area restriction.

Specifically, we became aware of an effort by Roberts *et al.* to update the 2015 North Atlantic right whale density models. As described in Roberts *et al.* (2017), the updates greatly expanded the dataset used to derive density outputs, especially within the planned survey area, as they incorporated a key dataset that was not included in the 2015 model version: Aerial surveys conducted over multiple years by several organizations in the southeast United States. In addition, the AMAPPS survey data were incorporated into the revised models. By including these additional data sources, the number of right whale sightings used to inform the model within the planned survey area increased by approximately 2,500 sightings (approximately 40 sightings informing the 2015 models versus approximately 2,560 sightings informing the updated 2017 models). In addition, these models incorporated several improvements to minimize known biases and used an improved seasonal definition that more closely aligns with right whale biology. Importantly, the revised models showed a strong relationship between right whale abundance in the mid-Atlantic during the winter (December-March) and distance to shore out to approximately 80 km (Roberts *et al.,* 2017), which was previously estimated out to approximately 50 km (Roberts *et al.,* 2015p). As described above, a 10 km buffer is provided to encompass the area within which sound exceeding 160 dB rms would reasonably be expected to occur. Mid-Atlantic SMAs for vessel speed limits are in effect from November 1 through April 30, while southeast SMAs are in effect from November 15 through April 15 (see 50 CFR 224.105). Therefore, the area discussed here for spatial mitigation would be in effect from November 1 through April 30.

While we acknowledge that some whales may be present at distances further offshore during the November through April restriction—though whales are not likely to occur in waters deeper than 1,500 m—and that there may be whales present during months outside the restriction (*e.g.,* Davis *et al.,* 2017; Krzystan *et al.,* 2018), we have accounted for the best available information in reasonably limiting the potential for acoustic exposure of right whales to levels exceeding harassment thresholds. When coupled with the expanded shutdown provision described previously for right whales,

the prescribed mitigation may reasonably be expected to eliminate most potential for behavioral harassment of right whales.

However, as discussed above, in lieu of this requirement, applicants may alternatively develop and submit a monitoring and mitigation plan for NMFS's approval that would be sufficient to achieve comparable protection for North Atlantic right whales. If approved, applicants would be required to maintain a minimum coastal standoff distance of 47 km from November through April while operating in adherence with the approved plan from 47 through 80 km offshore. (Note that the 80 km distance is assumed to represent to a reasonable extent right whale occurrence on the migratory pathway; therefore, under an approved plan the 10-km buffer would not be relevant.)

DMAs are associated with a scheme established by the final rule for vessel speed limits (73 FR 60173; October 10, 2008; extended by 78 FR 73726; December 9, 2013) to reduce the risk of ship strike for right whales. In association with those regulations, NMFS established a program whereby vessels are requested, but not required, to abide by speed restrictions or avoid locations when certain aggregations of right whales are detected outside SMAs. Generally, the DMA construct is intended to acknowledge that right whales can occur outside of areas where they predictably and consistently occur due to, *e.g.,* varying oceanographic conditions that dictate prey concentrations. NMFS establishes DMAs by surveying right whale habitat and, when a specific aggregation is sighted, creating a temporary zone (*i.e.,* DMA) around the aggregation. DMAs are in effect for 15 days when designated and automatically expire at the end of the period, but may be extended if whales are re-sighted in the same area.

NMFS issues announcements of DMAs to mariners via its customary maritime communication media (*e.g.,* NOAA Weather radio, websites, email and fax distribution lists) and any other available media outlets. Information on the possibility of establishment of such zones is provided to mariners through written media such as *U.S. Coast Pilots* and *Notice to Mariners* including, in particular, information on the media mariners should monitor for notification of the establishment of a DMA. Upon notice via the above media of DMA designation, survey operators must cease operation within 24 hours if within 10 km of the boundary of a designated DMA and may not conduct survey operations within 10 km of a designated DMA during the period in which the DMA is active. It is the responsibility of the survey operators to monitor appropriate media and to be aware of designated DMAs.

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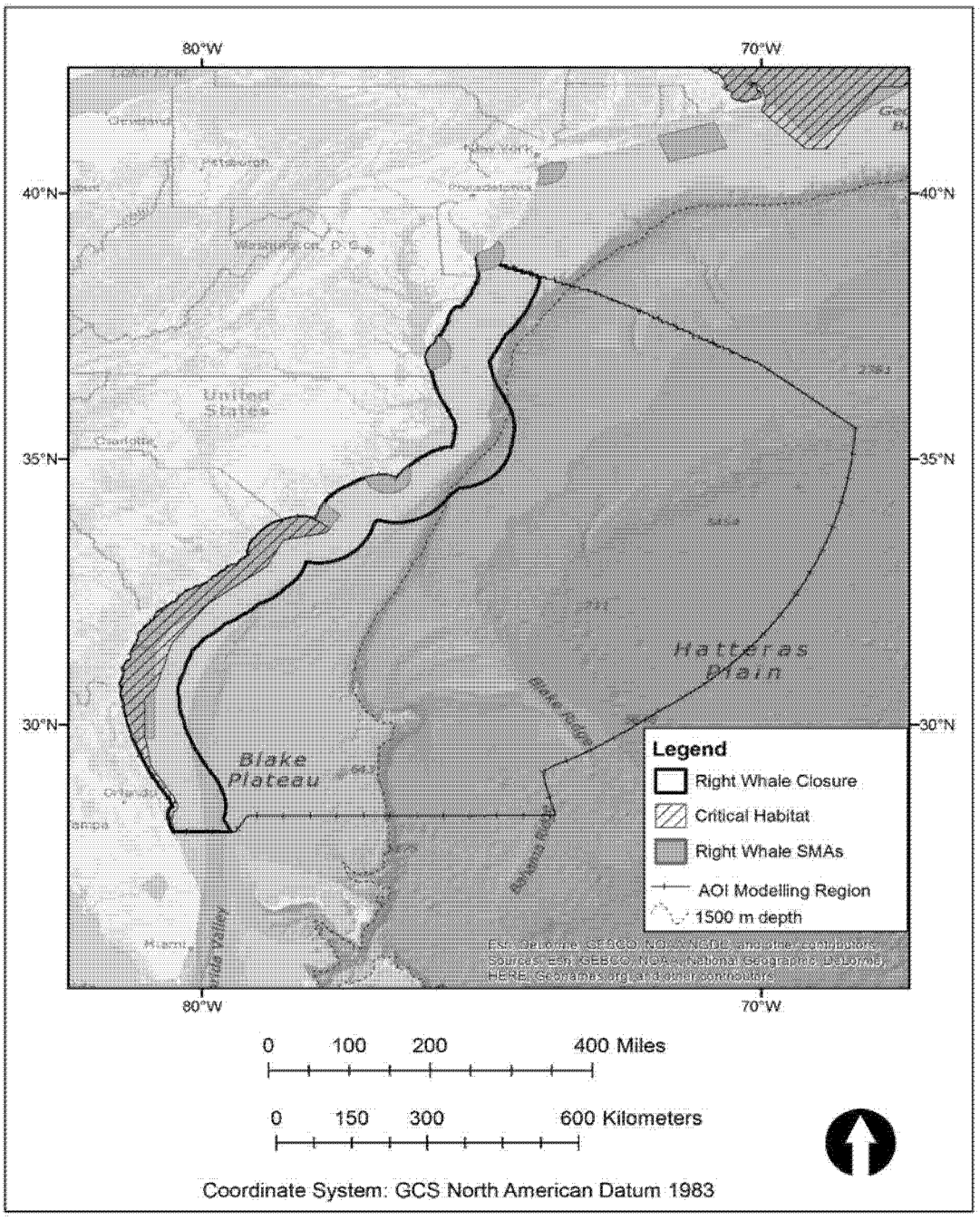

Figure 3. Time-Area Restriction for North Atlantic Right Whales in Relation to Existing Areas Designated for Right Whale Protection.

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Other Species—Predicted acoustic exposures are moderate to high for certain potentially affected marine mammal species (see Table 6) and, regardless of the absolute numbers of predicted exposures, the scope of planned activities (*i.e.,* survey activity throughout substantial portions of many species range and for substantial portions of the year) gives rise to concern regarding the impact on certain potentially affected stocks. Therefore, we take the necessary step of identifying additional spatiotemporal restrictions on survey effort, as described here (Figure 4 and Table 7). In response to public comment, where possible we conducted a quantitative assessment of take avoided (described previously in ''Estimated Take''). Our qualitative assessment leads us to believe that

implementation of these measures is expected to provide biologically meaningful benefit for the affected animals by restricting survey activity and the effects of the sound produced in areas of residency and/or preferred habitat that support higher densities for the stocks during substantial portions of the year.

The restrictions described here are primarily targeted towards protection of sperm whales, beaked whales (*i.e.,* Cuvier's beaked whale or *Mesoplodon* spp. but not the northern bottlenose whale; see ''Description of Marine Mammals in the Area of the Specified Activity''), and pilot whales. For all three species or guilds, the amount of predicted exposures is moderate to high. The moderate to high amount of predicted exposures in conjunction with other contextual elements provides the impetus to develop appropriate restrictions. Beaked whales are considered to be a particularly acoustically sensitive species. The sperm whale is an endangered species, also considered to be acoustically sensitive and potentially subject to significant disturbance of important foraging behavior. Pilot whale populations in U.S. waters of the Atlantic are considered vulnerable due to high levels of mortality in commercial fisheries, and are therefore likely to be less resilient to other stressors, such as disturbance from the planned surveys.

In some cases, we expect substantial subsidiary benefit for additional species that also find preferred habitat in the designated area of restriction. In particular, Area #4 (Figure 4), although delineated in order to specifically provide an area of anticipated benefit to beaked whales, sperm whales, and pilot whales, is expected to host a diverse cetacean fauna (*e.g.,* McAlarney *et al.,* 2015). Our analysis (described below) indicates that species most likely to derive subsidiary benefit from this time-area restriction include the bottlenose dolphin, Risso's dolphin, and common dolphin. For species with density predicted through stratified models, similar analysis is not possible and assumptions regarding potential benefit of time-area restrictions are based on known ecology of the species and sightings patterns and are less robust. Nevertheless, subsidiary benefit for Areas #1–3 (Figure 4) should be expected for species known to be present in these areas (*e.g.,* assumed affinity for slope/abyss areas off Cape Hatteras): *Kogia* spp., pantropical spotted dolphin, Clymene dolphin, and rough-toothed dolphin.

We described our rationale for and development of these time-area restrictions in detail in our Notice of Proposed IHAs; please see that document for more detail. Literature newly available since publication of the Notice of Proposed IHAs provides additional support for the importance of these areas. For example, McLellan *et al.* (2018), reporting the results of aerial surveys conducted from 2011–2015, provide additional confirmation that a portion of the region described below as Area #4 (''Hatteras and North'') hosts high densities of beaked whales, concluding that the area off Cape Hatteras at the convergence of the Labrador Current and Gulf Stream is a particularly important habitat for several species of beaked whales. Stanistreet *et al.* (2017) report the results of a multi-year (2011–2015) passive acoustic monitoring effort to assess year-round marine mammal occurrence along the continental slope, including four locations within the planned survey area (*i.e.,* Norfolk Canyon, Cape Hatteras, Onslow Bay, and Jacksonville) and, in this paper, they further document the presence of beaked whales in Area #4. Stanistreet *et al.* (2018) report the results of this study for sperm whale occurrence at the same sites along the continental slope. These results showed that sperm whales were present frequently at the first three sites, with few detections at Jacksonville. The greatest monitoring effort was conducted at the Cape Hatteras site, where detections were made on 65 percent of 734 recording days across all seasons. In addition to having the highest detection rate of sites within the specific geographic region (in conjunction with roughly double the amount of recording effort compared with the next highest site), Cape Hatteras exhibited the most distinct seasonal pattern of any recording site (Stanistreet *et al.,* 2018). The authors reported consistently higher sperm whale occurrence at Cape Hatteras during the winter than any other season. On the basis of this new information, we shifted the timing of the seasonal restriction in Area #4 from July through September (as proposed) to January through March (*i.e.,* ''winter''; Stanistreet *et al.,* 2018). Our previously proposed timing of the seasonal restriction was based on barely discernable distribution shifts based on monthly model predictions (Roberts *et al.,* 2016). However, the revised timing, as indicated by Stanistreet *et al.* (2018), is generally consistent with the seasonal shift in sperm whale concentrations previously described in the western North Atlantic (Perry *et al.,* 1999, Waring *et al.,* 2014).

Please note that, following review of public comments, former Area #1 was eliminated from consideration (discussed in greater detail under ''Comments and Responses''). Therefore, numbering of areas described here has shifted down by one as compared with the discussion presented in our Notice of Proposed IHAs, *i.e.,* former Area #5 is now Area #4, etc. In order to consider potential restriction of survey effort in time and space, we considered the outputs of habitat-based predictive density models (Roberts *et al.,* 2016) as well as available information concerning focused marine mammal studies within the survey areas, *e.g.,* photo-identification, telemetry, acoustic monitoring. The latter information was used primarily to provide verification for some of the areas and times considered, and helps to confirm that areas of high predicted density are in fact preferred habitat for these species. We used the density model outputs by creating core abundance areas, *i.e.,* an area that contains some percentage of predicted abundance for a given species or species group. We were not able to consider core abundance areas for species with stratified models showing uniform density; however, this information informs us as to whether those species may receive subsidiary benefit from a given time-area restriction.

A core abundance area is the smallest area that represents a given percentage of abundance. As described in our Notice of Proposed IHAs, we created a range of core abundance areas for each species of interest and determined that in most cases the 25 percent core abundance area best balanced adequate protection for the target species with concerns regarding practicability for applicants. The larger the percentage of abundance captured, the larger the area. However, Area #4 was designed as a conglomerate by merging areas indicated to be important through the core abundance analysis and available scientific literature for beaked whales, pilot whales, and sperm whales. In particular, for sperm whales (which are predicted to be broadly distributed on the slope throughout the year), we included an area predicted to consistently host higher relative densities in all months (corresponding with the five percent core abundance threshold). We assessed different levels of core abundance in order to define a relatively restricted area of preferred habitat across all seasons. This area in the vicinity of the shelf break to the north of Cape Hatteras (which forms the

conglomerate Area #4), together with spatially separated canyon features contained within the 25 percent core abundance areas and previously identified as preferred habitat for beaked whales, form the basis for our time-area restriction for sperm whales. Core abundance maps are provided online at *www.fisheries.noaa.gov/action/incidental-take-authorization-oil-and-gas-industry-geophysical-survey-activity-atlantic.*

In summary, we require the following time-area restrictions:

- In order to protect coastal bottlenose dolphins, a 30-km coastal strip (20 km plus 10 km buffer) would be closed to use of the acoustic source year-round;
- In order to protect the North Atlantic right whale, a 90-km coastal strip (80 km plus 10 km buffer) would be closed to use of the acoustic source from November through April (Figure 3) (or comparable protection would be provided through implementation of a NMFS-approved mitigation and monitoring plan at distances between 47–80 km offshore). Dynamic management areas (buffered by 10 km) are also closed to use of the acoustic source when in effect;

The 10-km buffer is built into the areas defined below and in Table 7. Therefore, we do not separately mention the addition of the buffer.

- Deepwater canyon areas. Areas #1–3 (Figure 4) are defined in Table 7 and will be closed to use of the acoustic source year-round. Although they may be protective of additional species (*e.g., Kogia* spp.), Area #1 is expected to be particularly beneficial for beaked whales and Areas #2–3 are expected to be particularly beneficial for both beaked whales and sperm whales;
- Shelf break off Cape Hatteras and to the north (''Hatteras and North''), including slope waters around ''The Point.'' Area #4 is defined in Table 7 and will be closed to use of the acoustic source from January through March. Although this closure is expected to be beneficial for a diverse species assemblage, Area #4 is expected to be particularly beneficial for beaked whales, sperm whales, and pilot whales.

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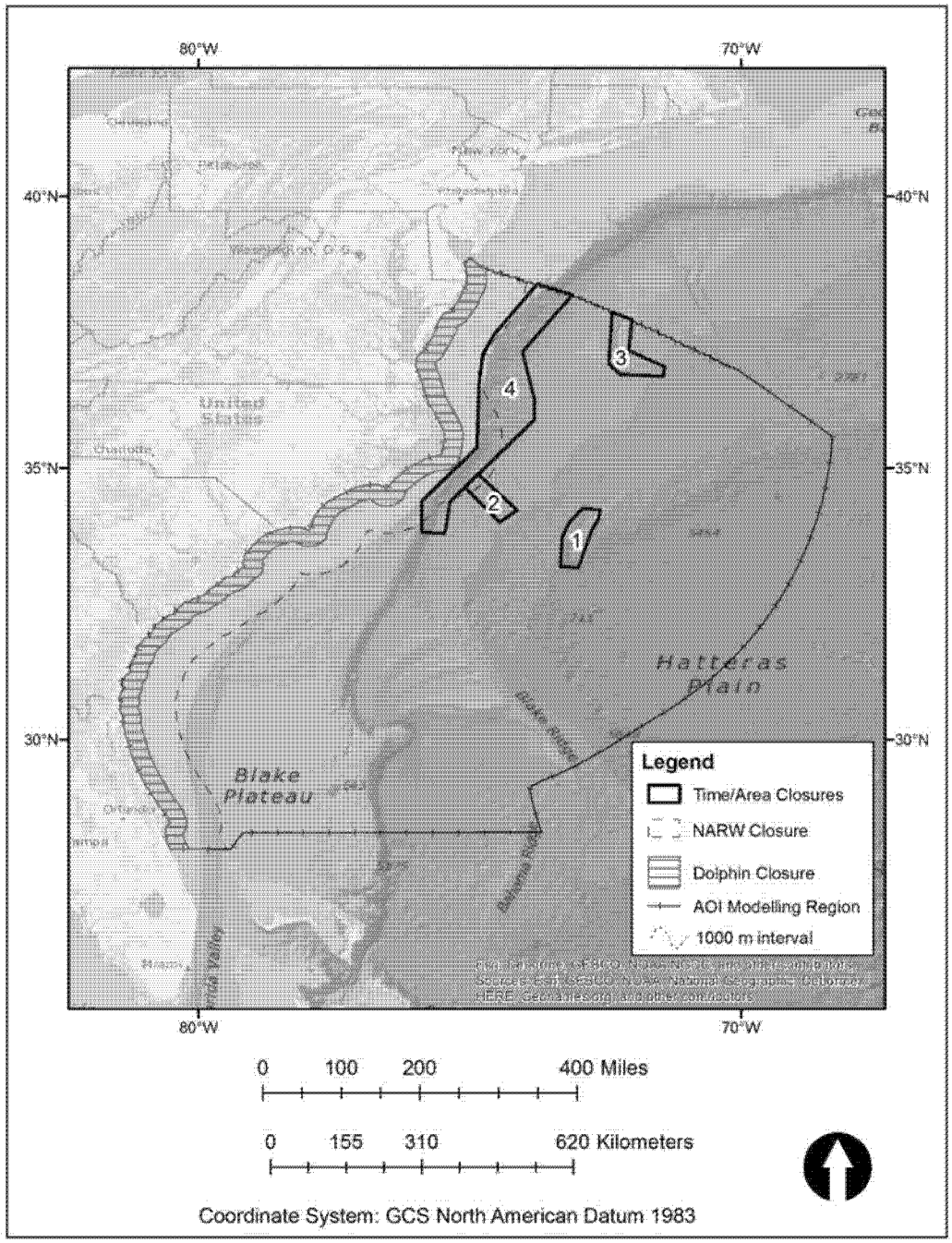

Figure 4. Time-Area Restrictions.

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TABLE 7—BOUNDARIES OF TIME-AREA RESTRICTIONS DEPICTED IN FIGURE 4

Area	Latitude	Longitude
1	33°31′16″ N	72°52′07″ W
1	33°10′05″ N	72°59′59″ W
1	33°11′23″ N	73°19′36″ W
1	33°43′34″ N	73°17′43″ W
1	33°59′43″ N	73°10′16″ W
1	34°15′10″ N	72°55′37″ W
1	34°14′02″ N	72°36′00″ W
1	34°03′33″ N	72°37′27″ W
1	33°53′00″ N	72°44′31″ W
2	34°13′21″ N	74°07′33″ W
2	34°00′07″ N	74°26′41″ W
2	34°38′40″ N	75°05′52″ W
2	34°53′24″ N	74°51′11″ W
3	36°41′17″ N	71°25′47″ W
3	36°43′20″ N	72°13′25″ W
3	36°55′20″ N	72°26′18″ W
3	37°52′21″ N	72°22′31″ W
3	37°43′54″ N	72°00′40″ W
3	37°09′52″ N	72°04′31″ W
3	36°52′01″ N	71°24′31″ W
4	37°08′30″ N	74°01′42″ W
4	36°15′12″ N	73°48′37″ W
4	35°53′14″ N	73°49′02″ W
4	34°23′07″ N	75°21′33″ W
4	33°47′37″ N	75°27′25″ W
4	33°48′31″ N	75°52′58″ W
4	34°23′57″ N	75°52′50″ W
4	35°22′29″ N	74°51′50″ W
4	36°32′31″ N	74°49′31″ W
4	37°05′39″ N	74°45′37″ W
4	37°27′53″ N	74°32′40″ W
4	38°23′15″ N	73°45′06″ W
4	38°11′17″ N	73°06′36″ W

Vessel Strike Avoidance

These measures apply to all vessels associated with the planned survey activity (*e.g.,* source vessels, chase vessels, supply vessels); however, we note that these requirements do not apply in any case where compliance would create an imminent and serious threat to a person or vessel or to the extent that a vessel is restricted in its ability to maneuver and, because of the restriction, cannot comply. These measures include the following:

1. Vessel operators and crews must maintain a vigilant watch for all marine mammals and slow down, stop their vessel, or alter course, as appropriate and regardless of vessel size, to avoid striking any marine mammal. A single marine mammal at the surface may indicate the presence of submerged animals in the vicinity of the vessel; therefore, precautionary measures should be exercised when an animal is observed. A visual observer aboard the vessel must monitor a vessel strike avoidance zone around the vessel (specific distances detailed below), to ensure the potential for strike is minimized. Visual observers monitoring the vessel strike avoidance zone can be either third-party observers or crew members, but crew members responsible for these duties must be provided sufficient training to distinguish marine mammals from other phenomena and broadly to identify a marine mammal to broad taxonomic group (*i.e.,* as a right whale, other whale, or other marine mammal). In this context, ''other whales'' includes sperm whales and all baleen whales other than right whales;

2. All vessels, regardless of size, must observe the 10 kn speed restriction in specific areas designated for the protection of North Atlantic right whales: Any DMAs when in effect, the Mid-Atlantic SMAs (from November 1 through April 30), and critical habitat and the Southeast SMA (from November 15 through April 15). See *www.fisheries.noaa.gov/national/endangered-species-conservation/reducing-ship-strikes-north-atlantic-right-whales* for more information on these areas;

3. Vessel speeds must also be reduced to 10 kn or less when mother/calf pairs, pods, or large assemblages of any marine mammal are observed near a vessel;

4. All vessels must maintain a minimum separation distance of 500 m from right whales. If a whale is observed but cannot be confirmed as a species other than a right whale, the vessel operator must assume that it is a right whale and take appropriate action;

5. All vessels must maintain a minimum separation distance of 100 m from sperm whales and all other baleen whales;

6. All vessels must attempt to maintain a minimum separation distance of 50 m from all other marine mammals, with an exception made for those animals that approach the vessel; and

7. When marine mammals are sighted while a vessel is underway, the vessel should take action as necessary to avoid violating the relevant separation distance (*e.g.,* attempt to remain parallel to the animal's course, avoid excessive speed or abrupt changes in direction until the animal has left the area). If marine mammals are sighted within the relevant separation distance, the vessel should reduce speed and shift the engine to neutral, not engaging the engines until animals are clear of the area. This recommendation does not apply to any vessel towing gear.

General Measures

All vessels associated with survey activity (*e.g.,* source vessels, chase vessels, supply vessels) must have a functioning Automatic Identification System (AIS) onboard and operating at all times, regardless of whether AIS would otherwise be required. Vessel names and call signs must be provided to NMFS, and applicants must notify NMFS when survey vessels are operating.

We have carefully evaluated the suite of mitigation measures described here and considered a range of other measures in the context of ensuring that we prescribe the means of effecting the least practicable adverse impact on the affected marine mammal species and stocks and their habitat. Based on our evaluation of these measures, we have determined that the required mitigation measures provide the means of effecting the least practicable adverse impact on marine mammal species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

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 the authorized taking. NMFS's MMPA implementing regulations further describe the information that an applicant should provide when requesting an authorization (50 CFR 216.104(a)(13)), including the means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and the level of taking or impacts on populations of marine mammals. 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 in action area (*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 important physical components of marine mammal habitat); and

• Mitigation and monitoring effectiveness.

Changes From the Notice of Proposed IHAs

Here we summarize substantive changes to monitoring and reporting requirements from our Notice of Proposed IHAs. All changes were made on the basis of review of public comments received and/or review of new information.

• As described in our Notice of Proposed IHAs, we preliminarily reached small numbers findings for some species on the basis of the proposed limitation of authorized take to approximately one-third of the abundance estimate deemed at the time to be most appropriate. In order to ensure that IHA-holders would not exceed this cap without limiting the planned survey activity, we proposed to require interim reporting in which IHA-holders would report all observations of marine mammals as well as corrected numbers of marine mammals ''taken.'' We received information from several commenters—including several of the applicants—strongly indicating that such a de facto limitation, coupled with a novel reporting requirement, was impracticable. In summary, commenters noted that such surveys are multi-million dollar endeavors and stated that the surveys would simply not be conducted rather than commit such costs to the survey in the face of significant uncertainty as to whether the survey might be suddenly shut down as a result of reaching a pre-determined cap on the basis of novel modeling of ''corrected'' takes. We also received many comments indicating that our small numbers analyses were flawed and, as described in detail later in this notice (see ''Small Numbers Analyses'') we reconsidered the available information and re-evaluated our analyses in response to these comments. As a result of our revised small numbers analyses, such a cap coupled with reporting scheme is not necessary. Further, we agree with commenters that the proposal presented significant practicability concerns. Therefore, the proposed ''interim'' reporting requirement is eliminated.

• Separately, while we recognize the importance of producing the most accurate estimates of actual take possible, we agree that the proposed approach to correcting observations to produce estimates of actual takes was (1) not the best available approach; (2) is novel in that it has not been previously required of applicants conducting similar activities; and (3) may not be appropriate for application to observations conducted from working source vessels. We have adopted a different approach to performing these ''corrections,'' as recommended through comment from the Marine Mammal Commission, but in this case we will perform these corrections upon submission of reports from IHA-holders and evaluate the appropriateness of this approach and the validity of the results prior to requiring it for future IHAs.

• As a result of concerns expressed through public comment, we have revised requirements relating to reporting of injured or dead marine mammals and have added newly crafted requirements relating to actions that should be taken in response to stranding events in certain circumstances.

Monitoring requirements are the same for all applicants, and a single discussion is provided here.

PSO Eligibility and Qualifications

All PSO resumes must be submitted to NMFS and PSOs must be approved by NMFS after a review of their qualifications. These qualifications include whether the individual has successfully completed the necessary training (see ''Training,'' below) and, if relevant, whether the individual has the requisite experience (and is in good standing). PSOs should provide a current resume and information related to PSO training; submitted resumes should not include superfluous information. Information related to PSO training should include (1) a course information packet that includes the name and qualifications (*e.g.,* experience, training, or education) of the instructor(s), the course outline or syllabus, and course reference material; and (2) a document stating the PSO's successful completion of the course. PSOs must be trained biologists, with the following minimum qualifications:

• A bachelor's degree from an accredited college or university with a major in one of the natural sciences and a minimum of 30 semester hours or equivalent in the biological sciences and at least one undergraduate course in math or statistics;

• Experience and ability to conduct field observations and collect data according to assigned protocols (may include academic experience) and experience with data entry on computers;

• Visual acuity in both eyes (correction is permissible) sufficient for discernment of moving targets at the water's surface with ability to estimate target size and distance; use of binoculars may be necessary to correctly identify the target (required for visual PSOs only);

• Experience or training in the field identification of marine mammals, including the identification of behaviors (required for visual PSOs only);

• Sufficient training, orientation, or experience with the survey operation to ensure personal safety during observations;

• Writing skills sufficient to prepare a report of observations (*e.g.,* description, summary, interpretation, analysis) including but not limited to the number and species of marine mammals observed; marine mammal behavior; and descriptions of activity conducted and implementation of mitigation;

• Ability to communicate orally, by radio or in person, with survey personnel to provide real-time information on marine mammals detected in the area as necessary; and

• Successful completion of relevant training (described below), including completion of all required coursework and passing (80 percent or greater) a written and/or oral examination developed for the training program.

The educational requirements may be waived if the PSO has acquired the relevant skills through alternate experience. Requests for such a waiver must include written justification, and prospective PSOs granted waivers must satisfy training requirements described below. Alternate experience that may be considered includes, but is not limited to, the following:

• Secondary education and/or experience comparable to PSO duties;

• Previous work experience conducting academic, commercial, or government-sponsored marine mammal surveys; and

• Previous work experience as a PSO; the PSO should demonstrate good standing and consistently good performance of PSO duties.

Training—NMFS does not currently approve specific training programs; however, acceptable training may include training previously approved by BSEE, or training that adheres generally to the recommendations provided by ''*National Standards for a Protected Species Observer and Data Management*

Program: A Model Using Geological and Geophysical Surveys'' (Baker *et al.,* 2013). Those recommendations include the following topics for training programs:

- Life at sea, duties, and authorities;
- Ethics, conflicts of interest, standards of conduct, and data confidentiality;
- Offshore survival and safety training;
- Overview of oil and gas activities (including geophysical data acquisition operations, theory, and principles) and types of relevant sound source technology and equipment;
- Overview of the MMPA and ESA as they relate to protection of marine mammals;
- Mitigation, monitoring, and reporting requirements as they pertain to geophysical surveys;
- Marine mammal identification, biology and behavior;
- Background on underwater sound;
- Visual surveying protocols, distance calculations and determination, cues, and search methods for locating and tracking different marine mammal species (visual PSOs only);
- Optimized deployment and configuration of PAM equipment to ensure effective detections of cetaceans for mitigation purposes (PAM operators only);
- Detection and identification of vocalizing species or cetacean groups (PAM operators only);
- Measuring distance and bearing of vocalizing cetaceans while accounting for vessel movement (PAM operators only);
- Data recording and protocols, including standard forms and reports, determining range, distance, direction, and bearing of marine mammals and vessels; recording GPS location coordinates, weather conditions, Beaufort wind force and sea state, etc.;
- Proficiency with relevant software tools;
- Field communication/support with appropriate personnel, and using communication devices (*e.g.,* two-way radios, satellite phones, internet, email, facsimile);
- Reporting of violations, noncompliance, and coercion; and
- Conflict resolution.

PAM operators should regularly refresh their detection skills through practice with simulation-modeling software, and should keep up to date with training on the latest software/hardware advances.

Visual Monitoring

The lead PSO is responsible for establishing and maintaining clear lines of communication with vessel crew. The vessel operator shall work with the lead PSO to accomplish this and shall ensure any necessary briefings are provided for vessel crew to understand mitigation requirements and protocols. While on duty, PSOs will continually scan the water surface in all directions around the acoustic source and vessel for presence of marine mammals, using a combination of the naked eye and high-quality binoculars, from optimum vantage points for unimpaired visual observations with minimum distractions. PSOs will collect observational data for all marine mammals observed, regardless of distance from the vessel, including species, group size, presence of calves, distance from vessel and direction of travel, and any observed behavior (including an assessment of behavioral responses to survey activity). Upon observation of marine mammal(s), a PSO will record the observation and monitor the animal's position (including latitude/longitude of the vessel and relative bearing and estimated distance to the animal) until the animal dives or moves out of visual range of the observer, and a PSO will continue to observe the area to watch for the animal to resurface or for additional animals that may surface in the area. PSOs will also record environmental conditions at the beginning and end of the observation period and at the time of any observations, as well as whenever conditions change significantly in the judgment of the PSO on duty.

The vessel operator must provide bigeye binoculars (*e.g.,* 25 x 150; 2.7 view angle; individual ocular focus; height control) of appropriate quality (*e.g.,* Fujinon or equivalent) solely for PSO use. These should be pedestal-mounted on the deck at the most appropriate vantage point that provides for optimal sea surface observation, PSO safety, and safe operation of the vessel. The operator must also provide a night-vision device suited for the marine environment for use during nighttime ramp-up pre-clearance, at the discretion of the PSOs. NVDs may include night vision binoculars or monocular or forward-looking infrared device (*e.g.,* Exelis PVS–7 night vision goggles; Night Optics D–300 night vision monocular; FLIR M324XP thermal imaging camera or equivalents). At minimum, the device should feature automatic brightness and gain control, bright light protection, infrared illumination, and optics suited for low-light situations. Other required equipment, which should be made available to PSOs by the third-party observer provider, includes reticle binoculars (*e.g.,* 7 x 50) of appropriate quality (*e.g.,* Fujinon or equivalent), GPS, digital single-lens reflex camera of appropriate quality (*e.g.,* Canon or equivalent), compass, and any other tools necessary to adequately perform the tasks described above, including accurate determination of distance and bearing to observed marine mammals.

Individuals implementing the monitoring protocol will assess its effectiveness using an adaptive approach. Monitoring biologists will use their best professional judgment throughout implementation and seek improvements to these methods when deemed appropriate. Specifically, implementation of shutdown requirements will be made on the basis of the PSO's best professional judgment. While PSOs should not insert undue ''precaution'' into decision-making, it is expected that PSOs may call for mitigation action on the basis of reasonable certainty regarding the need for such action, as informed by professional judgment. Any modifications to protocol will be coordinated between NMFS and the applicant.

Acoustic Monitoring

Monitoring of a towed PAM system is required at all times, from 30 minutes prior to ramp-up and throughout all use of the acoustic source. Towed PAM systems generally consist of hardware (*e.g.,* hydrophone array, cables) and software (*e.g.,* data processing and monitoring system). Some type of automated detection software must be used; while not required, we recommend use of industry standard software (*e.g.,* PAMguard, which is open source). Hydrophone signals are processed for output to the PAM operator with software designed to detect marine mammal vocalizations. Current PAM technology has some limitations (*e.g.,* limited directional capabilities and detection range, masking of signals due to noise from the vessel, source, and/or flow, localization) and there are no formal guidelines currently in place regarding specifications for hardware, software, or operator training requirements.

Our requirement to use PAM refers to the use of calibrated hydrophone arrays with full system redundancy to detect, identify, and estimate distance and bearing to vocalizing cetaceans, to the extent possible. With regard to calibration, the PAM system should have at least one calibrated hydrophone, sufficient for determining whether background noise levels on the towed PAM system are sufficiently low to meet performance expectations. Additionally,

if multiple hydrophone types occur in a system (*i.e.,* monitor different bandwidths), then one hydrophone from each such type should be calibrated, and whenever sets of hydrophones (of the same type) are sufficiently spatially separated such that they would be expected to experience ambient noise environments that differ by 6 dB or more across any integrated species cluster bandwidth, then at least one hydrophone from each set should be calibrated. The arrays should incorporate appropriate hydrophone elements (1 Hz to 180 kHz range) and sound data acquisition card technology for sampling relevant frequencies (*i.e.,* to 360 kHz). This hardware should be coupled with appropriate software to aid monitoring and listening by a PAM operator skilled in bioacoustics analysis and computer system specifications capable of running appropriate software.

Applicant-specific PAM plans were made available for review either in individual applications or as separate documents online at: *www.fisheries.noaa.gov/action/incidental-take-authorization-oil-and-gas-industry-geophysical-survey-activity-atlantic.* As recommended by Thode *et al.* (2017), PAM plans should, at minimum, adequately address and describe (1) the hardware and software planned for use, including a hardware performance diagram demonstrating that the sensitivity and dynamic range of the hardware is appropriate for the operation; (2) deployment methodology, including target depth/tow distance; (3) definitions of expected operational conditions, used to summarize background noise statistics; (4) proposed detection-classification-localization methodology, including anticipated species clusters (using a cluster definition table), target minimum detection range for each cluster, and the proposed localization method for each cluster; (5) operation plans, including the background noise sampling schedule; (6) array design considerations for noise abatement; and (7) cluster-specific details regarding which real-time displays and automated detectors the operator would monitor.

In coordination with vessel crew, the lead PAM operator will be responsible for deployment, retrieval, and testing and optimization of the hydrophone array. While on duty, the PAM operator must diligently listen to received signals and/or monitoring display screens in order to detect vocalizing cetaceans, except as required to attend to PAM equipment. The PAM operator must use appropriate sample analysis and filtering techniques and, as described below, must report all cetacean detections. While not required prior to development of formal standards for PAM use, we recommend that vessel self-noise assessments are undertaken during mobilization in order to optimize PAM array configuration according to the specific noise characteristics of the vessel and equipment involved, and to refine expectations for distance/bearing estimations for cetacean species during the survey. Copies of any vessel self-noise assessment reports must be included with the summary trip report.

Data Collection

PSOs must use standardized data forms, whether hard copy or electronic. PSOs will record detailed information about any implementation of mitigation requirements, including the distance of animals to the acoustic source and description of specific actions that ensued, the behavior of the animal(s), any observed changes in behavior before and after implementation of mitigation, and if shutdown was implemented, the length of time before any subsequent ramp-up of the acoustic source to resume survey. If required mitigation was not implemented, PSOs should submit a description of the circumstances. We require that, at a minimum, the following information be reported:

- Vessel names (source vessel and other vessels associated with survey) and call signs;
- PSO names and affiliations;
- Dates of departures and returns to port with port name;
- Dates and times (Greenwich Mean Time) of survey effort and times corresponding with PSO effort;
- Vessel location (latitude/longitude) when survey effort begins and ends; vessel location at beginning and end of visual PSO duty shifts;
- Vessel heading and speed at beginning and end of visual PSO duty shifts and upon any line change;
- Environmental conditions while on visual survey (at beginning and end of PSO shift and whenever conditions change significantly), including wind speed and direction, Beaufort sea state, Beaufort wind force, swell height, weather conditions, cloud cover, sun glare, and overall visibility to the horizon;
- Factors that may be contributing to impaired observations during each PSO shift change or as needed as environmental conditions change (*e.g.,* vessel traffic, equipment malfunctions);
- Survey activity information, such as acoustic source power output while in operation, number and volume of airguns operating in the array, tow depth of the array, and any other notes of significance (*i.e.,* pre-ramp-up survey, ramp-up, shutdown, testing, shooting, ramp-up completion, end of operations, streamers, etc.);
- If a marine mammal is sighted, the following information should be recorded:
  - Watch status (sighting made by PSO on/off effort, opportunistic, crew, alternate vessel/platform);
  - PSO who sighted the animal;
  - Time of sighting;
  - Vessel location at time of sighting;
  - Water depth;
  - Direction of vessel's travel (compass direction);
  - Direction of animal's travel relative to the vessel;
  - Pace of the animal;
  - Estimated distance to the animal and its heading relative to vessel at initial sighting;
  - Identification of the animal (*e.g.,* genus/species, lowest possible taxonomic level, or unidentified); also note the composition of the group if there is a mix of species;
  - Estimated number of animals (high/low/best);
  - Estimated number of animals by cohort (adults, yearlings, juveniles, calves, group composition, etc.);
  - Description (as many distinguishing features as possible of each individual seen, including length, shape, color, pattern, scars or markings, shape and size of dorsal fin, shape of head, and blow characteristics);
  - Detailed behavior observations (*e.g.,* number of blows, number of surfaces, breaching, spyhopping, diving, feeding, traveling; as explicit and detailed as possible; note any observed changes in behavior);
  - Animal's closest point of approach (CPA) and/or closest distance from the acoustic source;
  - Platform activity at time of sighting (*e.g.,* deploying, recovering, testing, shooting, data acquisition, other); and
  - Description of any actions implemented in response to the sighting (*e.g.,* delays, shutdown, ramp-up, speed or course alteration, etc.); time and location of the action should also be recorded;
- If a marine mammal is detected while using the PAM system, the following information should be recorded:
  - An acoustic encounter identification number, and whether the detection was linked with a visual sighting;
  - Time when first and last heard;
  - Types and nature of sounds heard (*e.g.,* clicks, whistles, creaks, burst pulses, continuous, sporadic, strength of signal, etc.); and

○ Any additional information recorded such as water depth of the hydrophone array, bearing of the animal to the vessel (if determinable), species or taxonomic group (if determinable), spectrogram screenshot, and any other notable information.

Reporting

Applicants must submit a draft comprehensive report to NMFS within 90 days of the completion of survey effort or expiration of the IHA (whichever comes first), and must include all information described above under ''Data Collection.'' If a subsequent IHA request is planned, a report must be submitted a minimum of 75 days prior to the requested date of issuance for the subsequent IHA. The report must describe the operations conducted and sightings of marine mammals near the operations; provide full documentation of methods, results, and interpretation pertaining to all monitoring; summarize the dates and locations of survey operations, and all marine mammal sightings (dates, times, locations, activities, associated survey activities); and provide information regarding locations where the acoustic source was used. The IHA-holder shall provide geo-referenced time-stamped vessel tracklines for all time periods in which airguns (full array or single) were operating. Tracklines should include points recording any change in airgun status (*e.g.,* when the airguns began operating, when they were turned off). GIS files shall be provided in ESRI shapefile format and include the UTC date and time, latitude in decimal degrees, and longitude in decimal degrees. All coordinates should be referenced to the WGS84 geographic coordinate system. In addition to the report, all raw observational data shall be made available to NMFS. This report must also include a validation document concerning the use of PAM, which should include necessary noise validation diagrams and demonstrate whether background noise levels on the PAM deployment limited achievement of the planned detection goals. The draft report must be accompanied by a certification from the lead PSO as to the accuracy of the report. A final report must be submitted within 30 days following resolution of any NMFS comments on the draft report.

In association with the final comprehensive reports, NMFS will calculate and make available estimates of the number of takes based on the observations and in consideration of the detectability of the marine mammal species observed (as described below). PSO effort, survey details, and sightings data should be recorded continuously during surveys and reports prepared each day during which survey effort is conducted. As described below, NMFS will use these observational data to calculate corrected numbers of marine mammals taken.

There are multiple reasons why marine mammals may be present and yet be undetected by observers. Animals are missed because they are underwater (availability bias) or because they are available to be seen, but are missed by observers (perception and detection biases) (*e.g.,* Marsh and Sinclair, 1989). Negative bias on perception or detection of an available animal may result from environmental conditions, limitations inherent to the observation platform, or observer ability. In this case, we do not have prior knowledge of any potential negative bias on detection probability due to observation platform or observer ability. Therefore, observational data corrections must be made with respect to assumed species-specific detection probability as evaluated through consideration of environmental factors (*e.g., f*(0)). In order to make these corrections, we plan to use a method recommended by the Marine Mammal Commission (MMC) for estimating the number of cetaceans in the vicinity of the surveys based on the number of groups detected. This method is described in full in the MMC's comment letter for these actions, which is available online at: *www.fisheries.noaa.gov/action/incidental-take-authorization-oil-and-gas-industry-geophysical-survey-activity-atlantic.*

Reporting Injured or Dead Marine Mammals

Discovery of Injured or Dead Marine Mammal—In the event that personnel involved in the survey activities covered by the authorization discover an injured or dead marine mammal, the IHA-holder shall report the incident to the Office of Protected Resources (OPR), NMFS and to regional stranding coordinators as soon as feasible. The report must include the following information:

- Time, date, and location (latitude/longitude) of the first discovery (and updated location information if known and applicable);
- Species identification (if known) or description of the animal(s) involved;
- Condition of the animal(s) (including carcass condition if the animal is dead);
- Observed behaviors of the animal(s), if alive;
- If available, photographs or video footage of the animal(s); and
- General circumstances under which the animal was discovered.

Vessel Strike—In the event of a ship strike of a marine mammal by any vessel involved in the activities covered by the authorization, the IHA-holder shall report the incident to OPR, NMFS and to regional stranding coordinators as soon as feasible. The report must include the following information:

- Time, date, and location (latitude/longitude) of the incident;
- Species identification (if known) or description of the animal(s) involved;
- Vessel's speed during and leading up to the incident;
- Vessel's course/heading and what operations were being conducted (if applicable);
- Status of all sound sources in use;
- Description of avoidance measures/requirements that were in place at the time of the strike and what additional measures were taken, if any, to avoid strike;
- Environmental conditions (*e.g.,* wind speed and direction, Beaufort sea state, cloud cover, visibility) immediately preceding the strike;
- Estimated size and length of animal that was struck;
- Description of the behavior of the marine mammal immediately preceding and following the strike;
- If available, description of the presence and behavior of any other marine mammals immediately preceding the strike;
- Estimated fate of the animal (*e.g.,* dead, injured but alive, injured and moving, blood or tissue observed in the water, status unknown, disappeared); and
- To the extent practicable, photographs or video footage of the animal(s).

Actions To Minimize Additional Harm to Live-Stranded (or Milling) Marine Mammals

In the event of a live stranding (or near-shore atypical milling) event within 50 km of the survey operations, where the NMFS stranding network is engaged in herding or other interventions to return animals to the water, the Director of OPR, NMFS (or designee) will advise the IHA-holder of the need to implement shutdown procedures for all active acoustic sources operating within 50 km of the stranding. Shutdown procedures for live stranding or milling marine mammals include the following:

- If at any time, the marine mammals die or are euthanized, or if herding/intervention efforts are stopped, the Director of OPR, NMFS (or designee) will advise the IHA-holder that the

shutdown around the animals' location is no longer needed.

• Otherwise, shutdown procedures will remain in effect until the Director of OPR, NMFS (or designee) determines and advises the IHA-holder that all live animals involved have left the area (either of their own volition or following an intervention).

• If further observations of the marine mammals indicate the potential for re-stranding, additional coordination with the IHA-holder will be required to determine what measures are necessary to minimize that likelihood (*e.g.,* extending the shutdown or moving operations farther away) and to implement those measures as appropriate.

Shutdown procedures are not related to the investigation of the cause of the stranding and their implementation is not intended to imply that the specified activity is the cause of the stranding. Rather, shutdown procedures are intended to protect marine mammals exhibiting indicators of distress by minimizing their exposure to possible additional stressors, regardless of the factors that contributed to the stranding.

Additional Information Requests—If NMFS determines that the circumstances of any marine mammal stranding found in the vicinity of the activity suggest investigation of the association with survey activities is warranted (example circumstances noted below), and an investigation into the stranding is being pursued, NMFS will submit a written request to the IHA-holder indicating that the following initial available information must be provided as soon as possible, but no later than 7 business days after the request for information.

• Status of all sound source use in the 48 hours preceding the estimated time of stranding and within 50 km of the discovery/notification of the stranding by NMFS; and

• If available, description of the behavior of any marine mammal(s) observed preceding (*i.e.,* within 48 hours and 50 km) and immediately after the discovery of the stranding.

Examples of circumstances that could trigger the additional information request include, but are not limited to, the following:

• Atypical nearshore milling events of live cetaceans;

• Mass strandings of cetaceans (two or more individuals, not including cow/calf pairs);

• Beaked whale strandings;

• Necropsies with findings of pathologies that are unusual for the species or area; or

• Stranded animals with findings consistent with blast trauma.

In the event that the investigation is still inconclusive, the investigation of the association of the survey activities is still warranted, and the investigation is still being pursued, NMFS may provide additional information requests, in writing, regarding the nature and location of survey operations prior to the time period above.

Negligible Impact Analyses and Determinations

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 a negligible impact determination. In addition to considering estimates of the number of marine mammals that might be ''taken'' by mortality, serious injury, and Level A or Level B harassment, we consider other factors, such as the type of take, the likely nature of any behavioral responses (*e.g.,* intensity, duration), the context of any such responses (*e.g.,* critical reproductive time or location, migration), as well as effects on habitat, and the likely effectiveness of 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 these analyses 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).

We first provide a generic description of our approach to the negligible impact analyses for these actions, which incorporates elements of the assessment methodology described by Wood *et al.* (2012), before providing applicant-specific analysis. For each potential activity-related stressor, we consider the potential effects to marine mammals and the likely significance of those effects to the species or stock as a whole. Potential risk due to vessel collision and related mitigation measures as well as potential risk due to entanglement and contaminant spills were addressed under ''Mitigation'' and in the ''Potential Effects of the Specified Activity on Marine Mammals'' section of our Notice of Proposed IHAs and are not discussed further, as there are minimal risks expected from these potential stressors.

Our analyses incorporate a simple matrix assessment approach to generate relative impact ratings that couple potential magnitude of effect on a stock and likely consequences of those effects for individuals, given biologically relevant information (*e.g.,* compensatory ability). These impact ratings are then combined with consideration of contextual information, such as the status of the stock or species, in conjunction with our required mitigation strategy, to ultimately inform our negligible impact determinations. Figure 5 provides an overview of this framework. Elements of this approach are subjective and relative within the context of these particular actions and, overall, these analyses necessarily require the application of professional judgment. As shown in Figure 5, it is important to be clear that the ''impact rating'' does not equate to the ultimate assessment of impact to the species or stock, *i.e.,* the negligible impact determination. The ''impact rating'' is considered in conjunction with relevant contextual factors to inform the overall assessment of impact to the species or stock.

Changes From the Notice of Proposed IHAs

Following review of public comments, we largely retain the negligible impact analysis framework and specific analyses described in our Notice of Proposed IHAs. However, we have made several adjustments on the basis of our review.

• As a result of our revised take estimates (''Estimated Take'') and reconsideration of available information (''Description of Marine Mammals in the Area of the Specified Activities'' and ''Small Numbers Analyses''), the amount of take has changed for some species for some applicants. In some cases, this leads to a change in overall magnitude rating.

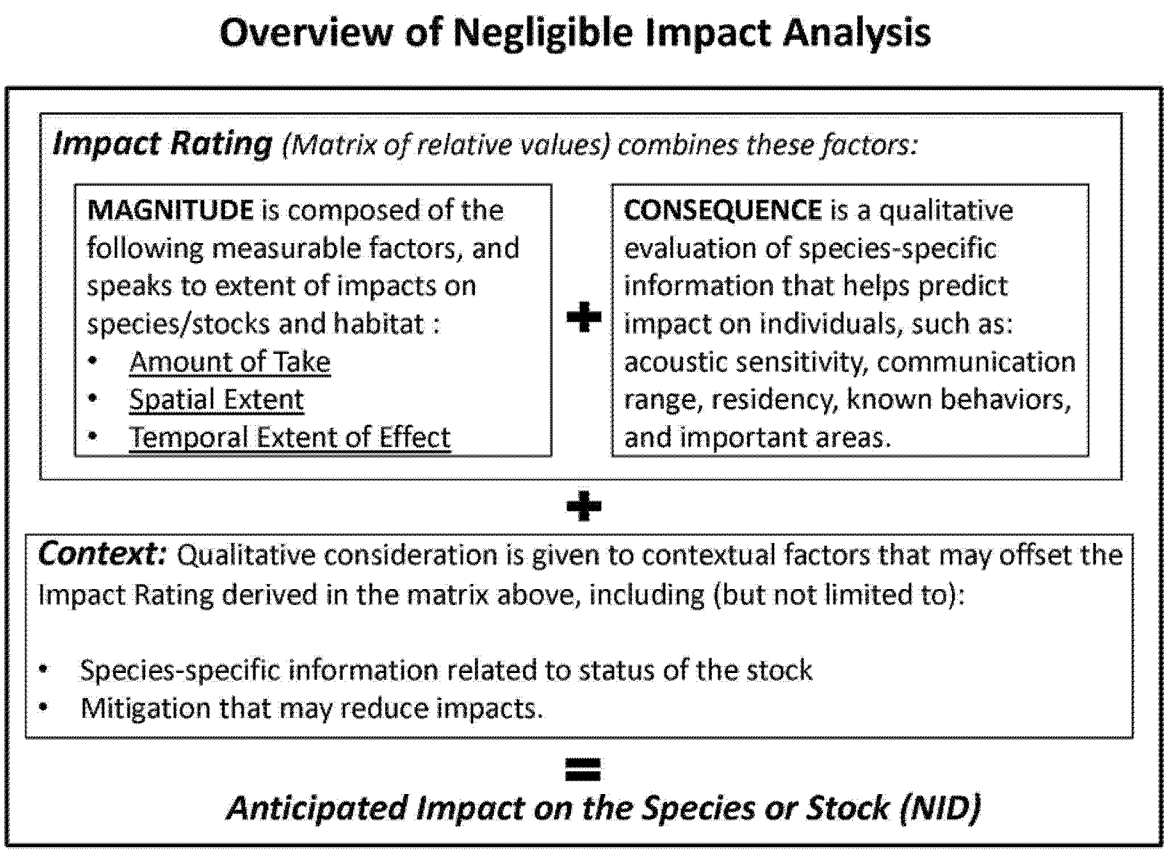

Figure 5. Overview of Negligible Impact Analysis Structure.

• We agree with commenters who pointed out that a de minimis magnitude rating should not render consequences for individuals irrelevant to the impact rating. Rather, the assessed level of consequences pairs with the magnitude rating to produce the overall impact rating. In our preliminary negligible impact analyses, for example, mysticete whales with a de minimis amount of take were assigned an overall de minimis impact rating, as consequences were considered not applicable in cases where a de minimis magnitude rating was assigned. However, the assessed level of potential consequences for individual mysticetes of ''medium''—which is related to inherent vulnerabilities of the taxon, and is therefore not dependent on the specific magnitude rating—would still exist, regardless of the amount of take/magnitude rating. Therefore, under our revised approach, a mysticete whale with a de minimis magnitude rating is now assigned a low impact rating.

In order to reflect the change described in the preceding paragraph, we have adjusted the impact rating scheme (Table 9). Whereas before a de minimis magnitude rating previously resulted in a de minimis impact rating regardless of assessed potential consequences to individuals, a de minimis magnitude rating now leads to a de minimis impact rating only if the assessed consequences are low; the de minimis impact rating with medium assessed potential consequences for individuals would lead to an impact rating of low.

Impact Rating

Magnitude—We consider magnitude of effect as a semi-quantitative evaluation of measurable factors presented as relative ratings that address the spatiotemporal extent of expected effects to a species or stock and their habitat. Magnitude ratings are developed as a combination of measurable factors: The amount of take, the spatial extent of the effects in the context of the species range, and the duration of effects.

Amount of Take

We consider authorized take by Level B harassment of less than five percent of the most appropriate population abundance to be de minimis, while authorized Level B harassment taking between 5–15 percent is low. A moderate amount of authorized taking by Level B harassment would be from 15–25 percent, and high above 25 percent.

Although we do not define quantitative metrics relating to amount of potential take by Level A harassment, for all applicant companies the expected potential for Level A harassment and, therefore, the authorized taking, is very low (Table 6). For these specified activities, as described in detail in ''Estimated Take,'' the best available science indicates that there is no reasonable potential for Level A harassment of mid-frequency cetaceans, while there is only limited potential for Level A harassment of low-frequency cetaceans when considering that Level A harassment is dependent on accumulation of energy from a mobile acoustic source. Similarly, estimated takes by Level A harassment are very low for all high-frequency cetacean species.

Overall, while these limited incidents of Level A harassment would result in

permanent hearing loss, the effects of such hearing loss are expected to be minor for several reasons. First, the acoustic thresholds used in our exposure analysis represent thresholds for the onset of PTS (*i.e.,* the minimum sound levels at which minor PTS could occur; NMFS, 2018), not thresholds for moderate or severe PTS. In order to determine the likelihood of moderate or severe PTS, one needs to consider the actual level of exposure (for high-frequency cetaceans) or, for low-frequency cetaceans, the duration of exposure at the PTS onset threshold distances from the airgun arrays or closer. High-frequency cetaceans that may be present (*i.e.,* harbor porpoise and *Kogia* spp.) are known to be behaviorally sensitive to acoustic disturbance and are unlikely to approach source vessels at distances that might lead to more severe PTS. Similarly, mysticete whales are known to display avoidance behaviors in the vicinity of airgun surveys (*e.g.,* Ellison *et al.,* 2016) and, when considered in conjunction with the estimated distances to the thresholds for the onset of PTS (Table 5), it is likely that such PTS exposure would be brief and at or near PTS onset levels. For example, a recent study analyzing 16 years of PSO data consisting of marine mammal observations during seismic surveys in waters off the United Kingdom found that the median closest approach by fin whales during active airgun use was 1,225 m (Stone *et al.,* 2017), a distance well beyond the PTS onset threshold distances estimated for these specific airgun arrays. The degree of PTS would be further minimized through use of the ramp-up procedure, which will alert animals to the source prior to its achieving full power, and through shutdown requirements, which will not necessarily prevent exposure but are expected to reduce the intensity and duration of exposure. Available data suggest that such PTS would primarily occur at frequencies where the majority of the energy from airgun sounds occurs (below 500 Hz). For high-frequency cetaceans, any PTS would therefore occur at frequencies well outside their estimated range of maximum sensitivity. For low-frequency cetaceans, these frequencies overlap with the frequencies used for communication and so may interfere somewhat with their ability to communicate, though still below the estimated range of maximum sensitivity for these species. The expected mild PTS would not likely meaningfully impact the affected high-frequency cetaceans, and may have minor effects on the ability of affected low-frequency cetaceans to hear conspecific calls and/or other environmental cues. For all applicants, the expected effects of Level A harassment on all stocks to which such take may occur is appropriately considered de minimis.

Spatial Extent

Spatial extent relates to overlap of the expected range of the affected stock with the expected footprint of the stressor. While we do not define quantitative metrics relative to assessment of spatial extent, a relatively low impact is defined here as a localized effect on the stock's range, a relatively moderate impact is defined as a regional-scale effect (meaning that the overlap between stressor and range was partial), and a relatively high impact is one in which the degree of overlap between stressor and range is near total. For a mobile activity occurring over a relatively large, regional-scale area, this categorization is made largely on the basis of the stock range in relation to the action area. For example, the harbor porpoise is expected to occur almost entirely outside of the planned survey areas (Hayes *et al.,* 2017; Roberts *et al.,* 2016) and therefore despite the large extent of planned survey activity, the spatial extent of potential stressor effect would be low. A medium degree of effect would be expected for a species such as the Risso's dolphin, which has a distribution in shelf and slope waters along the majority of the U.S. Atlantic coast, and which also would be expected to have greater abundance in mid-Atlantic waters north of the survey areas in the summer (Hayes *et al.,* 2018a; Roberts *et al.,* 2016). This means that the extent of potential stressor for this species would at all times be expected to have some overlap with a portion of the stock, while some portion (increasing in summer and fall months) would at all times be outside the stressor footprint. A higher degree of impact with regard to spatial extent would be expected for a species such as the Clymene dolphin, which is expected to have a generally more southerly distribution (Waring *et al.,* 2014; Roberts *et al.,* 2016) and thus more nearly complete overlap with the expected stressor footprint in the specific geographic region.

In Tables 10–14 below, spatial extent is presented as a range for certain species with known migratory patterns. We expect spatial extent (overlap of stock range with planned survey area) to be low for right whales from May through October but moderate from November through April, due to right whale movements into southeastern shelf waters in the winter for calving. The overlap is considered moderate during winter because not all right whales make this winter migration, and those that do are largely found in shallow waters where little survey effort is planned (and when/where we prescribe a spatial restriction that would largely preclude any potential overlap between right whales and effects of the survey activities). Spatial extent for humpback whales is expected to be low for most of the year, but likely moderate during winter, while spatial extent for minke whales is likely low in summer, moderate in spring and fall, and high in winter. While we consider spatial extent to be low year-round for fin whales, their range overlap with the planned survey area does vary across the seasons and is closer to moderate in winter and spring. We expect spatial extent for common dolphins to be lower in fall but generally moderate. Similarly, we expect spatial extent for Risso's dolphins to be lower in summer but generally moderate. Although survey plans differ across applicants, all cover large spatial scales that extend throughout much of the specific geographic region, and we do not expect meaningful differences across surveys with regard to spatial extent.

Temporal Extent

The temporal aspect of the stressor is measured through consideration of duration and frequency. Duration describes how long the effects of the stressor last. Temporal frequency may range from continuous to isolated (may occur one or two times), or may be intermittent. We consider a temporary effect lasting up to one month (prior to the animal or habitat reverting to a ''normal'' condition) to be short-term, whereas long-term effects are more permanent, lasting beyond one season (with animals or habitat potentially reverting to a ''normal'' condition). Moderate-term is defined as between 1–3 months. These metrics and their potential combinations help to derive the ratings summarized in Table 8. Temporal extent is not indicated in Tables 10–14 below, as it did not affect the magnitude rating for any applicant's specified activity.

With regard to the duration of each estimated instance of exposure, we are unable to produce estimates specific to the specified activities due to the temporal and spatial uncertainty of vessel and cetacean movements within the geographic region. However, given the constant movement of vessels and animals, all exposures are expected to be less than a single day in duration. For example, based on modeling of similar activities in the Gulf of Mexico, we

assume that most instances of exposure would only last for a few minutes (see Table 26–27 of Zeddies *et al.,* 2015; available online at *www.fisheries.noaa.gov/action/incidental-take-authorization-oil-and-gas-industry-geophysical-survey-activity-gulf-mexico*), especially in the case of animals migrating through the immediate vicinity of the source vessel (*e.g.,* Costa *et al.,* 2016).

TABLE 8—MAGNITUDE RATING

Amount of take	Spatial extent	Duration and frequency	Magnitude rating
High	Any	Any	High.
Any except de minimis	High	Any	
Moderate	Moderate	Any except short-term/isolated	
Moderate	Moderate	Short-term/isolated	Medium.
Moderate	Low	Any	
Low	Moderate	Any	
Low	Low	Any except short-term/intermittent or isolated	
Low	Low	Short-term/intermittent or isolated	Low.
De minimis	Any	Any	De minimis.

Adapted from Table 3.4 of Wood *et al.* (2012).

Consequences—Considerations of amount, extent, and duration give an understanding of expected magnitude of effect for the stock or species and their habitat, which is next considered in context of the likely consequences of those effects for individuals. We consider likely relative consequences through a qualitative evaluation of species-specific information that helps predict the consequences of the information addressed through the magnitude rating, *i.e.,* expected effects. The likely consequences of a given effect to individuals is independent of the magnitude of effect, *i.e.,* although we recognize that the ultimate impact is to some degree scaled to the magnitude of effect, the extent to which a species is inherently vulnerable to harm from the effects (and therefore sensitive to magnitude) is captured by the ''consequences'' factor. This evaluation considers factors including acoustic sensitivity, communication range, known aspects of behavior relevant to a consideration of consequences of effects, and assumed compensatory abilities to engage in important behaviors (*e.g.,* breeding, foraging) in alternate areas. The magnitude rating and likely consequences are combined to produce an ''impact rating'' (Table 9).

For example, if a delphinid species is predicted to have a high amount of disturbance and over a high degree of spatial extent, that stock would receive a high magnitude rating for that particular survey. However, we may then assess that the species may have a high degree of compensatory ability among individuals; therefore, our conclusion would be that the consequences of any effects on individuals are likely low. The overall impact rating in this scenario would be moderate. Table 9 summarizes impact rating scenarios.

TABLE 9—IMPACT RATING

Magnitude rating	Consequences (for individuals)	Impact rating (for species or stock)
High	High/medium	High.
High	Low	Moderate.
Medium	High/medium	
Low	High	
Medium	Low	Low.
Low	Medium/low	
De minimis	Medium	
De minimis	Low	De minimis.

Adapted from Table 3.5 of Wood *et al.* (2012).

Likely consequences, as presented in Tables 10–14 below, are considered medium for each species of mysticete whales (low-frequency hearing specialists), due to the greater potential for masking impacts at longer ranges than other taxa and at frequencies that overlap a larger portion of both their hearing and vocalization ranges. Likely consequences are considered medium for sperm whales due to potential for survey noise to disrupt foraging activity (*e.g.,* Miller *et al.,* 2009; Farmer *et al.,* 2018). The likely consequences are considered high for beaked whales due to the combination of known acoustic sensitivity and expected residency patterns, as we expect that compensatory ability for beaked whales will be low due to presumed residency in certain shelf break and deepwater canyon areas covered by the planned survey areas. Similarly, *Kogia* spp. are presumed to be more acoustically sensitive species, but unlike beaked whales we expect that *Kogia* spp. would have a reasonable compensatory ability to perform important behavior in alternate areas, as they are expected to occur broadly over the continental slope (*e.g.,* Bloodworth and Odell, 2008)—therefore, we assume that consequences would be low for *Kogia* spp. generally. Consequences are also considered low for harbor porpoise; although they are considered to be an acoustically sensitive species and potentially vulnerable to limited instances of auditory injury (as are *Kogia* spp.), we have no information to suggest that porpoises are resident within the specific geographic region or that the expected disturbance events would significantly impede their ability to engage in critical behaviors.

Consequences are considered low for most delphinids, as it is unlikely that disturbance due to survey noise would entail significant disruption of normal behavioral patterns, long-term displacement, or significant potential for masking of acoustic space. However, for pilot whales we believe likely consequences to be medium due to expected residency in areas of importance and, therefore, lack of compensatory ability. Because the nature of the stressor is the same across applicants, we do not expect meaningful differences with regard to likely consequences.

Context

In addition to our initial impact ratings, we then also consider additional relevant contextual factors in a qualitative fashion. This important consideration of context is applied to a given impact rating in order to produce a final assessment of impact to the stock or species, *i.e.,* our negligible impact determinations. Relevant contextual factors include population status, other stressors (including impacts on prey and other habitat), and required mitigation.

Here, we reiterate discussion relating to our development of targeted mitigation measures and note certain contextual factors, which are applicable to negligible impact analyses for all five applicants. Applicant-specific analyses are provided later.

• We developed mitigation requirements (*i.e.,* time-area restrictions) designed specifically to provide benefit to certain species or stocks for which we predict a relatively moderate to high amount of exposure to survey noise and/or which have contextual factors that we believe necessitate special consideration. Time-area restrictions, described in detail in ''Mitigation'' and depicted in Figures 3–4, are designed specifically to provide benefit to the North Atlantic right whale, bottlenose dolphin, sperm whale, beaked whales, and pilot whales. In addition, we expect these areas to provide some subsidiary benefit to additional species that may be present. In particular, Area #4 (Figure 4), although delineated in order to specifically provide an area of anticipated benefit to beaked whales, sperm whales, and pilot whales, is expected to host a diverse assemblage of cetacean species. The output of the Roberts *et al.* (2016) models, as used in core abundance area analyses (described in detail in ''Mitigation''), indicates that species most likely to derive subsidiary benefit from this time-area restriction include the bottlenose dolphin (offshore stock), Risso's dolphin, and common dolphin. For species with density predicted through stratified models, core abundance analysis is not possible and assumptions regarding potential benefit of time-area restrictions are based on known ecology of the species and sightings patterns and are less robust. Nevertheless, subsidiary benefit for Areas #1–4 (Figure 4) should be expected for species known to be present in these areas (*e.g.,* assumed affinity for shelf/slope/abyss areas off Cape Hatteras): *Kogia* spp., pantropical spotted dolphin, Clymene dolphin, and rough-toothed dolphin.

These mitigation measures benefit both the primary species for which they were designed and the species that may benefit secondarily by reducing impacts to marine mammal habitat and by reducing the numbers of individuals likely to be exposed to survey noise. For resident species in areas where seasonal closures are required, we also expect reduction in the numbers of times that individuals are exposed to survey noise (also discussed in ''Small Numbers Analyses,'' below). Perhaps of greater importance, we expect that these restrictions will reduce disturbance of these species in the places most important to them for critical behaviors such as foraging and socialization. Area #1 (Figure 4), which is a year-round closure, is assumed to be an area important for beaked whale foraging, while Areas #2–3 (also year-round closures) are assumed to provide important foraging opportunities for sperm whales as well as beaked whales. Area #4, a seasonal closure, is comprised of shelf-edge habitat where beaked whales and pilot whales are believed to be year-round residents as well as slope and abyss habitat predicted to contain high abundance of sperm whales during the period of closure. Further detail regarding rationale for these closures is provided under ''Mitigation.''

• The North Atlantic right whale, sei whale, fin whale, blue whale, and sperm whale are listed as endangered under the Endangered Species Act, and all coastal stocks of bottlenose dolphin are designated as depleted under the MMPA (and have recently experienced an Unusual Mortality Event, described earlier in this document). However, sei whales and blue whales are unlikely to be meaningfully impacted by the specified activities (see ''Rare Species'' below). All four mysticete species are also classified as endangered (*i.e.,* ''considered to be facing a very high risk of extinction in the wild'') on the International Union for Conservation of Nature Red List of Threatened Species, whereas the sperm whale is classified as vulnerable (*i.e.,* ''considered to be facing a high risk of extinction in the wild'') (IUCN, 2017). Our required mitigation is designed to avoid impacts to the right whale and to depleted stocks of bottlenose dolphin. Survey activities must avoid all areas where the right whale and coastal stocks of bottlenose dolphin are reasonably expected to occur (or, for the right whale, comparable protection would be achieved through implementation of a NMFS-approved mitigation and monitoring plan at distances between 47–80 km offshore; see ''Mitigation''), and we require shutdown of the acoustic source upon observation of any right whale at extended distance compared with the standard shutdown requirement. If the observed right whale is within the behavioral harassment zone, it would still be considered taken, but by immediately shutting down the acoustic source the duration of harassment is minimized and the significance of the harassment event reduced as much as possible.

Although listed as endangered, the primary threat faced by the sperm whale (*i.e.,* commercial whaling) has been eliminated and, further, sperm whales in the western North Atlantic were little affected by modern whaling (Taylor *et al.,* 2008). Current potential threats to the species globally include vessel strikes, entanglement in fishing gear, anthropogenic noise, exposure to contaminants, climate change, and marine debris. However, for the North Atlantic stock, the most recent estimate of annual human-caused mortality and serious injury (M/SI) is 22 percent of the potential biological removal (PBR) level for the stock. As described previously, PBR is defined 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.'' For depleted stocks, levels of human-caused mortality and serious injury exceeding the PBR level are likely to delay restoration of the stock to OSP level by more than ten percent in comparison with recovery time in the absence of human-caused M/SI.

The most recent status review for the species stated that existing regulatory mechanisms appear to minimize threats to sperm whales and that, despite uncertainty regarding threats such as climate change, contaminants, and anthropogenic noise, the significance of threat facing the species should be considered low to moderate (NMFS, 2015b). Nevertheless, existing empirical data (*e.g.,* Miller *et al.,* 2009; Farmer *et al.,* 2018) highlight the potential for seismic survey activity to negatively

impact foraging behavior of sperm whales. In consideration of this likelihood, the species status, and the relatively high amount of predicted exposures to survey noise, we have given special consideration to mitigation focused on sperm whales and have defined time-area restrictions (see ''Mitigation'' and Figure 4) specifically designed to reduce such impacts on sperm whales in areas expected to be of greatest importance (*i.e.,* slope habitat and deepwater canyons).

Although the primary direct threat to fin whales was addressed through the moratorium on commercial whaling, vessel strike and entanglement in commercial fishing gear remain as substantial direct threats for the species in the western North Atlantic. As noted below, the most recent estimate of annual average human-caused mortality for the fin whale in U.S. waters is equal to the PBR value (Table 2). In addition, mysticete whales are particularly sensitive to sound in the frequency range output from use of airgun arrays (*e.g.,* NMFS, 2018). However, there is conflicting evidence regarding the degree to which this sound source may significantly disrupt the behavior of mysticete whales. Generally speaking, mysticete whales have been observed to react to seismic vessels but have also been observed continuing normal behavior in the presence of seismic vessels, and behavioral context at the time of acoustic exposure may be influential in the degree to which whales display significant behavioral reactions. In addition, while Edwards *et al.* (2015) found that fin whales were likely present in all seasons in U.S. waters north of 35° N, most important habitat areas are not expected to occur in the planned survey areas. Primary feeding areas are outside the project area in the Gulf of Maine and off Long Island (LaBrecque *et al.,* 2015) and, while Hain *et al.* (1992) suggested that calving occurs during winter in the mid-Atlantic, Hayes *et al.* (2017) state that it is unknown where calving, mating, and wintering occur for most of the population. Further, fin whales are not considered to engage in regular mass movements along well-defined migratory corridors (NMFS, 2010b). The models described by Roberts *et al.* (2016), which predicted density at a monthly time step, suggest an expectation that, while fin whales may be present year-round in shelf and slope waters north of Cape Hatteras, the large majority of predicted abundance in U.S. waters would be found outside the planned survey areas to the north. Very few fin whales are likely present in the planned survey areas in summer months. Therefore, we have determined that development of time-area restriction specific to fin whales is not warranted. However, fin whales present along the shelf break north of Cape Hatteras during the closure period associated with Area #4 (Figure 4) would be expected to benefit from the time-area restriction designed primarily to benefit pilot whales, beaked whales, and sperm whales.

- Critical habitat is designated only for the North Atlantic right whale, and there are no biologically important areas (BIA) described within the region (other than for the right whale, and the described BIA is similar to designated critical habitat). Our required mitigation is designed to avoid impacts to important habitat for the North Atlantic right whale (or achieve comparable protection through implementation of a NMFS-approved mitigation and monitoring plan at distances between 47–80 km offshore; see ''Mitigation'').
- High levels of average annual human-caused M/SI (approaching or exceeding the PBR level) are ongoing for the North Atlantic right whale, sei whale, fin whale, and for both long-finned and short-finned pilot whales (see Table 2). Average annual M/SI is considered unknown for the blue whale and the false killer whale (PBR is undetermined for a number of other species (Table 2), but average annual human-caused M/SI is zero for all of these). Separately, there are ongoing UMEs for humpback whales and minke whales (as well as for the right whale), as discussed previously in this notice. Although threats are considered poorly known for North Atlantic blue whales, PBR is less than one and ship strike is a known cause of mortality for all mysticete whales. The most recent record of ship strike mortality for a blue whale in the U.S. EEZ is from 1998 (Waring *et al.,* 2010). False killer whales also have a low PBR value (2.1), and may be susceptible to mortality in commercial fisheries. One false killer whale was reported as entangled in the pelagic longline fishery in 2011, but was released alive and not seriously injured. Separately, a stranded false killer whale in 2009 was classified as due to a fishery interaction. Incidental take of the sei whale, blue whale, false killer whale, and long-finned pilot whale is considered unlikely and we authorize take by behavioral harassment only for a single group of each of the first three species as a precaution. Although long-finned pilot whales are unlikely to occur in the action area in significant numbers, the density models that inform our exposure estimates consider pilot whales as a guild. It is important to note that our discussion of M/SI in relation to PBR values provides necessary contextual information related to the status of stocks; we do not equate harassment with M/SI.

We addressed our consideration of specific mitigation efforts for the right whale and fin whale above. For minke whales, although the ongoing UME is under investigation (as occurs for all UMEs), this event does not provide cause for concern regarding population-level impacts, as the likely population abundance is greater than 20,000 whales. Even though the PBR value is based on an abundance for U.S. waters that is negatively biased and a small fraction of the true population abundance, annual M/SI does not exceed the calculated PBR value for minke whales.

With regard to humpback whales, the UME does not yet provide cause for concern regarding population-level impacts. Despite the UME, the relevant population of humpback whales (the West Indies breeding population, or distinct population segment (DPS)) remains healthy. Prior to 2016, humpback whales were listed under the ESA as an endangered species worldwide. Following a 2015 global status review (Bettridge *et al.,* 2015), NMFS established 14 DPSs with different listing statuses (81 FR 62259; September 8, 2016) pursuant to the ESA. The West Indies DPS, which consists of the whales whose breeding range includes the Atlantic margin of the Antilles from Cuba to northern Venezuela, and whose feeding range primarily includes the Gulf of Maine, eastern Canada, and western Greenland, was delisted. The status review identified harmful algal blooms, vessel collisions, and fishing gear entanglements as relevant threats for this DPS, but noted that all other threats are considered likely to have no or minor impact on population size or the growth rate of this DPS (Bettridge *et al.,* 2015). As described in Bettridge *et al.* (2015), the West Indies DPS has a substantial population size (*i.e.,* approximately 10,000; Stevick *et al.,* 2003; Smith *et al.,* 1999; Bettridge *et al.,* 2015), and appears to be experiencing consistent growth.

In response to this population context concern for pilot whales, in conjunction with relatively medium to high amount of predicted exposures to survey noise for pilot whales, we have given special consideration to mitigation focused on pilot whales and have defined time-area restrictions (see ''Mitigation'' and Figure 4) specifically designed to reduce such impacts on pilot whales in areas

expected to be of greatest importance (*i.e.,* shelf edge north of Cape Hatteras).

• Beaked whales are considered to be particularly acoustically sensitive (*e.g.,* Tyack *et al.,* 2011; DeRuiter *et al.,* 2013; Stimpert *et al.,* 2014; Miller *et al.,* 2015). Considering this sensitivity in conjunction with the relatively high amount of predicted exposures to survey noise, we have given special consideration to mitigation focused on beaked whales and have defined time-area restrictions (see ''Mitigation'' and Figure 4) specifically designed to reduce such impacts on beaked whales in areas expected to be of greatest importance (*i.e.,* shelf edge south of Cape Hatteras and deepwater canyon areas).

• Given the current declining population status of North Atlantic right whales, it is important to understand the likely demographics of the expected taking. Therefore, we obtained data from the North Atlantic Right Whale Consortium Database (pers. comm., T.A. Gowan to E. Patterson, November 8, 2017), consisting of standardized sighting records of right whales from 2005 to 2013 from South Carolina to Florida. Because of the low total number of expected exposure for right whales, we could not reasonably apply this information on an applicant-specific basis and therefore present these findings for the total expected taking across all applicants. Based on this information, of the total 23 takes of North Atlantic right whales (now revised downward to 19 takes on the basis of Spectrum's modified survey plan; see ''Spectrum Survey Plan Modification''), it should be expected that four exposures could be of adult females with calves, two of adult females without calves, five of adult males, 11 of juveniles of either sex, three of calves of either sex, one of an adult of unknown sex, and two of animals of unknown age and sex. It is important to note that age class estimates sum to greater than the originally expected total of 23 due to conservative rounding up in presenting the maximum number of each age-sex class that might be exposed; this should not be construed as an assumption that there would be more total takes of right whales than are authorized across all applicants. Each of these exposures represents a single instance of Level B harassment and is therefore not considered as a meaningful impact to individuals that could lead to population-level impacts.

Rare Species

As described previously, there are multiple species that should be considered rare in the survey areas and for which we authorize only nominal and precautionary take of a single group for each applicant survey. Specific to each of the five applicant companies, we do not expect meaningful impacts to these species (*i.e.,* sei whale, Bryde's whale, blue whale, killer whale, false killer whale, pygmy killer whale, melon-headed whale, northern bottlenose whale, spinner dolphin, Fraser's dolphin, Atlantic white-sided dolphin) and find that the take from each of the specified activities will have a negligible impact on these marine mammal species. We do not discuss these 11 species further in these analyses.

Spectrum

Spectrum originally planned a 165-day survey program, or 45 percent of the year (approximately two seasons). The original survey plan would cover a large spatial extent (*i.e.,* a majority of the mid- and south Atlantic; see Figure 1 of Spectrum's application). Therefore, although that survey would be long-term (*i.e.,* greater than one season) in total duration, we would not expect the duration of effect to be greater than moderate and intermittent in any given area. Table 10 displays relevant information leading to impact ratings for each species resulting from Spectrum's original survey plan. In general, we note that although the temporal and spatial scale of the planned survey activity is large, it is not occupying the spatial extent all at one time. The fact that this mobile acoustic source would be moving across large areas (as compared with geophysical surveys with different objectives that may require focused effort over long periods of time in smaller areas) means that more individuals may receive limited exposure to survey noise, versus fewer individuals receiving more intense exposure and/or for longer periods of time. The nature of such potentially transitory exposure (which we nevertheless assume here is of moderate duration and intermittent, versus isolated) means that the potential significance of behavioral disruption and potential for longer-term avoidance of important areas is limited. Please see ''Spectrum Survey Plan Modification,'' below, for additional information describing the modified survey plan, findings made in context of the analysis presented below, and authorized take for Spectrum (Table 17).

TABLE 10—MAGNITUDE AND IMPACT RATINGS, SPECTRUM

Species	Amount	Spatial extent	Magnitude rating	Consequences	Impact rating [1]
North Atlantic right whale	De minimis	Low-Moderate	De minimis	Medium	Low.
Humpback whale	De minimis	Low-Moderate	De minimis	Medium	Low.
Minke whale	De minimis	Low-High	De minimis	Medium	Low.
Fin whale	Low	Low	Medium	Medium	Moderate.
Sperm whale	Low	Moderate	Medium	Medium	Moderate.
Kogia spp	Low	High	High	Low	Moderate.
Beaked whales	Low	Moderate	Medium	High	Moderate.
Rough-toothed dolphin	Moderate	High	High	Low	Moderate.
Bottlenose dolphin	High	High	High	Low	Moderate.
Clymene dolphin	High	High	High	Low	Moderate.
Atlantic spotted dolphin	Moderate	Moderate	High	Low	Moderate.
Pantropical spotted dolphin	Moderate	High	High	Low	Moderate.
Striped dolphin	Low	Low	Medium	Low	Low.
Common dolphin	Low	Low-moderate	Medium	Low	Low.
Risso's dolphin	De minimis	Low-moderate	De minimis	Low	De minimus.
Pilot whales	Low	Moderate	Medium	Medium	Moderate.
Harbor porpoise	De minimis	Low	De minimis	Low	De minimis.

[1] Impact rating does not indicate whether overall impact to the species or stock is negligible, but is considered with relevant contextual factors (described generally above and specifically below) in order to ultimately determine whether the effects of the specified activity on the affected species or stock are negligible.

The North Atlantic right whale is endangered, has a very low population size, and faces significant additional stressors. Therefore, regardless of even a low impact rating, we believe that the required mitigation described previously is critically important in order for us to make the necessary finding and it is with consideration of this mitigation that we find the take from Spectrum's survey activities will have a negligible impact on the North Atlantic right whale. The fin whale receives a moderate impact rating overall, but we expect that for two seasons (summer and fall) almost no fin whales will be present in the survey area. For the remainder of the year, it is likely that less than one quarter of the population will be present within the survey area (Roberts *et al.,* 2016), meaning that despite medium rankings for magnitude and likely consequences, these impacts would be experienced by only a small subset of the overall population. In consideration of the moderate impact rating, the likely proportion of the population that may be affected by the specified activities, and the lack of evidence that the survey area is host to important behaviors that may be disrupted, we find the take from Spectrum's survey activities will have a negligible impact on the fin whale.

Magnitude ratings for the sperm whale and beaked whales are medium; however, consequence factors are medium and high, respectively. Magnitude rating for pilot whales is medium, but similar to beaked whales, we expect that compensatory ability will be low (high consequence rating) due to presumed residency in areas targeted by the planned survey. These factors lead to moderate impact ratings for all three species/species groups. However, regardless of impact rating, the consideration of likely consequences and contextual factors for all three taxa leads us to conclude that targeted mitigation is important to support a finding that the effects of the survey will have a negligible impact on these species. As described previously, sperm whales are an endangered species with particular susceptibility to disruption of foraging behavior, beaked whales are particularly acoustically sensitive (with presumed low compensatory ability), and pilot whales are sensitive to additional stressors due to a high degree of mortality in commercial fisheries (and also with low compensatory ability). Finally, due to their acoustic sensitivity, we require shutdown of the acoustic source upon detection of a beaked whale at extended distance from the source vessel. In consideration of the required mitigation, we find the take from Spectrum's survey activities will have a negligible impact on the sperm whale, beaked whales (*i.e., Ziphius cavirostris* and *Mesoplodon* spp.), and pilot whales (*i.e., Globicephala* spp.).

Kogia spp. receive a moderate impact rating. However, although NMFS does not currently identify a trend for these populations, recent survey effort and stranding data show a simultaneous increase in at-sea abundance and strandings, suggesting growing *Kogia* spp. abundance (NMFS, 2011; 2013a; Waring *et al.,* 2007; 2013). Finally, we expect that *Kogia* spp. will receive subsidiary benefit from the required mitigation targeted for sperm whales, beaked whales, and pilot whales and, although minimally effective due to the difficulty of at-sea observation of *Kogia* spp., we require shutdown of the acoustic source upon observation of *Kogia* spp. at extended distance from the source vessel. In consideration of these factors—likely population increase and required mitigation—we find the take from Spectrum's survey activities will have a negligible impact on *Kogia* spp.

As described in the introduction to this analysis, it is assumed that likely consequences are somewhat higher for species of mysticete whales (low-frequency hearing specialists) due to the greater potential for masking impacts at longer ranges than other taxa and at frequencies that overlap a larger portion of both their hearing and vocalization ranges. Therefore, despite de minimis magnitude ratings, we expect some consequences to individual humpback and minke whales, *i.e.,* leading to a low impact rating. However, given the minimal amount of interaction expected between these species and the survey activities, and in consideration of the overall low impact ratings, we find the take from Spectrum's planned survey activities will have a negligible impact on the humpback whale and minke whale.

Despite medium to high magnitude ratings, remaining delphinid species receive low to moderate impact ratings due to low consequences rating relating to a lack of propensity for behavioral disruption due to airgun survey activity and our expectation that these species would generally have relatively high compensatory ability. In addition, contextually these species do not have significant issues relating to population status or context. Many oceanic delphinid species are generally more associated with dynamic oceanographic characteristics rather than static physical features, and those species (such as common dolphin) with substantial distribution to the north of the survey area would likely be little affected at the population level by the activity. For example, both species of spotted dolphin and the offshore stock of bottlenose dolphin range widely over slope and abyssal waters (*e.g.,* Waring *et al.,* 2014; Hayes *et al.,* 2017; Roberts *et al.,* 2016), while the rough-toothed dolphin does not appear bound by water depth in its range (Ritter, 2002; Wells *et al.,* 2008). Our required mitigation largely eliminates potential effects to depleted coastal stocks of bottlenose dolphin. We also expect that meaningful subsidiary benefit will accrue to certain species from the mitigation targeted for sperm whales, beaked whales, and pilot whales, most notably to species presumed to have greater association with shelf break waters north of Cape Hatteras (*e.g.,* offshore bottlenose dolphins, common dolphins, and Risso's dolphins). In consideration of these factors—overall impact ratings and context including required mitigation—we find the take from Spectrum's planned survey activities will have a negligible impact on remaining delphinid species (*i.e.,* all stocks of bottlenose dolphin, two species of spotted dolphin, rough-toothed dolphin, striped dolphin, common dolphin, and Clymene dolphin).

For those species with de minimis impact ratings we believe that, absent additional relevant concerns related to population status or context, the rating implies that a negligible impact should be expected as a result of the specified activity. No such concerns exist for these species, and we find the take from Spectrum's survey activities will have a negligible impact on the Risso's dolphin and harbor porpoise.

In summary, 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 required monitoring and mitigation measures, we find that the total marine mammal take from Spectrum's survey activities will have a negligible impact on all affected marine mammal species or stocks.

TGS—TGS has planned a 308-day survey program, or 84 percent of the year (slightly more than three seasons). However, the planned survey would cover a large spatial extent (*i.e.,* a majority of the mid- and south Atlantic; see Figures 1–1 to 1–4 of TGS's application). Therefore, although the survey would be long-term (*i.e.,* greater than one season) in total duration, we would not expect the duration of effect to be greater than moderate and intermittent in any given area. We note

that TGS plans to deploy two independent source vessels, which would in effect increase the spatial extent of survey noise at any one time but, because the vessels would not be operating within the same area or reshooting lines already covered, this would not be expected to increase the duration or frequency of exposure experienced by individual animals. Table 11 displays relevant information leading to impact ratings for each species resulting from TGS's survey. In general, we note that although the temporal and spatial scale of the planned survey activity is large, the fact that these mobile acoustic sources would be moving across large areas (as compared with geophysical surveys with different objectives that may require focused effort over long periods of time in smaller areas) means that more individuals may receive limited exposure to survey noise, versus fewer individuals receiving more intense exposure and/or for longer periods of time. The nature of such potentially transitory exposure (which we nevertheless assume here is of moderate duration and intermittent, versus isolated) means that the potential significance of behavioral disruption and potential for longer-term avoidance of important areas is limited.

TABLE 11—MAGNITUDE AND IMPACT RATINGS, TGS

Species	Amount	Spatial extent	Magnitude rating	Consequences	Impact rating [1]
North Atlantic right whale	De minimis	Low-Moderate	De minimis	Medium	Low.
Humpback whale	De minimis	Low-Moderate	De minimis	Medium	Low.
Minke whale	De minimis	Low-High	De minimis	Medium	Low.
Fin whale	Moderate	Low	Medium	Medium	Moderate.
Sperm whale	High	Moderate	High	Medium	High.
Kogia spp	High	High	High	Low	Moderate.
Beaked whales	High	Moderate	High	High	High.
Rough-toothed dolphin	High	High	High	Low	Moderate.
Bottlenose dolphin	High	High	High	Low	Moderate.
Clymene dolphin	De minimis	High	De minimis	Low	De minimis.
Atlantic spotted dolphin	High	Moderate	High	Low	Moderate.
Pantropical spotted dolphin	Moderate	High	High	Low	Moderate.
Striped dolphin	Low	Low	Medium	Low	Low.
Common dolphin	High	Low-moderate	High	Low	Moderate.
Risso's dolphin	Moderate	Low-moderate	High	Low	Moderate.
Pilot whales	High	Moderate	High	Medium	High.
Harbor porpoise	De minimis	Low	De minimis	Low	De minimis.

[1] Impact rating does not indicate whether overall impact to the species or stock is negligible, but is considered with relevant contextual factors (described generally above and specifically below) in order to ultimately determine whether the effects of the specified activity on the affected species or stock are negligible.

The North Atlantic right whale is endangered, has a very low population size, and faces significant additional stressors. Therefore, regardless of even a low impact rating, we believe that the required mitigation described previously is critically important in order for us to make the necessary finding and it is with consideration of this mitigation that we find the take from TGS's survey activities will have a negligible impact on the North Atlantic right whale. The fin whale receives a moderate impact rating overall, but we expect that for two seasons (summer and fall) almost no fin whales will be present in the survey area. For the remainder of the year, it is likely that less than one quarter of the population will be present within the survey area (Roberts *et al.,* 2016), meaning that despite medium rankings for magnitude and likely consequences, these impacts would be experienced by only a small subset of the overall population. In consideration of the moderate impact rating, the likely proportion of the population that may be affected by the specified activities, and the lack of evidence that the survey area is host to important behaviors that may be disrupted, we find the take from TGS's survey activities will have a negligible impact on the fin whale.

Magnitude ratings for the sperm whale, beaked whales, and pilot whales are high and, further, consequence factors reinforce high impact ratings for all three. In addition, the consideration of likely consequences and contextual factors leads us to conclude that targeted mitigation is important to support a finding that the effects of the survey will have a negligible impact on these species. As described previously, sperm whales are an endangered species with particular susceptibility to disruption of foraging behavior, beaked whales are particularly acoustically sensitive (with presumed low compensatory ability and, therefore, high consequence rating), and pilot whales are sensitive to additional stressors due to a high degree of mortality in commercial fisheries (and also with low compensatory ability). Finally, due to their acoustic sensitivity, we have required shutdown of the acoustic source upon observation of a beaked whale at extended distance from the source vessel. In consideration of the required mitigation, we find the take from TGS's survey activities will have a negligible impact on the sperm whale, beaked whales (*i.e., Ziphius cavirostris* and *Mesoplodon* spp.), and pilot whales (*i.e., Globicephala* spp.).

Kogia spp. receive a moderate impact rating. However, although NMFS does not currently identify a trend for these populations, recent survey effort and stranding data show a simultaneous increase in at-sea abundance and strandings, suggesting growing *Kogia* spp. abundance (NMFS, 2011; 2013a; Waring *et al.,* 2007; 2013). Finally, we expect that *Kogia* spp. will receive subsidiary benefit from the mitigation targeted for sperm whales, beaked whales, and pilot whales and, although minimally effective due to the difficulty of at-sea observation of *Kogia* spp., we have required shutdown of the acoustic source upon observation of *Kogia* spp. at extended distance from the source vessel. In consideration of these factors—likely population increase and required mitigation—we find the take from TGS's survey activities will have a negligible impact on *Kogia* spp.

As described in the introduction to this analysis, it is assumed that likely consequences are somewhat higher for

species of mysticete whales (low-frequency hearing specialists) due to the greater potential for masking impacts at longer ranges than other taxa and at frequencies that overlap a larger portion of both their hearing and vocalization ranges. Therefore, despite de minimis magnitude ratings, we expect some consequences to individual humpback and minke whales, *i.e.,* leading to a low impact rating. However, given the minimal amount of interaction expected between these species and the survey activities, and in consideration of the overall low impact ratings, we find the take from TGS's planned survey activities will have a negligible impact on the humpback whale and minke whale.

Despite high magnitude ratings, most remaining delphinid species receive moderate impact ratings (with the exception of the striped dolphin, with medium magnitude rating and low impact rating), due to low consequences rating relating to a lack of propensity for behavioral disruption due to airgun survey activity and our expectation that these species would generally have relatively high compensatory ability. In addition, contextually these species do not have significant issues relating to population status or context. Many oceanic delphinid species are generally more associated with dynamic oceanographic characteristics rather than static physical features, and those species (such as common dolphin) with substantial distribution to the north of the survey area would likely be little affected at the population level by the specified activity. For example, both species of spotted dolphin and the offshore stock of bottlenose dolphin range widely over slope and abyssal waters (*e.g.,* Waring *et al.,* 2014; Hayes *et al.,* 2017; Roberts *et al.,* 2016), while the rough-toothed dolphin does not appear bound by water depth in its range (Ritter, 2002; Wells *et al.,* 2008). Our required mitigation largely eliminates potential effects to depleted coastal stocks of bottlenose dolphin. We also expect that meaningful subsidiary benefit will accrue to certain species from the mitigation targeted for sperm whales, beaked whales, and pilot whales, most notably to species presumed to have greater association with shelf break waters north of Cape Hatteras (*e.g.,* offshore bottlenose dolphins, common dolphins, and Risso's dolphins). In consideration of these factors—overall impact ratings and context including required mitigation—we find the take from TGS's survey activities will have a negligible impact on most remaining delphinid species (*i.e.,* all stocks of bottlenose dolphin, two species of spotted dolphin, rough-toothed dolphin, striped dolphin, common dolphin, and Risso's dolphin).

For those species with de minimis impact ratings we believe that, absent additional relevant concerns related to population status or context, the rating implies that a negligible impact should be expected as a result of the specified activity. No such concerns exist for these species, and we find the take from TGS's survey activities will have a negligible impact on the Clymene dolphin and harbor porpoise.

In summary, 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 required monitoring and mitigation measures, we find that the total marine mammal take from TGS's survey activities will have a negligible impact on all affected marine mammal species or stocks.

ION—ION has planned a 70-day survey program, or 19 percent of the year (slightly less than one season). However, the planned survey would cover a large spatial extent (*i.e.,* a majority of the mid- and south Atlantic; see Figure 1 of ION's application). Therefore, although the survey would be moderate-term (*i.e.,* from 1–3 months) in total duration, we would not expect the duration of effect to be greater than short and isolated to intermittent in any given area. Table 12 displays relevant information leading to impact ratings for each species resulting from ION's survey. In general, we note that although the temporal and spatial scale of the planned survey activity is large, the fact that this mobile acoustic source would be moving across large areas (as compared with geophysical surveys with different objectives that may require focused effort over long periods of time in smaller areas) means that more individuals may receive limited exposure to survey noise, versus fewer individuals receiving more intense exposure and/or for longer periods of time. The nature of such potentially transitory exposure means that the potential significance of behavioral disruption and potential for longer-term avoidance of important areas is limited.

TABLE 12—MAGNITUDE AND IMPACT RATINGS, ION

Species	Amount	Spatial extent	Magnitude rating	Consequences	Impact rating [1]
North Atlantic right whale	De minimis	Low-Moderate	De minimis	Medium	Low.
Humpback whale	De minimis	Low-Moderate	De minimis	Medium	Low.
Minke whale	De minimis	Low-High	De minimis	Medium	Low.
Fin whale	De minimis	Low	De minimis	Medium	Low.
Sperm whale	De minimis	Moderate	De minimis	Medium	Low.
Kogia spp	De minimis	High	De minimis	Low	De minimis.
Beaked whales	De minimis	Moderate	De minimis	High	Low.
Rough-toothed dolphin	De minimis	High	De minimis	Low	De minimis.
Bottlenose dolphin	De minimis	High	De minimis	Low	De minimis.
Clymene dolphin	De minimis	High	De minimis	Low	De minimis.
Atlantic spotted dolphin	De minimis	Moderate	De minimis	Low	De minimis.
Pantropical spotted dolphin	De minimis	High	De minimis	Low	De minimis.
Striped dolphin	De minimis	Low	De minimis	Low	De minimis.
Common dolphin	De minimis	Low-moderate	De minimis	Low	De minimis.
Risso's dolphin	De minimis	Low-moderate	De minimis	Low	De minimis.
Pilot whales	De minimis	Moderate	De minimis	Medium	Low.
Harbor porpoise	De minimis	Low	De minimis	Low	De minimis.

[1] Impact rating does not indicate whether overall impact to the species or stock is negligible, but is considered with relevant contextual factors (described generally above and specifically below) in order to ultimately determine whether the effects of the specified activity on the affected species or stock are negligible.

The North Atlantic right whale is endangered, has a very low population size, and faces significant additional stressors. Therefore, regardless of impact rating, we believe that the required mitigation described previously is critically important in order for us to make the necessary finding and it is with consideration of this mitigation that we find the take from ION's planned survey activities will have a negligible impact on the North Atlantic right whale.

Also regardless of impact rating, consideration of assumed behavioral susceptibility and lack of compensatory ability (*i.e.,* consequence factors) as well as additional contextual factors leads us to conclude that the required targeted time-area mitigation described previously is important to support a finding that the effects of the planned survey will have a negligible impact for the sperm whale, beaked whales (*i.e., Ziphius cavirostris* and *Mesoplodon* spp.), and pilot whales (*i.e., Globicephala* spp.). As described previously, sperm whales are an endangered species with particular susceptibility to disruption of foraging behavior, beaked whales are particularly acoustically sensitive, and pilot whales are sensitive to additional stressors due to a high degree of mortality in commercial fisheries. Further, we expect that compensatory ability for beaked whales will be low due to presumed residency in certain shelf break and deepwater canyon areas covered by the survey area and that compensatory ability for pilot whales will also be low due to presumed residency in areas targeted by the planned survey (when compensatory ability is assumed to be low, we assign a high consequence factor). *Kogia* spp. are also considered to have heightened acoustic sensitivity and therefore we have required shutdown of the acoustic source upon observation of a beaked whale or a *Kogia* spp. at extended distance from the source vessel. In consideration of the required mitigation, we find the take from ION's survey activities will have a negligible impact on the sperm whale, beaked whales, pilot whales, and *Kogia* spp.

As described in the introduction to this analysis, it is assumed that likely consequences are somewhat higher for species of mysticete whales (low-frequency hearing specialists) due to the greater potential for masking impacts at longer ranges than other taxa and at frequencies that overlap a larger portion of both their hearing and vocalization ranges. Therefore, despite de minimis magnitude ratings, we expect some consequences to individual humpback, fin, and minke whales, *i.e.,* leading to a low impact rating. However, given the minimal amount of interaction expected between these species and the survey activities, and in consideration of the overall low impact ratings, we find the take from ION's planned survey activities will have a negligible impact on the humpback whale, fin whale, and minke whale.

For those species with de minimis impact ratings we believe that, absent additional relevant concerns related to population status or context, the rating implies that a negligible impact should be expected as a result of the specified activity. No such concerns exist for these species, and we find the take from ION's planned survey activities will have a negligible impact on all stocks of bottlenose dolphin, two species of spotted dolphin, rough-toothed dolphin, striped dolphin, common dolphin, Clymene dolphin, Risso's dolphin, and harbor porpoise.

In summary, 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 required monitoring and mitigation measures, we find that the total marine mammal take from ION's survey activities will have a negligible impact on all affected marine mammal species or stocks.

Western—Western has planned a 208-day survey program, or 57 percent of the year (slightly more than two seasons). However, the planned survey would cover a large spatial extent (*i.e.,* a majority of the mid- and south Atlantic; see Figures 1–1 to 1–4 of Western's application). Therefore, although the survey would be long-term (*i.e.,* greater than one season) in total duration, we would not expect the duration of effect to be greater than moderate and intermittent in any given area. Table 13 displays relevant information leading to impact ratings for each species resulting from Western's survey. In general, we note that although the temporal and spatial scale of the planned survey activity is large, the fact that this mobile acoustic source would be moving across large areas (as compared with geophysical surveys with different objectives that may require focused effort over long periods of time in smaller areas) means that more individuals may receive limited exposure to survey noise, versus fewer individuals receiving more intense exposure and/or for longer periods of time. The nature of such potentially transitory exposure (which we nevertheless assume here is of moderate duration and intermittent, versus isolated) means that the potential significance of behavioral disruption and potential for longer-term avoidance of important areas is limited.

TABLE 13—MAGNITUDE AND IMPACT RATINGS, WESTERN

Species	Amount	Spatial extent	Magnitude rating	Consequences	Impact rating [1]
North Atlantic right whale	De minimis	Low-Moderate	De minimis	Medium	Low.
Humpback whale	De minimis	Low-Moderate	De minimis	Medium	Low.
Minke whale	De minimis	Low-High	De minimis	Medium	Low.
Fin whale	Low	Low	Medium	Medium	Moderate.
Sperm whale	Moderate	Moderate	High	Medium	High.
Kogia spp	Moderate	High	High	Low	Moderate.
Beaked whales	Moderate	Moderate	High	High	High.
Rough-toothed dolphin	Low	High	High	Low	Moderate.
Bottlenose dolphin	Moderate	High	High	Low	Moderate.
Clymene dolphin	De minimis	High	De minimis	Low	De minimis.
Atlantic spotted dolphin	Moderate	Moderate	High	Low	Moderate.
Pantropical spotted dolphin	Low	High	High	Low	Moderate.
Striped dolphin	Low	Low	Medium	Low	Low.
Common dolphin	Low	Low-moderate	Medium	Low	Low.
Risso's dolphin	Low	Low-moderate	Medium	Low	Low.
Pilot whales	Low	Moderate	Medium	Medium	Moderate.

TABLE 13—MAGNITUDE AND IMPACT RATINGS, WESTERN—Continued

Species	Amount	Spatial extent	Magnitude rating	Consequences	Impact rating [1]
Harbor porpoise	De minimis	Low	De minimis	Low	De minimis

[1] Impact rating does not indicate whether overall impact to the species or stock is negligible, but is considered with relevant contextual factors (described generally above and specifically below) in order to ultimately determine whether the effects of the specified activity on the affected species or stock are negligible.

The North Atlantic right whale is endangered, has a very low population size, and faces significant additional stressors. Therefore, regardless of impact rating, we believe that the required mitigation described previously is critically important in order for us to make the necessary finding and it is with consideration of this mitigation that we find the take from Western's survey activities will have a negligible impact on the North Atlantic right whale. The fin whale receives a moderate impact rating overall, but we expect that for two seasons (summer and fall) almost no fin whales will be present in the survey area. For the remainder of the year, it is likely that less than one quarter of the population will be present within the survey area (Roberts *et al.,* 2016), meaning that despite medium rankings for magnitude and likely consequences, these impacts would be experienced by only a small subset of the overall population. In consideration of the moderate impact rating, the likely proportion of the population that may be affected by the specified activities, and the lack of evidence that the survey area is host to important behaviors that may be disrupted, we find the take from Western's survey activities will have a negligible impact on the fin whale.

Magnitude ratings for the sperm whale and beaked whales are high and, further, consequence factors reinforce high impact ratings for both. Magnitude rating for pilot whales is medium but, similar to beaked whales, we expect that compensatory ability will be low (high consequence rating) due to presumed residency in areas targeted by the planned survey—leading to a moderate impact rating. However, regardless of impact rating, the consideration of likely consequences and contextual factors for all three taxa leads us to conclude that targeted mitigation is important to support a finding that the effects of the survey will have a negligible impact on these species. As described previously, sperm whales are an endangered species with particular susceptibility to disruption of foraging behavior, beaked whales are particularly acoustically sensitive (with presumed low compensatory ability), and pilot whales are sensitive to additional stressors due to a high degree of mortality in commercial fisheries (and also with low compensatory ability). Finally, due to their acoustic sensitivity, we have required shutdown of the acoustic source upon observation of a beaked whale at extended distance from the source vessel. In consideration of the required mitigation, we find the take from Western's survey activities will have a negligible impact on the sperm whale, beaked whales (*i.e., Ziphius cavirostris* and *Mesoplodon* spp.), and pilot whales (*i.e., Globicephala* spp.).

Kogia spp. receive a moderate impact rating. However, although NMFS does not currently identify a trend for these populations, recent survey effort and stranding data show a simultaneous increase in at-sea abundance and strandings, suggesting growing *Kogia* spp. abundance (NMFS, 2011; 2013a; Waring *et al.,* 2007; 2013). Finally, we expect that *Kogia* spp. will receive subsidiary benefit from the mitigation targeted for sperm whales, beaked whales, and pilot whales and, although minimally effective due to the difficulty of at-sea observation of *Kogia* spp., we have required shutdown of the acoustic source upon observation of *Kogia* spp. at extended distance from the source vessel. In consideration of these factors—likely population increase and required mitigation—we find the take from Western's survey activities will have a negligible impact on *Kogia* spp.

As described in the introduction to this analysis, it is assumed that likely consequences are somewhat higher for species of mysticete whales (low-frequency hearing specialists) due to the greater potential for masking impacts at longer ranges than other taxa and at frequencies that overlap a larger portion of both their hearing and vocalization ranges. Therefore, despite de minimis magnitude ratings, we expect some consequences to individual humpback and minke whales, *i.e.,* leading to a low impact rating. However, given the minimal amount of interaction expected between these species and the survey activities, and in consideration of the overall low impact ratings, we find the take from Western's planned survey activities will have a negligible impact on the humpback whale and minke whale.

Despite medium to high magnitude ratings (with the exception of the Clymene dolphin), remaining delphinid species receive low to moderate impact ratings due to consequences relating to a lack of propensity for behavioral disruption due to airgun survey activity and our expectation that these species would generally have relatively high compensatory ability. In addition, contextually these species do not have significant issues relating to population status or context. Many oceanic delphinid species are generally more associated with dynamic oceanographic characteristics rather than static physical features, and those species (such as common dolphin) with substantial distribution to the north of the survey area would likely be little affected at the population level by the specified activity. For example, both species of spotted dolphin and the offshore stock of bottlenose dolphin range widely over slope and abyssal waters (*e.g.,* Waring *et al.,* 2014; Hayes *et al.,* 2017; Roberts *et al.,* 2016), while the rough-toothed dolphin does not appear bound by water depth in its range (Ritter, 2002; Wells *et al.,* 2008). Our required mitigation largely eliminates potential effects to depleted coastal stocks of bottlenose dolphin. We also expect that meaningful subsidiary benefit will accrue to certain species from the mitigation targeted for sperm whales, beaked whales, and pilot whales, most notably to species presumed to have greater association with shelf break waters north of Cape Hatteras (*e.g.,* offshore bottlenose dolphins, common dolphins, and Risso's dolphins). In consideration of these factors—overall impact ratings and context including required mitigation—we find the take from Western's survey activities will have a negligible impact on most remaining delphinid species (*i.e.,* all stocks of bottlenose dolphin, two species of spotted dolphin, rough-toothed dolphin, striped dolphin, common dolphin, and Risso's dolphin).

For those species with de minimis impact ratings we believe that, absent additional relevant concerns related to

population status or context, the rating implies that a negligible impact should be expected as a result of the specified activity. No such concerns exist for these species, and we find the take from Western's survey activities will have a negligible impact on the Clymene dolphin and harbor porpoise.

In summary, 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 required monitoring and mitigation measures, we find that the total marine mammal take from Western's survey activities will have a negligible impact on all affected marine mammal species or stocks.

CGG—CGG has planned an approximately 155-day survey program, or 42 percent of the year (approximately two seasons). However, the planned survey would cover a large spatial extent (*i.e.,* a majority of the mid- and south Atlantic; see Figure 3 of CGG's application). Therefore, although the survey would be long-term (*i.e.,* greater than one season) in total duration, we would not expect the duration of effect to be greater than moderate and intermittent in any given area. Table 14 displays relevant information leading to impact ratings for each species resulting from CGG's survey. In general, we note that although the temporal and spatial scale of the planned survey activity is large, the fact that this mobile acoustic source would be moving across large areas (as compared with geophysical surveys with different objectives that may require focused effort over long periods of time in smaller areas) means that more individuals may receive limited exposure to survey noise, versus fewer individuals receiving more intense exposure and/or for longer periods of time. The nature of such potentially transitory exposure means that the potential significance of behavioral disruption and potential for longer-term avoidance of important areas is limited.

TABLE 14—MAGNITUDE AND IMPACT RATINGS, CGG

Species	Amount	Spatial extent	Magnitude rating	Consequences	Impact rating [1]
North Atlantic right whale	De minimis	Low-Moderate	De minimis	Medium	Low.
Humpback whale	De minimis	Low-Moderate	De minimis	Medium	Low.
Minke whale	De minimis	Low-High	De minimis	Medium	Low.
Fin whale	De minimis	Low	De minimis	Medium	Low.
Sperm whale	Low	Moderate	Medium	Medium	Moderate.
Kogia spp	Low	High	High	Low	Moderate.
Beaked whales	Low	Moderate	Medium	High	Moderate.
Rough-toothed dolphin	Moderate	High	High	Low	Moderate.
Bottlenose dolphin	Low	High	High	Low	Moderate.
Clymene dolphin	High	High	High	Low	Moderate.
Atlantic spotted dolphin	Low	Moderate	Medium	Low	Low.
Pantropical spotted dolphin	Moderate	High	High	Low	Moderate.
Striped dolphin	De minimis	Low	De minimis	Low	De minimis.
Common dolphin	De minimis	Low-moderate	De minimis	Low	De minimis.
Risso's dolphin	De minimis	Low-moderate	De minimis	Low	De minimis.
Pilot whales	Low	Moderate	Medium	Medium	Moderate.
Harbor porpoise	De minimis	Low	De minimis	Low	De minimis.

[1] Impact rating does not indicate whether overall impact to the species or stock is negligible, but is considered with relevant contextual factors (described generally above and specifically below) in order to ultimately determine whether the effects of the specified activity on the affected species or stock are negligible.

The North Atlantic right whale is endangered, has a very low population size, and faces significant additional stressors. Therefore, regardless of impact rating, we believe that the required mitigation described previously is critically important in order for us to make the necessary finding and it is with consideration of this mitigation that we find the take from CGG's survey activities will have a negligible impact on the North Atlantic right whale.

Magnitude ratings for the sperm whale and beaked whales are medium; however, consequence factors are medium and high, respectively. Magnitude rating for pilot whales is medium but, similar to beaked whales, we expect that compensatory ability will be low (high consequence rating) due to presumed residency in areas targeted by the planned survey—leading to a moderate impact rating. However, regardless of impact rating, the consideration of likely consequences and contextual factors for all three taxa leads us to conclude that targeted mitigation is important to support a finding that the effects of the survey will have a negligible impact on these species. As described previously, sperm whales are an endangered species with particular susceptibility to disruption of foraging behavior, beaked whales are particularly acoustically sensitive (with presumed low compensatory ability), and pilot whales are sensitive to additional stressors due to a high degree of mortality in commercial fisheries (and also with low compensatory ability). Finally, due to their acoustic sensitivity, we require shutdown of the acoustic source upon detection of a beaked whale at extended distance from the source vessel. In consideration of the required mitigation, we find the take from CGG's survey activities will have a negligible impact on the sperm whale, beaked whales (*i.e., Ziphius cavirostris* and *Mesoplodon* spp.), and pilot whales (*i.e., Globicephala* spp.).

Kogia spp. receive a moderate impact rating. However, although NMFS does not currently identify a trend for these populations, recent survey effort and stranding data show a simultaneous increase in at-sea abundance and strandings, suggesting growing *Kogia* spp. abundance (NMFS, 2011; 2013a; Waring *et al.,* 2007; 2013). Finally, we expect that *Kogia* spp. will receive subsidiary benefit from the required mitigation targeted for sperm whales, beaked whales, and pilot whales and, although minimally effective due to the difficulty of at-sea observation of *Kogia* spp., we have required shutdown of the acoustic source upon observation of *Kogia* spp. at extended distance from the source vessel. In consideration of these factors—likely population increase and required mitigation—we find the take from CGG's survey activities will have a negligible impact on *Kogia* spp.

As described in the introduction to this analysis, it is assumed that likely consequences are somewhat higher for species of mysticete whales (low-frequency hearing specialists) due to the greater potential for masking impacts at longer ranges than other taxa and at frequencies that overlap a larger portion of both their hearing and vocalization ranges. Therefore, despite de minimis magnitude ratings, we expect some consequences to individual humpback, fin, and minke whales, *i.e.,* leading to a low impact rating. However, given the minimal amount of interaction expected between these species and the survey activities, and in consideration of the overall low impact ratings, we find the take from CGG's planned survey activities will have a negligible impact on the humpback whale, fin whale, and minke whale.

Despite medium to high magnitude ratings (with some exceptions), most remaining delphinid species receive low to moderate impact ratings due to consequences relating to a lack of propensity for behavioral disruption due to airgun survey activity and our expectation that these species would generally have relatively high compensatory ability. In addition, contextually these species do not have significant issues relating to population status or context. Many oceanic delphinid species are generally more associated with dynamic oceanographic characteristics rather than static physical features, and those species (such as common dolphin) with substantial distribution to the north of the survey area would likely be little affected at the population level by the specified activity. For example, both species of spotted dolphin and the offshore stock of bottlenose dolphin range widely over slope and abyssal waters (*e.g.,* Waring *et al.,* 2014; Hayes *et al.,* 2017; Roberts *et al.,* 2016), while the rough-toothed dolphin does not appear bound by water depth in its range (Ritter, 2002; Wells *et al.,* 2008). Our required mitigation largely eliminates potential effects to depleted coastal stocks of bottlenose dolphin. We also expect that meaningful subsidiary benefit will accrue to certain species from the mitigation targeted for sperm whales, beaked whales, and pilot whales, most notably to species presumed to have greater association with shelf break waters north of Cape Hatteras (*e.g.,* offshore bottlenose dolphins). In consideration of these factors—overall impact ratings and context including required mitigation—we find the take from CGG's survey activities will have a negligible impact on remaining delphinid species (*i.e.,* all stocks of bottlenose dolphin, two species of spotted dolphin, rough-toothed dolphin, and Clymene dolphin).

For those species with de minimis impact ratings we believe that, absent additional relevant concerns related to population status or context, the rating implies that a negligible impact should be expected as a result of the specified activity. No such concerns exist for these species, and we find the take from CGG's survey activities will have a negligible impact on the common dolphin, striped dolphin, Risso's dolphin, and harbor porpoise.

In summary, 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 required monitoring and mitigation measures, we find that the total marine mammal take from CGG's survey activities will have a negligible impact on all affected marine mammal species or stocks.

Small Numbers Analyses

The MMPA does not define ''small numbers.'' NMFS's and the U.S. Fish and Wildlife Service's 1989 implementing regulations defined small numbers as a portion of a marine mammal species or stock whose taking would have a negligible impact on that species or stock. This definition was invalidated in *Natural Resources Defense Council* v. *Evans,* 279 F.Supp.2d 1129 (2003) (N.D. Cal. 2003), based on the court's determination that the regulatory definition of small numbers was improperly conflated with the regulatory definition of ''negligible impact,'' which rendered the small numbers standard superfluous. As the court observed, ''the plain language indicates that small numbers is a separate requirement from negligible impact.'' Since that time, NMFS has not applied the definition found in its regulations. Rather, consistent with Congress' pronouncement that small numbers is not a concept that can be expressed in absolute terms (House Committee on Merchant Marine and Fisheries Report No. 97–228 (September 16, 1981)), NMFS makes its small numbers findings based on an analysis of whether the number of individuals authorized to be taken annually from a specified activity is small relative to the stock or population size. The Ninth Circuit has upheld a similar approach. See *Center for Biological Diversity* v. *Salazar,* No. 10–35123, 2012 WL 3570667 (9th Cir. Aug. 21, 2012). However, we have not historically indicated what we believe the upper limit of small numbers is.

To maintain an interpretation of small numbers as a proportion of a species or stock that does not conflate with negligible impact, we use the following framework. A plain reading of ''small'' implies as corollary that there also could be ''medium'' or ''large'' numbers of animals from the species or stock taken. We therefore use a simple approach that establishes equal bins corresponding to small, medium, and large proportions of the population abundance.

NMFS's practice for making small numbers determinations is to compare the number of individuals estimated and authorized to be taken (often using estimates of total instances of take, without regard to whether individuals are exposed more than once) against the best available abundance estimate for that species or stock. We note, however, that although NMFS's implementing regulations require applications for incidental take to include an estimate of the marine mammals to be taken, there is nothing in paragraphs (A) or (D) of section 101(a)(5) that requires NMFS to quantify or estimate numbers of marine mammals to be taken for purposes of evaluating whether the number is small. (See *CBD* v. *Salazar.*) While it can be challenging to predict the numbers of individual marine mammals that will be taken by an activity (again, many models calculate instances of take and are unable to account for repeated exposures of individuals), in some cases we are able to generate a reasonable estimate utilizing a combination of quantitative tools and qualitative information. When it is possible to predict with relative confidence the number of individual marine mammals of each species or stock that are likely to be taken, the small numbers determination should be based directly upon whether or not these estimates exceed one third of the stock abundance. In other words, consistent with past practice, when the estimated number of individual animals taken (which may or may not be assumed as equal to the total number of takes, depending on the available information) is up to, but not greater than, one third of the species or stock abundance, NMFS will determine that the numbers of marine mammals taken of a species or stock are small.

Another circumstance in which NMFS considers it appropriate to make a small numbers finding is in the case of a species or stock that may potentially be taken but is either rarely encountered or only expected to be taken on rare occasions. In that

circumstance, one or two assumed encounters with a group of animals (meaning a group that is traveling together or aggregated, and thus exposed to a stressor at the same approximate time) should reasonably be considered small numbers, regardless of consideration of the proportion of the stock (if known), as rare encounters resulting in take of one or two groups should be considered small relative to the range and distribution of any stock.

In summary, when quantitative take estimates of individual marine mammals are available or inferable through consideration of additional factors, and the number of animals taken is one third or less of the best available abundance estimate for the species or stock, NMFS considers it to be of small numbers. NMFS may appropriately find that one or two predicted group encounters will result in small numbers of take relative to the range and distribution of a species, regardless of the estimated proportion of the abundance.

Please see Table 15 for information relating to the basis for our small numbers analyses. For the sei whale, Bryde's whale, blue whale, northern bottlenose whale, Fraser's dolphin, melon-headed whale, false killer whale, pygmy killer whale, killer whale, spinner dolphin, and white-sided dolphin, we authorize take resulting from a single exposure of one group of each species or stock, as appropriate (using average group size), for each applicant. We believe that a single incident of take of one group of any of these species represents take of small numbers for that species. Therefore, for each applicant, based on the analyses contained herein of their specified activity, we find that small numbers of marine mammals will be taken for each of these 11 affected species or stocks for each specified activity. We do not discuss these 11 species further in the applicant-specific analyses that follow.

TABLE 15—TOTAL INSTANCES OF TAKE AUTHORIZED [1] AND PROPORTION OF BEST ABUNDANCE ESTIMATE [2]

Common name	Abundance estimate [4]	Spectrum [8]		TGS [3]		ION		Western		CGG	
		Take	%	Take	%	Take	%	Take	%	Take	%
North Atlantic right whale	458	6	1	9	2	2	<1	4	1	2	<1
Humpback whale	[5] 2,002	45	2	60	3	7	<1	49	2	7	<1
Minke whale	20,741	423	2	212	1	12	<1	100	<1	128	1
Fin whale	[5] 6,582	337	5	1,144	17	5	<1	537	8	49	1
Sperm whale	[5] 9,649	1,077	11	3,579	37	16	<1	1,941	20	1,304	14
Kogia spp	3,785	205	5	1,221	32	30	1	572	15	240	6
Beaked whales	[6] 25,284	3,357	13	12,072	48	490	2	4,960	20	3,511	14
Rough-toothed dolphin	[7] 845	201	24	261	31	14	2	123	15	177	21
Bottlenose dolphin	[5] 149,785	37,562	25	40,595	27	2,599	2	23,600	16	9,063	6
Clymene dolphin	[7] 24,018	6,459	27	821	3	252	1	391	2	6,382	27
Atlantic spotted dolphin	[6] 107,100	16,926	16	41,222	38	568	1	18,724	17	6,596	6
Pantropical spotted dolphin	[7] 7,217	1,632	23	1,470	20	78	1	690	10	1,566	22
Striped dolphin	[6] 158,258	8,022	5	23,418	15	162	<1	8,845	6	6,328	4
Common dolphin	173,486	11,087	6	52,728	30	372	<1	20,683	12	6,026	3
Risso's dolphin	[5] 19,437	755	4	3,241	17	90	<1	1,608	8	809	4
Globicephala spp	[6] 34,531	2,765	8	8,902	26	199	1	4,682	14	1,964	6
Harbor porpoise	[5] 50,406	627	1	325	1	21	<1	155	<1	30	<1

[1] Total take authorized includes take by Level A and Level B harassment. Please see Table 6 for details.
[2] Species for which take resulting from a single exposure of one group of each species or stock are not included in this table. Please see discussion preceding this table.
[3] Additional analysis was conducted to specify the number of individuals taken for TGS. Please see discussion below and Table 16.
[4] Best abundance estimate; please see discussion under ''Description of Marine Mammals in the Area of the Specified Activities.'' For most taxa, the best abundance estimate for purposes of comparison with take estimates is considered here to be the model-predicted abundance (Roberts *et al.,* 2016). For these taxa, model-predicted abundances within the EEZ and estimates for the portion of the specific geographic region beyond the EEZ are combined to obtain the total abundance. For those taxa where a density surface model was produced, maximum monthly abundance was considered appropriate for some, and for others the maximum mean seasonal abundance was used as a precaution. For those taxa where only a stratified model was produced, only mean annual abundance is available. For several taxa, other abundance estimates were deemed most appropriate, as described previously in this notice.
[5] Maximum monthly abundance.
[6] Maximum seasonal abundance.
[7] Mean annual abundance.
[8] Small numbers analyses were completed prior to receipt of a modified survey plan from Spectrum and subsequent revision of authorized take numbers reflecting the modification. Here, we retain the original take estimates for Spectrum in context of the small numbers analysis described below. Please see ''Spectrum Survey Plan Modification,'' below, for additional information describing the modified survey plan, findings made in context of the analysis presented below, and authorized take for Spectrum (Table 17).

As discussed previously, the MMPA does not define small numbers. NMFS compares the estimated numbers of individuals expected to be taken (when available; often take estimates are presented as estimated instances of take) to the most appropriate estimation of the relevant species or stock size in our determination of whether an authorization is limited to small numbers of marine mammals, *i.e.,* less than one-third of the most appropriate abundance estimate (Table 15). In the Notice of Proposed Authorization, we proposed to limit the authorization of take to approximately one-third of the most appropriate stock abundance estimate, assuming no other relevant factors that provide more context for the estimate (*e.g.,* information that the take estimate numbers represent instances of multiple exposures of the same animals). Further, we proposed that, in order to limit actual take to this proportion of estimated stock abundance, we would require monthly reporting from those applicants with predicted exposures of any species exceeding this threshold. Those interim reports would include corrected numbers of marine mammals ''taken'' and, upon reaching the pre-determined take threshold, any issued IHA would be withdrawn.

However, as discussed elsewhere in this notice (including in ''Comments and Responses''), we received numerous comments criticizing this approach. Notably, comments indicated that the pre-determined threshold (described in our Notice of Proposed IHAs as30 percent) was arbitrary and not rooted in any meaningful biological consideration, and that the proposal—*i.e.,* to limit the actual take authorization to less than what was estimated in terms of potential exposures, require a novel reporting scheme, and potentially withdraw IHAs if the threshold was crossed—was impracticable. However, in this Notice we have more fully described and clarified our approach to small numbers, and used this approach for

issuance of the IHAs. As a result of the concerns presented by applicants and commenters regarding the justification for and practicability of our proposal, we reconsidered the available information and re-evaluated and refined our small numbers analyses, as described next. With regard to use of the most appropriate population abundance (Table 15), please see additional discussion under ''Description of Marine Mammals in the Area of the Specified Activities.''

The number of exposures presented in Table 15 represent the estimated number of instantaneous instances in which an individual from each species or stock would be exposed to sound fields from airgun surveys at or above the 160 dB rms threshold. They do not necessarily represent the estimated number of individuals of each species that would be exposed, nor do they provide information on the duration of the exposure. In this case, the likelihood that any individual of a given species is exposed more than once is low due to the movement of both the vessels and the animals themselves. That said, for species where the estimated exposure numbers are higher compared to the population abundance, we assume that some individuals may be exposed more than once, meaning the exposures given in Table 15 overestimate the numbers of individuals that would be exposed. Applicant-specific analyses follow.

Spectrum—The total amount of taking assessed for all affected stocks on the basis of Spectrum's original survey plan ranges from 1 to 27 percent of the most appropriate population abundance estimate, and is therefore less than the appropriate small numbers threshold (*i.e.,* one-third of the most appropriate population abundance estimate). These proportions are considered overestimates with regard to the small numbers findings, as they likely represent multiple exposures of some of the same individuals for some stocks. However, we do not have sufficient information on which to base an estimate of individuals taken versus instances of take. Please see ''Spectrum Survey Plan Modification,'' below, for additional information describing the modified survey plan, findings made in context of the analysis presented here, and authorized take for Spectrum (Table 17).

Based on the analysis contained herein of Spectrum's specified activity, the required monitoring and mitigation measures, and the anticipated take of marine mammals, we find that small numbers of marine mammals will be taken relative to the population sizes of the affected species or stocks.

TGS—The total amount of taking (in consideration of instances of take) authorized for a majority of affected stocks ranges from 1 to 32 percent of the most appropriate population abundance estimate, and is therefore less than the appropriate small numbers threshold (*i.e.,* one-third of the most appropriate population abundance estimate). The total amount of taking (in consideration of instances of take) authorized for the sperm whale, beaked whales, and the Atlantic spotted dolphin is higher than the threshold. In this case, we have information available to distinguish between an estimate of individuals taken versus instances of take.

TGS is the only applicant that provided an analysis of estimated individuals exposed versus instances of exposure (see Table 6–5 of TGS's application). As described in the introduction to this section, the number of individuals taken (versus total instances of take), is the relevant metric for comparison to population abundance in a small numbers analysis. We note, though, that total instances of take are routinely used to evaluate small numbers when data to distinguish individuals is not available, and we further note the conservativeness of the assumption, as the number of total instances of take equates to the highest possible number of individuals. For example, in some cases the total number of takes may exceed the number of individuals in a population abundance, meaning there are multiple exposures of at least some animals.

We do not typically attempt to quantitatively assess this comparison of individuals taken versus instances of take when we do not have direct information regarding individuals exposed (*e.g.,* we know that only a specific sub-population is potentially exposed or we know that uniquely identified individuals are exposed); therefore, we did not initially make use of the information provided by TGS in their application, instead proposing the take cap and reporting scheme described in the introduction to this section. As described above, commenters indicated that our proposed approach was flawed and, therefore, we further evaluated the available information.

The conceptual approach to the analysis involves a comparison of total ensonified area to the portion of that total area that is ensonified more than once. For TGS, 84 percent of the total ensonified area is area that is ensonified more than once, *i.e.,* ''overlap.'' In a static density model, the same animals occur in the overlap regardless of the time elapsed between the first and second exposure. If animals are static in space in the model, they are re-exposed in the model every time there is overlap. When overlap is counted toward the evaluation of small numbers (*i.e.,* percent of the abundance that is ''taken''), it effectively raises the total abundance possible in the model, creating a situation in which one could theoretically take more than the abundance to which one is comparing. This does not make sense from the perspective of comparing numbers of individuals taken to total abundance. Although portions of the overlap may be ensonified more than twice, we conservatively assume a maximum of one repeat ensonification.

The number of individuals potentially taken (versus total incidents of take) can then be determined using the following equation: (Numerical Output of the Model) − (0.84 * Numerical Output of the Model) + 0.5 * (0.84 * Numerical Output of the Model). This may be simplified as: 0.58 * Numerical Output of the Model. ''Numerical output of the model'' refers to the estimated total incidents of take. As we stated in the introduction to this section, where there are relatively few total takes, it is more likely that all takes occur to new individuals, though this is dependent on actual distribution and movement of animals in relation to the survey vessel. While there is no clear threshold as to what level of total takes indicates a likelihood of repeat taking of individuals, here we assume that total taking of a moderate or high magnitude (consistent with our approach to assessing magnitude in the negligible impact analysis framework; see ''Negligible Impact Analyses and Determinations''), *i.e.,* greater than 15 percent, is required for repeat taking of individuals to be likely and applied this analysis only to those stocks.

TABLE 16—ANALYSIS OF INDIVIDUALS TAKEN VERSUS TOTAL TAKES, TGS

Common name	Abundance estimate	Total take	%	Individuals taken	%	Individuals taken once	Individuals taken twice
Fin whale	6,582	1,144	17	664	10	480	184

TABLE 16—ANALYSIS OF INDIVIDUALS TAKEN VERSUS TOTAL TAKES, TGS—Continued

Common name	Abundance estimate	Total take	%	Individuals taken	%	Individuals taken once	Individuals taken twice
Sperm whale	9,649	3,579	37	2,076	22	1,503	573
Kogia spp.	3,785	1,221	32	708	19	513	195
Beaked whales	25,284	12,072	48	7,002	28	5,070	1,932
Rough-toothed dolphin	845	261	31	151	18	110	42
Bottlenose dolphin	149,785	40,595	27	23,545	16	17,050	6,495
Atlantic spotted dolphin	107,100	41,222	38	23,909	22	17,313	6,596
Pantropical spotted dolphin	7,217	1,470	20	853	12	617	235
Common dolphin	173,486	52,728	30	30,582	18	22,146	8,436
Risso's dolphin	19,437	3,241	17	1,880	10	1,361	519
Globicephala spp.	34,531	8,902	26	5,163	15	3,739	1,424

This approach also allows us to estimate the number of individuals that we assume to be taken once and the number assumed to be taken twice. As we noted previously, although it is possible that some individuals may be taken more than twice, we assume a maximum of one repeat ensonification (a conservative assumption in this small numbers analysis context). For example, if there are 1,144 total takes of fin whales, with 664 total individuals taken, and where:

a = number of animals with single take; b = number of animals with double take,

then: $a + b = 664$ and $2*a + b = 1{,}144$ and, therefore, $2*a + 664 - a = 1{,}144$. In this example for fin whales, we assume that 480 individuals are taken twice and 184 individuals are taken once. (Note that values given in Table 16 for individuals taken once versus twice may not sum to the value given for total individuals taken due to rounding.)

In summary, for those stocks for which we assume each authorized take represents a new individual, the total amount of taking authorized ranges from 1 to 15 percent of the most appropriate population abundance estimate (Table 15), and is therefore less than the appropriate small numbers threshold (*i.e.,* one-third of the most appropriate population abundance estimate). For those stocks for which we assessed the number of expected individuals taken, the total amount of taking authorized ranges from 10 to 28 percent of the most appropriate population abundance estimate (Table 16), and is therefore less than the appropriate small numbers threshold (*i.e.,* one-third of the most appropriate population abundance estimate). Based on the analysis contained herein of TGS's specified activity, the required monitoring and mitigation measures, and the anticipated take of marine mammals, we find that small numbers of marine mammals will be taken relative to the population sizes of the affected species or stocks.

ION—The total amount of taking authorized for all affected stocks ranges from less than 1 to 4 percent of the most appropriate population abundance estimate, and is therefore less than the appropriate small numbers threshold (*i.e.,* one-third of the most appropriate population abundance estimate).

Based on the analysis contained herein of ION's specified activity, the required monitoring and mitigation measures, and the anticipated take of marine mammals, we find that small numbers of marine mammals will be taken relative to the population sizes of the affected species or stocks.

Western—The total amount of taking authorized for all affected stocks ranges from less than 1 to 20 percent of the most appropriate population abundance estimate, and is therefore less than the appropriate small numbers threshold (*i.e.,* one-third of the most appropriate population abundance estimate). These proportions are considered overestimates with regard to the small numbers findings, as they likely represent multiple exposures of some of the same individuals for some stocks. However, we do not have sufficient information on which to base an estimate of individuals taken versus instances of take.

Based on the analysis contained herein of Western's specified activity, the required monitoring and mitigation measures, and the anticipated take of marine mammals, we find that small numbers of marine mammals will be taken relative to the population sizes of the affected species or stocks.

CGG—The total amount of taking authorized for all affected stocks ranges from less than 1 to 27 percent of the most appropriate population abundance estimate, and is therefore less than the appropriate small numbers threshold (*i.e.,* one-third of the most appropriate population abundance estimate). These proportions are considered overestimates with regard to the small numbers findings, as they likely represent multiple exposures of some of the same individuals for some stocks. However, we do not have sufficient information on which to base an estimate of individuals taken versus instances of take.

Based on the analysis contained herein of CGG's specified activity, the required monitoring and mitigation measures, and the anticipated take of marine mammals, we find that small numbers of marine mammals will be taken relative to the population sizes of the affected species or stocks.

Impact on Availability of Affected Species for Taking for Subsistence Uses

There are no relevant subsistence uses of marine mammals implicated by these actions. Therefore, relevant to the Spectrum, TGS, ION, CGG, and Western IHAs, we have determined that the total taking of affected species or stocks would not have an unmitigable adverse impact on the availability of such species or stocks for taking for subsistence purposes.

Spectrum Survey Plan Modification

As described earlier in this notice, Spectrum's proposed survey plan described in our Notice of Proposed IHAs included ~21,635 km of survey line (see Figure 1 of Spectrum's application). However, on June 4, 2018, Spectrum notified NMFS of a modification to their survey plan. NMFS's understanding is this modification is based on a voluntary collaborative effort between Spectrum and TGS, another IHA applicant, to reduce duplication of effort and expense. Subsequently, on June 26, 2018, Spectrum submitted a final, revised modified survey plan. The modified survey plan occurs roughly within the same survey ''footprint'' and consists of ~13,766 km of survey line (see Figure provided on p. 2 of Spectrum's letter notifying us of their intent to modify their survey plan). Therefore, the modified survey plan represents an approximate 36 percent decrease in total survey line. With this reduction in survey effort, Spectrum now estimates that the survey plan will require approximately 108 days of

operations (previously estimated as 165 days of operations).

The changes to the survey plan, in summary, include the following: (1) Rotated the survey grid by approximately 5 degrees; (2) trimmed lines from most time-area restrictions; (3) removed certain lines; and (4) shifted certain lines. The figure provided on p. 3 of Spectrum's letter notifying us of their intent to modify their survey plan shows an overlay of the modified survey plan (red lines) with the previously proposed survey plan (black lines).

Following receipt of the notification from Spectrum, we evaluated the potential effect of the change through use of a spatial analysis. In summary, we compared marine mammal densities within assumed ensonified areas associated with the original survey tracklines and associated with the modified survey tracklines. This allowed us to produce a ratio of the expected takes by Level B harassment from the modified survey to the original survey and, therefore, to evaluate the degree of change in terms of take. In conducting this evaluation, we used mean marine mammal densities over the 21 modeling areas or zones (extracted from Roberts *et al.* (2016)), as described previously in ''Estimated Take.'' Detailed steps of the evaluation are as follows:

- Obtain trackline lengths for each relevant season and zone for proposed (*i.e.,* the original) and modified Spectrum tracklines;
- Multiply trackline lengths by mean buffer widths for each zone to get area surveyed for both proposed and modified tracklines;
- Multiply these areas surveyed within each zone by each species density to get raw take by zone for proposed and modified tracklines for each species (accounting for implementation of North Atlantic right whale time-area restriction, in effect out to 90 km from shore from November through April);
- Create ratio of the expected take from the modified tracklines to the proposed tracklines; and
- Multiply this ratio by the originally proposed take numbers to obtain revised take numbers.

However, note that we did not follow this process (*i.e.,* developing a ratio for use in ''correcting'' the original take number) for North Atlantic right whales. Instead, we performed an identical analysis as that described previously in ''Description of Exposure Estimates—North Atlantic Right Whale,'' producing a new take estimate for this species (Table 17).

The results of this evaluation in terms of take numbers are shown in Table 17. Our analysis of the potential for auditory injury of mid-frequency cetaceans remains the same and, therefore, the amount of take by Level A harassment for these species is unchanged. For low-frequency cetaceans, the reduction in total survey line reduces the likely potential that take by Level A harassment would occur. The total amount of survey line in the modified survey plan is similar to that proposed by ION and, in fact, Spectrum's estimated auditory injury zone for low-frequency cetaceans is slightly smaller than ION's. Therefore, we adopt the logic presented previously for ION in revising the authorized take by Level A harassment for low-frequency cetaceans (see ''Estimated Take'' for more detail). For high-frequency cetaceans, we revise the take authorized by Level A harassment according to the same procedure described previously in ''Estimated Take.'' For rarely occurring species (*i.e.,* sei whale, Bryde's whale, blue whale, northern bottlenose whale, Fraser's dolphin, melon-headed whale, false killer whale, pygmy killer whale, killer whale, spinner dolphin, and white-sided dolphin), we retain our take authorization of a single exposure of one group of each species or stock, as appropriate (using average group size). Therefore, our original analysis is retained for these species or stocks and we do not address them here.

TABLE 17—TAKE ESTIMATES ASSOCIATED WITH PROPOSED AND MODIFIED TRACKLINES AND PROPORTION OF BEST ABUNDANCE ESTIMATE

Common name	Proposed tracklines			Modified tracklines			Reduction in total authorized take (%)
	Level A	Level B	%	Level A	Level B	%	
North Atlantic right whale	0	6	1	0	2	<1	67
Humpback whale	4	41	2	2	19	1	53
Minke whale	4	419	2	2	252	1	40
Fin whale	4	333	5	2	163	3	51
Sperm whale	0	1,077	11	0	684	7	36
Kogia spp.	5	200	5	3	125	3	38
Beaked whales	0	3,357	13	0	2,291	9	32
Rough-toothed dolphin	0	201	24	0	117	14	42
Common bottlenose dolphin	0	37,562	25	0	14,938	10	60
Clymene dolphin	0	6,459	27	0	4,045	17	37
Atlantic spotted dolphin	0	16,926	16	0	8,466	8	50
Pantropical spotted dolphin	0	1,632	23	0	1,017	14	38
Striped dolphin	0	8,022	5	0	5,144	3	36
Common dolphin	0	11,087	6	0	6,008	3	46
Risso's dolphin	0	755	4	0	414	2	45
Pilot whales	0	2,765	8	0	1,591	5	42
Harbor porpoise	16	611	1	8	355	1	42

Total authorized take for all species shown in Table 17 decreased. The modified survey plan largely remains within the footprint of the proposed survey plan, with the only notable change being the reduction of total survey line and the removal of survey line from certain areas within that footprint, including, importantly, the total removal of lines from within our designated seasonal ''Hatteras and North'' time-area restriction along the shelf break off of Cape Hatteras (Area #4; Figure 4). This area constitutes some of the most important marine mammal

habitat within the specific geographical region.

As previously described in ''Negligible Impact Analyses and Determinations,'' we have determined on the basis of Spectrum's proposed survey plan that the likely effects of the (previously described) specified activity on marine mammals and their habitat due to the total marine mammal take from Spectrum's survey activities would have a negligible impact on all affected marine mammal species or stocks. Based on our evaluation of Spectrum's modified survey plan, we affirm that this conclusion remains valid, and we authorize the revised take numbers shown in Table 17. Similarly, as previously described in ''Small Numbers Analyses,'' we have determined that the take of marine mammals incidental to Spectrum's specified activity would represent small numbers of marine mammals relative to the population sizes of the affected species or stocks. All authorized take numbers for Spectrum have decreased from what we considered in that small numbers analysis and, therefore, we affirm that this conclusion remains valid.

In conclusion, we affirm and restate our findings for Spectrum:

- All previously described mitigation, monitoring, and reporting requirements remain the same. Based on our evaluation of these measures, we have determined that the required mitigation measures provide the means of effecting the least practicable adverse impact on marine mammal species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.
- With regard to the negligible impact analysis, we refer the reader to the analysis presented previously. In addition, our evaluation of the modified survey plan shows (1) total survey line is reduced by approximately one-third; (2) the modified survey plan does not include new areas not originally considered in our assessment of the effects of Spectrum's specified activity; (3) Spectrum has removed lines from portions of the survey area, including important habitat for marine mammals; and (4) authorized take for all taxa has been reduced. Therefore, 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 required monitoring and mitigation measures, we find that the total marine mammal take from Spectrum's survey activities will have a negligible impact on the affected marine mammal species or stocks.
- With regard to the small numbers analysis, we refer the reader to the analysis presented previously. Our evaluation of Spectrum's modified survey plan results in a reduction of authorized take for all taxa. Therefore, based on the analysis contained herein of Spectrum's specified activity, the required monitoring and mitigation measures, and the anticipated take of marine mammals, we find that small numbers of marine mammals will be taken relative to the population sizes of the affected species or stocks.

Endangered Species Act (ESA)

Section 7 of the ESA requires Federal agencies to insure that their actions are not likely to jeopardize the continued existence of endangered or threatened species or adversely modify or destroy their designated critical habitat. Federal agencies must consult with NMFS for actions that may affect species under NMFS's jurisdiction listed as threatened or endangered or critical habitat designated for such species.

At the conclusion of consultation, the consulting agency provides an opinion stating whether the Federal agency's action is likely to jeopardize the continued existence of ESA-listed species or destroy or adversely modify designated critical habitat.

NMFS's issuance of IHAs to the five companies is subject to the requirements of Section 7 of the ESA. Therefore, NMFS's Office of Protected Resources (OPR), Permits and Conservation Division requested initiation of a formal consultation with the NMFS OPR, ESA Interagency Cooperation Division on the proposed issuance of IHAs on June 5, 2017. The formal consultation concluded in November 2018 and a final Biological Opinion (BiOp) was issued. The BiOp found that the Permits and Conservation Division's proposed action of issuing the five IHAs is not likely to jeopardize the continued existence or recovery of blue whales, fin whales, North Atlantic right whales, sei whales, or sperm whales. Furthermore, the BiOp found that the proposed action is also not likely to adversely affect designated critical habitat for North Atlantic right whales.

National Environmental Policy Act

In 2014, the BOEM produced a final Programmatic Environmental Impact Statement (PEIS) to evaluate the direct, indirect, and cumulative impacts of geological and geophysical survey activities on the Mid- and South Atlantic OCS, pursuant to requirements of NEPA. These activities include geophysical surveys in support of hydrocarbon exploration, as were proposed in the MMPA applications before NMFS. The PEIS is available at: *www.boem.gov/Atlantic-G-G-PEIS/.* NOAA, through NMFS, participated in preparation of the PEIS as a cooperating agency due to its legal jurisdiction and special expertise in conservation and management of marine mammals, including its responsibility to authorize incidental take of marine mammals under the MMPA.

NEPA, Council on Environmental Quality (CEQ) regulations, and NOAA's NEPA implementing procedures (NOAA Administrative Order (NAO) 216–6A) encourage the use of programmatic NEPA documents and tiering to streamline decision-making in staged decision-making processes that progress from programmatic analyses to site-specific reviews. NMFS reviewed the Final PEIS and determined that it meets the requirements of the CEQ regulations (40 CFR part 1500–1508) and NAO 216–6A. NMFS further determined, after independent review, that the Final PEIS satisfied NMFS's comments and suggestions in the NEPA process. In our Notice of Proposed IHAs, we stated our intention to adopt BOEM's analysis in order to assess the impacts to the human environment of issuance of the subject IHAs, and that we would review all comments submitted in response to the notice as we completed the NEPA process, including a final decision of whether to adopt BOEM's PEIS and sign a Record of Decision related to issuance of IHAs. Following review of public comments received, we confirmed that it would be appropriate to adopt BOEM's analysis in order to support our assessment of the impacts to the human environment of issuance of the subject IHAs. Therefore, on February 23, 2018, NMFS signed a Record of Decision for the following purposes: (1) To adopt the Final PEIS to support NMFS's analysis associated with issuance of incidental take authorizations pursuant to sections 101(a)(5)(A) or (D) of the MMPA and the regulations governing the taking and importing of marine mammals (50 CFR part 216), and (2) in accordance with 40 CFR 1505.2, to announce and explain the basis for our decision to review and potentially issue incidental take authorizations under the MMPA on a case-by-case basis, if appropriate.

Following review of public comment, we also determined that conducting additional NEPA review and preparing a tiered Environmental Assessment (EA) is appropriate to analyze environmental impacts associated with NMFS's issuance of separate IHAs to five different applicants. Through the description and analysis of NMFS's

activity provided in the EA as well as the analyses incorporated by reference from the Notice of Proposed IHAs and BOEM's PEIS, NMFS found that authorizing take of marine mammals by issuing individual IHAs to the five applicants will not result in significant direct, indirect, or cumulative impacts to the human environment. Accordingly, NMFS determined that issuance of IHAs to the five applicants would not significantly impact the quality of the human environment and signed a Finding of No Significant Impact (FONSI). NMFS's ROD, EA, and FONSI are available online at: *www.fisheries.noaa.gov/action/incidental-take-authorization-oil-and-gas-industry-geophysical-survey-activity-atlantic.*

Authorizations

As a result of these determinations, NMFS has issued five separate IHAs to the aforementioned applicant companies for conducting the described geophysical survey activities in the Atlantic Ocean within the specific geographic region, incorporating the previously mentioned mitigation, monitoring, and reporting requirements.

Dated: November 30, 2018.

Donna S. Wieting,

Director, Office of Protected Resources, National Marine Fisheries Service.

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