DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XC969

Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing—Underwater Acoustic Thresholds for Onset of **Permanent and Temporary Threshold Shifts**

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

ACTION: Notice.

SUMMARY: The National Marine Fisheries Service (NMFS) announces the availability of its final Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing—Underwater Acoustic Thresholds for Onset of Permanent and Temporary Threshold Shifts (Technical Guidance or Guidance) that provides updated received levels, or acoustic thresholds, above which individual marine mammals under NMFS' jurisdiction are predicted to experience changes in their hearing sensitivity (either temporary or permanent) for all underwater anthropogenic sound sources.

ADDRESSES: The Technical Guidance is available in electronic form via the Internet at http://www.nmfs.noaa.gov/ pr/acoustics/.

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SUPPLEMENTARY INFORMATION: The National Marine Fisheries Service in consultation with the National Ocean Service has developed Technical Guidance to help assess the effects of underwater anthropogenic sound on marine mammal species under NMFS' jurisdiction. Specifically, the Guidance identifies the received levels, or acoustic thresholds, above which individual marine mammals are predicted to experience changes in their hearing sensitivity (either temporary or permanent) for all underwater anthropogenic sound sources. NMFS compiled, interpreted, and synthesized scientific literature to produce updated acoustic thresholds for the onset of both temporary (TTS) and permanent threshold shifts (PTS). This is the first time NMFS has presented this information in a single, comprehensive document. This Technical Guidance is intended for use by NMFS analysts and

managers and other relevant user groups and stakeholders, including other federal agencies, when seeking to determine whether and how their activities are expected to result in hearing impacts to marine mammals via acoustic exposure.

The main body of the document contains NMFS' updated acoustic thresholds for onset of PTS for marine mammals exposed to underwater sound and NMFS' plan for periodically updating acoustic thresholds. Other information such as details on the development marine mammal auditory weighting functions and acoustic thresholds, research recommendations, alternative methodology (formerly referred to as a User Guide), the peer review and public comment process, and a glossary of acoustic terms can be found in the Technical Guidance appendices.

These thresholds update those currently in use by NMFS. Updates include a protocol for deriving PTS and TTS onset levels for impulsive (e.g., airguns, impact pile drivers) and nonimpulsive (e.g., tactical sonar, vibratory pile drivers) sound sources and the formation of marine mammal hearing groups (low- (LF), mid- (MF), and highfrequency (HF) cetaceans and otariid (OW) and phocid (PW) pinnipeds in water) and associated auditory weighting functions. Acoustic thresholds are presented using the dual metrics of cumulative sound exposure level (SEL_{cum}) and peak sound pressure level (PK) for impulsive sounds and the SEL_{cum} metric for non-impulsive sounds. While the updated acoustic thresholds are more complex than what has been in use by NMFS and regulated entities, they more accurately reflect the current state of scientific knowledge regarding the characteristics of sound that have the potential to impact marine mammal hearing sensitivity. Given the specific nature of these updates, it is not possible to generally or directly compare the updated acoustic thresholds presented in this document with the thresholds they will replace because outcomes will depend on

project-specific specifications.
Although NMFS has updated the acoustic thresholds, and these changes may necessitate new methodologies for calculating impacts, the application of the thresholds in the regulatory context of applicable statutes (Marine Mammal Protection Act (MMPA), Endangered Species Act (ESA), and National Marine Sanctuaries Act (NMSA)) remains consistent with current NOAA practice (see Regulatory Context in this Federal Register Notice). It is important to emphasize that these updated acoustic

thresholds do not represent the entirety of an impact assessment, but rather serve as one tool (in addition to behavioral impact thresholds, auditory masking assessments, evaluations to help understand the ultimate effects of any particular type of impact on an individual's fitness, population assessments, etc.), to help evaluate the effects of a proposed action.

NMFS recognizes that action proponents may have varying abilities to model and estimate exposure and that the Technical Guidance may be more complex than some action proponents are able to incorporate. Thus, NMFS has provided alternative methodology and an associated User Spreadsheet to aid action proponents with SEL_{cum} thresholds and marine mammal auditory weighting functions (http:// www.nmfs.noaa.gov/pr/acoustics/).

The Technical Guidance is classified as a Highly Influential Scientific Assessment (HISA) by the Office of Management and Budget. As such, three independent peer reviews were undertaken, at three different stages of the development of the Technical Guidance, including a follow-up to one of the peer reviews, prior to broad public dissemination by the Federal Government. Details of each peer review can be found within the Technical Guidance (Appendix C) and at the following Web site: http:// www.nmfs.noaa.gov/pr/acoustics/. NMFS acknowledges and thanks the Marine Mammal Commission (Commission) and the Acoustical Society of America's Underwater Technical Council for nominating peer reviewers and thanks the peer reviewers for their time and expertise in reviewing this document.

In additional to three independent peer reviews, the Technical Guidance was the subject of three public comment periods. NMFS evaluated all substantive comments made during each public comment period to determine their relevance to the Technical Guidance as it was revised. Public comments made on aspects of the Technical Guidance that are no longer relevant have not been included here. Substantive and relevant comments and NMFS' responses are included below (see Comments and Responses).

The Technical Guidance does not create or confer any rights for or on any person, or operate to bind the public. An alternative approach that has undergone independent peer review may be proposed (by federal agencies or prospective action proponents) and used if case-specific information/data indicate that the alternative approach is likely to produce a more accurate

portrayal of take for the project being evaluated, if NOAA determines the approach satisfies the requirements of the applicable statutes and regulations.

Transitioning to the Technical Guidance

NMFS considers the updated thresholds and associated weighting functions in the Technical Guidance to be the best available information for assessing whether exposure to specific activities is likely to result in changes in marine mammal hearing sensitivity (temporary or permanent). Prospective applicants for incidental take authorizations under the MMPA and federal agencies seeking ESA section 7 consultations that have not yet started their acoustic analyses should begin using the new Technical Guidance immediately. At the same time, we recognize that for some proposed actions, analyses may have already substantially progressed using the existing thresholds or other methods for assessing hearing effects, and it may be impractical to begin those analyses anew, taking into account timing constraints, expense, and other considerations. In such "pipeline" cases, the applicant or action agency should contact NMFS as soon as possible to discuss how to best include consideration of the Technical Guidance to satisfy the applicable requirements. A non-exhaustive list of factors that could affect the extent to which the Technical Guidance will be considered for an action include: The relative degree to which the Technical Guidance is expected to affect the results of the acoustic impact analyses; how far in the process the application or prospective application has progressed; when the activity is scheduled to begin or other timing constraints; the complexity of the analyses and the cost and practicality of redoing them; and the temporal and spatial scope of anticipated effects. We anticipate that after the initial transition period, all applications for MMPA incidental take authorization (ITA) and all requests for ESA section 7 consultations involving noise that may affect marine mammals will include full consideration of the Technical Guidance.

National Environmental Policy Act (NEPA)

In 2005, NMFS published a **Federal Register** Notice of Public Scoping and Intent to Prepare an EIS for a similar action (70 FR 1871, January 11, 2005). The nature of the Guidance has evolved significantly since then. After evaluating the contents of the Technical Guidance and the standards for a categorical

exclusion under NAO 216–6, sec. 6.03c.3(i), we have determined the Technical Guidance is categorically excluded from further NEPA review.

NAO 216–6, sec. 6.03c.3(i), provides that a categorical exclusion is appropriate for "policy directives, regulations, and guidelines of an administrative, technical, or procedural nature, or the environmental effects of which are too broad, speculative or conjectural to lend themselves to meaningful analysis and will be subject later to the NEPA process, either collectively or case by case."

Although changes to the PTS and TTS thresholds will likely change the take estimates for at least some portion of activities, any environmental effects of the draft guidance alone, without reference to a specific activity, are too speculative or conjectural to lend themselves to meaningful analysis at this stage. Effects analyses under the MMPA, ESA, and NMSA (and appropriate mitigation and monitoring) are activity-specific exercises that cannot be conducted absent some level of specificity regarding the nature of the proposed activity, the general location, and the time and duration. Moreover, direct comparisons cannot be made between the thresholds currently used and the updated thresholds, due to the different metrics and taxa-specific frequency weighting used in the new thresholds.

Any environmental effects from application of the updated PTS and TTS thresholds will flow from future actions that are the subject of ITAs under the MMPA and related consultations under the ESA or NMSA. The nature and magnitude of such effects will depend on the specific actions themselves, each of which would be subject to the NEPA process.

Because any effects from the Technical Guidance are speculative and conjectural, NOAA has determined it cannot meaningfully analyze potential effects in the manner contemplated by NEPA, which is to inform agency decisions about the effects of an action (and reasonable alternatives) on the environment. Any changes in future effects analyses resulting from the Guidance will be part of the NEPA and other statutorily-required analyses conducted for specific actions in the future.

Finally, the proposed action does not trigger any of the exceptions for categorical exclusions described in section 5.05c of NAO 216–6. It does not involve a geographic area with unique characteristics, is not a subject of public controversy due to potential environmental consequences, have

uncertain environmental impacts or unique or unknown risks, establish a precedent or decision in principle about future proposals, result in cumulatively significant impacts, or have any adverse effects upon endangered or threatened species or their habitats.

Regulatory Context

NMFS uses acoustic thresholds to help quantify "take" and as part of more comprehensive effects analyses under several statutes. The Technical Guidance's updated acoustic thresholds do not represent the entirety of the comprehensive effects analysis, but rather serve as one tool among others (e.g., behavioral impact thresholds, auditory masking assessments, evaluations to help understand the ultimate effects of any particular type of impact on an individual's fitness, population assessments, etc.) to help evaluate the effects of a proposed action and make findings required by NOAA's various statutes.

Under current agency practice, NMFS considers the onset of PTS, which is an auditory injury, as an example of "Level A Harassment" as defined in the MMPA and as "harm" as defined in ESA regulations, such that exposing an animal to weighted received sound levels at or above the indicated PTS threshold is predicted to result in these two types of "take" (i.e., Level A Harassment under the MMPA and harm under ESA).

As explained below, NMFS does not consider a TTS to be an auditory injury under the MMPA or ESA, and thus it does not qualify as Level A harassment or harm. Nevertheless, TTS is an adverse effect that historically has been treated as "take" by "Level B Harassment" under the MMPA and "harassment" under the ESA. The broad definition of "injury" under the NMSA regulations includes both PTS and TTS (as well as other adverse changes in physical or behavioral characteristics that are not addressed in the Technical Guidance).

Marine Mammal Protection Act

The MMPA prohibits the take of marine mammals, with certain exceptions, one of which is the issuance of ITAs. Sections 101(a)(5)(A) & (D) of the MMPA (16 U.S.C. 1361 et seq.) direct the Secretary of Commerce to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made. Through delegation by the Secretary of Commerce, NMFS is

required to authorize the incidental taking of marine mammals if it finds that the total taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for certain subsistence uses. NMFS must also set forth the permissible methods of taking and requirements pertaining to the mitigation, monitoring, and reporting of such takings. (The "small numbers" and "specified geographical region" provisions do not apply to military readiness activities.)

The term "take" means to harass, hunt, capture, or kill, or attempt to harass, hunt, capture or kill any marine mammal. 16 U.S.C. 1362(13).

Except with respect to certain activities described below, "harassment" means any act of pursuit, torment, or annoyance which:

- Has the potential to injure a marine mammal or marine mammal stock in the wild (Level A Harassment), or
- 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).

See id. at 1362(18)(A)(i) & (ii) (emphasis added).

Congress amended the definition of "harassment" as it applies to a "military readiness activity" or research conducted by or on behalf of the federal government consistent with MMPA section 104(c)(3) as follows (section 3(18)(B) of the MMPA):

- Any act that injures or has the significant potential to injure a marine mammal or marine mammal stock in the wild (Level A Harassment); or
- Any act that disturbs or is likely to disturb a marine mammal or marine mammal stock in the wild by causing disruption of natural behavioral patterns, including, but not limited to, migration, surfacing, nursing, breeding, feeding, or sheltering, to a point where such behavioral patterns are abandoned or significantly altered (Level B Harassment).

See id. at 1362(18)(B)(i) & (ii) (emphasis added).

The term "negligible impact" is defined 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.

In support of the analysis that is necessary to make the required statutory determinations, MMPA implementing regulations require ITA action proponents to provide NMFS with specific information. Although they may also be used to inform the development of mitigation measures, the updated acoustic thresholds are particularly relevant to the following two of the fourteen required pieces of information:

- The *type* of incidental taking authorization that is being requested (*i.e.*, takes by Level B Harassment only; *Level A Harassment*; or serious injury/mortality) and the method of incidental taking;
- By age, sex, and reproductive condition (if possible), the *number* of marine mammals (by species) that may be taken *by each type* of taking identified in paragraph (a)(5) of this section, and the number of times such takings by each type of taking are likely to

50 CFR 216.104 (emphasis added).

Endangered Species Act

Section 9 of the ESA prohibits the take of ESA-listed species, with limited exceptions. Section 7 of the ESA requires that each federal agency, in consultation with NMFS and/or the U.S. Fish and Wildlife Service (USFWS), ensure that any action authorized, funded, or carried out by the agency is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. See 16 U.S.C. 1536(a)(2). Provided that NMFS or the USFWS reaches these conclusions through a "formal consultation" process, incidental take of ESA-listed species may be exempted from the section 9 take prohibition through an "incidental take statement" that must specify the impact, i.e., the amount or extent, of the taking on the species. See id. at section 1536(b)(4). Incidental take statements must also include reasonable and prudent measures necessary or appropriate to minimize the impact, and the terms and conditions required to implement those measures.

Under ESA, "take" means to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct. See id.at section 1532(19). "Harm" is defined in NMFS regulations as "an act which actually kills or injures fish or wildlife" (and can include significant habitat modification or degradation). See 50 CFR 222.102.

Under NMFS and the USFWS implementing regulations for section 7 of the ESA, "jeopardize the continued existence of" means to engage in an action that reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or

distribution of that species. *See id.*at § 402.02.

In support of the analysis necessary to conduct the consultation, the ESA implementing regulations state that in order to initiate formal consultation, the federal action agency must submit a written request for formal consultation to the Director (of NMFS or the USFWS) that includes, among other things, a description of the manner in which the action may affect any listed species. *See id.*at § 402.14(c).

National Marine Sanctuaries Act

Section 304(d) of the NMSA requires federal agencies whose actions are likely to destroy, cause the loss of, or injure a sanctuary resource to consult with the Office of National Marine Sanctuaries (ONMS) before taking the action. See 16 U.S.C. 1434(d)(1). The NMSA defines sanctuary resource as "any living or nonliving resource of a national marine sanctuary that contributes to the conservation, recreational, ecological, historical, educational, cultural, archeological, scientific, or aesthetic value of the sanctuary."16 U.S.C. 1432(8). Through the sanctuary consultation process, ONMS may recommend reasonable and prudent alternatives that will protect sanctuary resources. Recommended alternatives may include alternative locations, timing, and/or methods for conducting the proposed action. See id.at § 1434(d)(2). Monitoring may also be recommended to better characterize impacts to sanctuary resources or accompany mitigation.

The term "injure" is defined in the ONMS implementing regulations as to "change adversely, either in the short or long term, a chemical, biological or physical attribute of, or the viability of." 15 CFR 922.3.

In support of the analysis necessary to conduct the consultation, the NMSA requires that any federal agency proposing an action that may injure a sanctuary resource provide ONMS with a written statement ("sanctuary resource statement") describing the action and its potential effects on sanctuary resources. See 16 U.S.C. 1434(d)(1)(B).

Application of Acoustic Thresholds for Permanent Threshold Shift

The acoustic thresholds for PTS will be used in conjunction with sound source characteristics, environmental factors that influence sound propagation, anticipated marine mammal occurrence and behavior in the vicinity of the activity, as well as other available activity-specific factors, to quantitatively estimate (acknowledging the gaps in scientific knowledge and the

inherent uncertainties in a marine environment) the takes of marine mammals (by Level A harassment and harm under the MMPA and ESA, respectively) and facilitate compliance with the MMPA, ESA, and NMSA as described above.

NMFS will use the same PTS acoustic thresholds in the identification and quantification of MMPA Level A harassment for both military readiness and non-military readiness activities. Because the acoustic thresholds for PTS predict the onset of PTS, they are inclusive of the "potential" and "significant potential" language in the two definitions of Level A harassment. The limited data now available do not support the parsing out of a meaningful quantitative difference between the 'potential" and "significant potential" for injury and, therefore, the designated PTS acoustic thresholds will be treated as Level A harassment for both types of activities.

Estimating the numbers of take by Level A harassment and harm is one component of the fuller analyses that inform NMFS' "negligible impact" and "jeopardy" determinations under the MMPA and ESA, respectively, as well as "likely to injure" or "may affect" determinations under the NMSA. Last, the PTS acoustic thresholds may be used to inform the development of mitigation and monitoring measures (such as shut-down zones) pursuant to the MMPA, ESA, or NMSA.

When initiating any of the MMPA, ESA, or NMSA processes described above, agencies and other action proponents should utilize the PTS acoustic thresholds, in combination with activity-specific information, to predict whether, and if so how many, instances of PTS are expected to occur.

Application of Acoustic Thresholds for Temporary Threshold Shift

As previously stated, NMFS has not considered TTS an auditory injury for purposes of the MMPA and ESA, based on the work of a number of investigators that have measured TTS before and after exposure to intense sound. For example, Ward (1997) suggested that a TTS is within the normal bounds of physiological variability and tolerance and does not represent physical injury. In addition, Southall et al. (2007) indicates that although PTS is a tissue injury, TTS is not because the reduced hearing sensitivity following exposure to intense sound results primarily from fatigue, not loss, of cochlear hair cells and supporting structures, and is reversible. Accordingly, TTS has been considered take by Level B harassment under the MMPA and harassment under

the ESA, which will be the subject of future guidance. However, TTS is considered injury under the broad definition of the term "injury" in NMSA regulations (along with PTS and behavioral impacts). For now, NMFS will continue the practice of requiring applicants to estimate take by TTS for explosive sources.

MMPA Level B harassment and ESA harassment are broad categories that encompass not only TTS but also other behaviorally related impacts that almost always involve a lower onset threshold than that for onset of TTS. In quantifying take by Level B harassment or harassment, NMFS considers all effects that fall into those categories of take, not just TTS. NMFS will be developing updated acoustic thresholds for the onset of behavioral effects and will further consider the best approach for considering TTS at that time. When that process is completed, NMFS will provide further guidance regarding how to best consider and/or quantify TTS for non-pulse and impulse sources not involving instantaneous explosives (see exception below for underwater explosives). In the meantime, action proponents not using instantaneous explosives do not need to quantify estimates of TTS separately from their overall behavioral harassment take calculations. For now, the TTS acoustic thresholds presented in the Technical Guidance will be considered as part of the larger comprehensive effects analyses under the MMPA and the ESA.

With respect to instantaneous explosives (as distinguished from repeated explosives such as gunnery exercises), NMFS already requires quantification of TTS estimates because an instantaneous explosive will not have a separate behavioral component from a lower exposure threshold and there is no time accumulation involved. The rationale for calculating TTS for instantaneous explosives continues to apply with the updated TTS thresholds for explosives.

NMFS is aware of studies by Kujawa and Liberman (2009) and Lin et al. (2011), which found that despite completely reversible TS that leave cochlear sensory cells intact, large (but temporary) TS could cause synaptic level changes and delayed cochlear nerve degeneration in mice and guinea pigs. However, the large TS (i.e., maximum 40 decibel dB) that led to the synaptic changes shown in these studies are in the range of the large shifts used by Southall et al. (2007) and in the Technical Guidance to define PTS onset (i.e., 40 dB). It is unknown whether smaller levels of TTS would lead to similar changes or 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.

The occurrence of, and estimated number of, TTS takes is one component of the larger analysis that informs NMFS's "negligible impact" and "jeopardy" determinations under the MMPA and ESA, respectively, as well as "likely to injure" or "may affect" determinations under the NMSA. As with PTS, TTS acoustic thresholds also may be used to inform the development of mitigation and monitoring measures pursuant to the MMPA, ESA, or NMSA.

Comments and Responses

On December 27, 2013, NMFS published the initial Draft Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammals: Acoustic Thresholds for Onset of Permanent and Temporary Threshold Shifts for a 30day public comment period (78 FR 78822), which was extended an additional 45-days (79 FR 4672; January 29, 2014) based on public request. During the public comment period, NMFS received comments from U.S. Representatives from Congress, Federal agencies, an international government agency, state governments, Alaskan native groups, industry groups, and non-governmental organizations, individual subject matter experts, a professional society, a regulatory watchdog group, and 89 private citizens.

After the close of the initial public comment period, as NMFS was addressing public comments and working towards finalizing the Guidance, a new methodology for identifying marine mammal auditory weighting functions and acoustic thresholds was developed by the U.S. Navy (Dr. James Finneran, SPAWAR Systems Center Pacific) based on new science. Additionally, NMFS reevaluated its methods for defining threshold usage for sources characterized as impulsive or nonimpulsive based on comments received during the initial public comment period. Incorporating these updated methodologies resulted in substantial changes to the Guidance, necessitating additional peer review, as well as another public comment period. As a result, NMFS solicited public comment on a revised Draft Guidance (July 2015) via a second 45-day public comment period (80 FR 45642, July 31, 2015). During the second public comment period, NMFS received 20 comments from Federal agencies, industry groups, environmental consultants, Alaskan native groups, non-governmental

organizations, individual subject matter experts, a professional society, a regulatory watchdog group, and two private citizens.

While NMFS was working to address public comments from the second public comment period and finalize the Guidance, NMFS and the Navy (Dr. James Finneran, SPAWAR Systems Center Pacific) further evaluated certain aspects of the U.S. Navy's methodology. As a result of the Navy's and NMFS' review, several focused recommendations/modifications were suggested, which did not change the overall methodology provided in the July 2015 Draft Guidance (the primary changes were related to deriving a composite audiogram for LF cetaceans). After consideration of these recommendations, NMFS updated sections of the July 2015 Draft Guidance to reflect the suggested changes and solicited public comment on those focused revisions via a focused 14-day public comment period (81 FR 14095, March 16, 2016). During this third public comment period, NMFS received 20 comments from Federal agencies, industry groups, non-governmental organizations, individual subject matter experts, a professional society, and a private citizen. Please refer to these Federal Register Notices for additional background about the 2013 and 2015 Draft Guidance, as well as the document containing proposed changes to the Draft Guidance during the public comment period in 2016.

During these three public comment periods several commenters' remarks pertained to topics beyond the scope of the final Technical Guidance (e.g., impacts beyond hearing: Non-auditory injury, mortality, gas emboli, stranding events, masking, stress, cumulative effects, ecosystem-wide effects, behavioral disturbance; activity-specific issues associated with specific permit/ authorization; effects of airborne noise on pinniped hearing; effects of noise on fishes and sea turtles; propagation modeling; animal distribution/density; data or modeling requirements; take estimation methodology). NMFS did not address comments outside the scope of this document. Additionally, in reevaluating substantive public comments made during the first (2013/2014), second (2015), and third (2016) public comment periods, those earlier comments pertaining to sections of the document no longer included in the final Technical Guidance are not addressed (e.g., proposed 1-hour accumulation period, transition range methodology, alternative thresholds).

Technical Guidance Scope

Comment 1: Several commenters were concerned about the potential impacts of sound on polar bear, sea otter, and walrus and asked if NMFS coordinated with the USFWS or other branches of NMFS when evaluating and establishing thresholds in the Guidance.

Response: The Technical Guidance only addresses the effects of underwater anthropogenic sound on marine mammal species under NMFS jurisdiction. The Technical Guidance does not pertain to marine mammal species under the USFWS's jurisdiction (e.g., walrus, polar bears, manatees, sea otters). The USFWS is aware of this document and was provided an opportunity to comment. NMFS Headquarters, Regions, and Science Centers coordinated in the development this Guidance, as did the National Ocean Service.

Comment 2: Multiple commenters, citing the technical complexity of the Draft Guidance, requested an extension during all three public comment periods. Additionally, multiple commenters expressed concern that the public comment period associated with the March 2016 Proposed Changes document was rushed, resulted in arbitrary decisions, and did not allow for meaningful input from those action proponents most impacted by changes (i.e., activities producing low-frequency sound). These commenters advocated that instead of NMFS adopting the changes in the March 2016 document, the July 2015 Draft Guidance instead be finalized.

Response: NMFS extended the initial 30-day public comment period on the 2013 Draft Guidance by an additional 45 days (79 FR 4672, January 29, 2014). In consideration of an appropriate duration for the 2015 Draft Guidance public comment period (80 FR 45642, July 31, 2015), NMFS chose a 45-day (opposed to 30 days) public comment period, based on the extent of changes from the Draft 2013 Guidance, but did not extend that public comment period. Regarding the third public comment period, due to the focused nature of the most recent proposed revision, presented in a standalone 24-page document, and significant previous opportunities for public comment, NMFS deemed a 14day public comment period appropriate (81 FR, 14095, March 16, 2016) and did not extend public comment period in response to requests. Based on input received during the robust review process (i.e., three public comment periods and three peer reviews, as well as follow-up peer review), NMFS does not believe additional or extended

public comment periods were necessary to finalize the Technical Guidance.

NMFS disagrees that the March 2016 public comment period was rushed or resulted in arbitrary decisions. The March 2016 public comment period was the third opportunity given to the public to review our Draft Guidance (following the 75-day first public comment period and 45-day second public comment period). Previous versions of the Draft Guidance had already been revised based upon peer review and public input. Due to the focused nature of the proposed changes since the prior draft (which were described in a 24-page standalone document) and balanced against the lengthy process to date and need for updated thresholds, NMFS determined a 14-day public comment period was appropriate.

Comment 3: A few commenters indicated that the 2015 Draft Guidance and the 2016 Proposed Changes document was incomplete and the Guidance should not be finalized until the public has an opportunity to comment on the following missing sections: Agency response to comments made during the initial and second public comment periods; optional User Spreadsheet for determining isopleths; and references associated with sirenian data used in the March 2016 Proposed

Changes document.

Response: NMFS disagrees that the 2015 Draft Guidance and 2016 Proposed Changes document were incomplete for public comment. In finalizing the Technical Guidance (via this Federal Register Notice), NMFS has addressed to substantive comments provided during all three public comment periods, except those no longer relevant due to subsequent changes to the Draft Guidance. Both the 2015 Draft Guidance and the 2016 Proposed Changes document encompassed modifications based on comments received during the first and second public comment periods.

NMFS disagrees that the User Spreadsheet associated with the Technical Guidance's alternative methodology requires public comment. This spreadsheet precisely follows the alternative methodology provided in the Technical Guidance (Appendix D), which was available for public comment. There is nothing additional or new provided by this spreadsheet.

As for the sirenian data used in the March 2016 Proposed Changes document, in response to this comment, these references (Gerstein et al., 1999; Mann et al., 2009) have been included in the finalized Technical Guidance. However, NMFS does not believe additional public review is necessary.

Comment 4: A few commenters requested clarification as to how the Technical Guidance will be used in management decisions (i.e., is the Technical Guidance's use a requirement? Is the Technical Guidance a rule?).

Response: The Technical Guidance provides a robust assessment and synthesis of a body of scientifically complex information to assess impacts of sound on marine mammal hearing. Although its use is not a binding requirement, it currently reflects the agency's expert assessment of the scientific literature and represents what the agency believes is the best approach for assessing auditory impacts. The Guidance allows for an alternative approach if case-specific information/ data indicate that such an approach is likely, in NMFS' view following peer review, to produce an equally or a more accurate estimate of auditory impacts.

Comment 5: Multiple commenters requested NMFS include a brief statement in the Guidance about what standards are currently in use and why they need to be updated. Additionally, the Commission requested that the Guidance include updated explosive thresholds for mortality (extensive lung injury) and injury (slight lung and gastrointestinal (G.I.) tract).

Response: A new section has been added to the Technical Guidance (see Section 1.1 of Main Document) to explain the justification for the updated acoustic thresholds for PTS and TTS. The Technical Guidance explicitly indicates that the thresholds within the document are meant to update all thresholds currently in use by NMFS for assessing PTS onset, including generic injury thresholds (i.e., root mean square sound pressure level (RMS SPL) thresholds of 180/190 dB), and PTS/TTS thresholds for explosives.

NMFS acknowledges that future Technical Guidance is needed for non-auditory impacts, but is planning on addressing this in a separate guidance document and recommends current non-auditory thresholds for explosives remain in use until updates can be completed via the appropriate processes.

Comment 6: Multiple commenters requested clarification on the applicability the National Environmental Policy Act (NEPA) to the Guidance.

Response: NMFS determined that the Technical Guidance satisfies the standards for a categorical exclusion under NAO 216–6. NAO 216–6, sec. 6.03c.3(i), which provides that a categorical exclusion is appropriate for "policy directives, regulations, and

guidelines of an administrative, technical, or procedural nature, or the environmental effects of which are too broad, speculative or conjectural to lend themselves to meaningful analysis and will be subject later to the NEPA process, either collectively or case by case." See the section addressing NEPA earlier in this Notice.

Comment 7: The Center for Regulatory Effectiveness (CRE) indicated that any use of the Guidance by NMFS in rules would have to be supported by costbenefit analyses because it "could have a potential impact of more than \$500 million in any one year on either the public or private sector; or . . . the dissemination is novel, controversial, or precedent-setting; or . . . [it has] significant interagency interest."

Response: The Technical Guidance is not a regulatory action subject to a costbenefit analysis under Executive Orders 12866 and 13563. The Technical Guidance was classified as a HISA because it was novel and precedent setting, not due to the potential financial implications. The Technical Guidance will inform assessments of activities that occur in a regulatory context as they arise. The Technical Guidance does not address or change NMFS' application of the thresholds in the regulatory context, under applicable statutes. Any required cost-benefit considerations will take place during future actions that are the subject of regulatory action, such as ITAs under the MMPA. The nature and magnitude of such effects will depend on the specific actions themselves. Because any direct effects from the Technical Guidance are speculative and conjectural, NMFS cannot meaningfully analyze potential effects by a costbenefit analysis.

Comment 8: The CRE states that NMFS needs to prepare and obtain Office of Management and Budget (OMB) approval of a new Paperwork Reduction Act (PRA) Information Collection Request (ICR) in compliance with Information Quality Act (IQA) Guidelines before they can use the Technical Guidance for any sound source.

Response: There is no collection of information requirement associated with the Technical Guidance. However, NMFS' information collection for Applications and Reporting Requirements for Incidental Taking of Marine Mammals by Specified Activities Under the Marine Mammal Protection Act, OMB approval number 0648–0151, could be affected by applicants using the Technical Guidance, possibly in added response time to prepare applications using the

Guidance. The current approval expires in March 2017 and will require renewal before then with an opportunity for public comment. In preparation for that renewal, NMFS will consider the effect of the Technical Guidance, specifically whether a revision in the burden hour estimates is appropriate, and invite public comment on its assessment. NMFS has complied with the IQA Guidelines with the development of the Guidance.

Comment 9: A commenter requested that NMFS provide more information how the Guidance's updated thresholds would be applied in conjunction with thresholds used to assess MMPA Level B behavioral harassment.

Response: The Technical Guidance does not provide updated acoustic thresholds for levels that could result in behavioral effects. NMFS' current acoustic thresholds for these impacts are not affected by the Technical Guidance. NMFS recognizes the Technical Guidance provides updated metrics that are different than those used for estimating behavioral harassment. Accordingly, where calculations or modeling suggest that some animals will be exposed to sound levels that are at or above the relevant PTS threshold under the Technical Guidance but behavioral harassment under the current behavioral harassment thresholds, an individual should be counted "taken" one time, by the more severe impact (i.e., PTS onset). However, the qualitative and contextual analysis of the likely impacts on that animal, at these exposure levels, will consider both the impacts of the likely PTS as well as anticipated behavioral responses.

Comment 10: During the third public comment period, the Commission recommended that NMFS review and revise this document every two years via a small expert panel, as opposed to the proposed three to five year schedule. Revising the Guidance on a two-year basis was also supported by other commenters. Additionally, the Commission recommended that rather than developing independent guidance, NMFS instead incorporate by reference technical reports and peer-reviewed literature already summarizing the best available science.

Response: NMFS will continue to monitor and evaluate new data as they become available and will periodically convene staff from our various offices, regions, and science centers, and to update the Guidance as appropriate (anticipating updates to occur on a three to five year cycle). NMFS believes this timeline is appropriate and does not need to be modified.

NMFS disagrees with the Commission's recommendation to incorporate by reference other reports or peer-reviewed literature and believes the process of developing Technical Guidance requires a more thorough evaluation of the science in the context of NOAA statutory requirements. Public comment would also be needed.

Comment 11: Several commenters expressed uncertainty and requested clarification as to how the Guidance would apply to mitigation and monitoring requirements (e.g., exclusion zones), often prescribed by the conditions of an MMPA permit or authorization.

Response: 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. NMFS acknowledges that in practice, exclusion zones and monitoring zones have often corresponded to acoustic impact thresholds, but that is not a legal requirement, and the updated thresholds may make such a simple correlation more challenging, given their greater complexity. The Technical Guidance will be used with other relevant information to inform impact assessments, and that in turn will be considered in the development of mitigation and monitoring.

Peer Review Process

Comment 12: One commenter expressed concerned about the peer review process and choice of peer reviewers, particularly in regards to potential financial ties to NMFS.

Response: NMFS adhered to appropriate procedures in the selection of the peer reviewers to prevent any real or perceived conflicts of interest. The Commission, specifically their Commissioners and members of their Committee of Scientific Advisors, nominated the peer reviewers for each of the three peer reviews. Additionally, the Acoustical Society of America's Underwater Technical Council nominated some of the peer reviewers in association with the third peer review. Each peer reviewer, for all three reviews, submitted a conflict of interest form. None of the Technical Guidance's reviewers indicated having a conflict of interest, defined as "any financial or other interest which conflicts with the service of the individual because it (1) could significantly impair the individual's objectivity, or (2) could

create an unfair competitive advantage for any person or organization."

Comment 13: Several commenters expressed concern that the March 2016 Proposed Changes document did not undergo peer review and believed peer review would result in significant changes to the Guidance necessitating the need for a fourth public comment period. If NMFS does not conduct a fourth public comment period, the commenters advocated that NMFS retract its March 2016 Proposed Changes document and proceed with issuing the July 2015 Draft Guidance (modified based on public comments from the first and second public comment period) as its finalized Guidance.

Response: The comments are incorrect. NMFS conducted a follow-up peer review concurrent with the third public comment period. NMFS disagrees with the recommendation to retract the March 2016 Proposed Changes document and that a fourth public comment period is needed based on comments made by the peer reviewers during this follow-up review. The follow-up peer review report is publicly available via: http:// www.cio.noaa.gov/services programs/ prplans/ID43.html and was available before the Guidance was finalized (May 2016).

Comment 14: One commenter indicated that Guidance should not be used until NMFS addresses all the peer reviewers' comments from its three peer reviews, and that failing to doing so would cause the finalized Guidance to be IQA non-compliant.

Response: NMFS adhered to IQA procedures and NOAA's IQG, making the finalized Technical Guidance IOA compliant. NMFS received valuable input from the peer reviewers and made changes to the Technical Guidance based on their comments during all three peer reviews, as well as during the follow-up review. The peer reviewers' comments greatly improved the Technical Guidance before it was available for public comment during the initial and second public comment periods. The manner in which NMFS addressed the peer reviewers' comments, from all three peer reviews, as well as the follow-up review, appear within our Peer Review Reports: http:// www.cio.noaa.gov/services programs/ prplans/ID43.html.

Comment 15: A commenter considered NMFS' treatment and peer review of the Finneran Technical Report, associated with the July 2015 Draft Guidance (Appendix A), as inconsistent, asserting the Finneran Technical Report should have been

treated similarly to other publications that did not undergo formal peer review associated with publication in a scientific journal. The commenter questioned why the methodology from the Finneran and Jenkins (2012) technical report was not subjected to an independent peer review by NMFS but was used in its 2013 Draft Guidance.

Response: NMFS disagrees that there was an inconsistency in its treatment of Finneran Technical Report (the methodology used for Navy's "Phase 3" environmental compliance analyses in any of the versions of our Technical Guidance. NMFS considered Finneran and Jenkins (2012) in the development of the 2013 Draft Guidance. However, that particular technical report served as a summary of methodology and previously published data on impacts of sound on protected species (i.e., it did not contain any new data). Although Finneran and Jenkins (2012) was not published, the portions used directly in the 2013 Draft Guidance were supported by peer reviewed publications. A separate peer review of Finneran and Jenkins (2012) was neither necessary nor required under HISA requirements.

For the 2015 Draft Guidance, the Finneran Technical Report, used to derive updated marine mammal auditory weighting functions and thresholds for the Navy's Phase 3 analyses, was directly incorporated into the Guidance via Appendix A. This was the first time the Finneran Technical Report was made public, and thus, was subject to HISA requirements for inclusion in the Technical Guidance, including peer review. We also note that after the July 2015 public comment period, part of the Finneran Technical Report, specifically a summary of available data on noise-induced hearing loss in marine mammals, was published in a peer reviewed journal (Finneran et al., 2015).

Comment 16: Several commenters expressed concerns over NMFS adopting the Finneran Technical Report within the Guidance. One commenter specifically stated that the Guidance "effectively results in the US Navy writing its own regulations" and recommended that the entire Guidance process be reconvened using a fully independent panel of experts.

Response: NMFS disagrees with the commenters' assessment. The author of the Finneran Technical Report that was incorporated into Technical Guidance (Appendix A) is a well-respected and recognized scientist with over 50 peer reviewed publications on marine mammal hearing and has served on the Southall et al., 2007 expert panel, as well as the current Southall panel that

is updating their 2007 publication. Additionally, this methodology underwent an independent peer review convened by NMFS and was evaluated internally within NMFS before it was incorporated into our Technical Guidance. NMFS believes the Finneran Technical Report represents the best available science, which is why we incorporated it in the Technical Guidance.

Comment 17: One commenter requested that the NMFS share their original documents and peer reviews from the first peer review (2013), in order to facilitate common understanding as to those aspects of science related to marine mammal behavior that may be limiting NMFS' ability to establish guidance and promote studies that would address significant data gaps.

Response: As noted in the first peer review report (2013), in light of the peer reviewers' comments and based upon internal discussions, NMFS decided to re-evaluate its proposed methodology for deriving acoustic thresholds for behavior and, therefore, included only thresholds for PTS and TTS onset in the Draft Technical Guidance (i.e., Draft 2013 and 2015 and 2016 Proposed Changes public comment versions). NMFS did not include peer reviewer comments on proposed behavioral thresholds in the peer review report because they were no longer relevant to the scope of the Draft Guidance contents. NMFS will publish this information, if relevant, once we reevaluate our approach for establishing updated guidance for behavior effects.

Use of Published Versus Unpublished Data

Comment 18: Several commenters remarked on the use of published and unpublished literature in the Guidance and sought clarification regarding the sources considered in the development of the Guidance.

Response: Not all data considered in the development of the Technical Guidance have been published in a peer review journal. For the development of PTS and TTS onset acoustic thresholds and marine mammal auditory weighting functions, NMFS primarily relied on published data. The scientific aspects of the Technical Guidance underwent some form of peer review, either via formal publication in a scientific journal and/or via the HISA process.

Comment 19: Several commenters recommended that unpublished information from more recent scientific conferences should be considered in the Guidance. One commenter specifically indicated Southall et al. (2007) will be

updated in the near future and that the Guidance's finalization should be delayed for this publication or NMFS should commit to updating its Guidance within six months of the finalization of the updated Southall *et al.* (2007) publication.

Response: NMFS notes that when these more recent studies become available, they can be considered and incorporated into future updates of the Technical Guidance. NMFS is aware that Southall et al. (2007) is being updated. We anticipate that the methodology in the Technical Guidance will be similar to that provided in the updated publication (the author of the Navy's Finneran Technical Report is also on the panel updating Southall et al., 2007). NMFS will evaluate and consider the updated Southall et al. publication when it becomes available and does not believe delaying the Technical Guidance is necessary. Regarding the request to update the Technical Guidance within six months of the updated Southall et al. (2007) publication, NMFS will evaluate the Southall update and consider next steps at the time rather than commit to any timeframe in advance.

Comment 20: One commenter suggested that the Verboom and Kastelein's (2005) unpublished report, specifically the "discomfort threshold," be included for consideration in the Guidance.

Response: NMFS reviewed Verboom and Kastelein (2005) and concluded the data are more relevant for consideration in future behavioral effects guidance.

Sound Sources

Comment 21: Some commenters indicated that the Guidance appears to focus on five sound sources (i.e., underwater detonations, seismic airguns, impact pile drivers, vibratory pile drivers, and sonar). They recommended the document consider other sound sources that have the potential to result in noise-induced hearing loss and provide a list of these potential sources within the Technical Guidance, so that other sounds sources are given explicit recognition.

Response: The Technical Guidance identifies the received levels, or thresholds, above which individual marine mammals are predicted to experience changes in their hearing sensitivity for acute, incidental exposure to all underwater anthropogenic sound sources. NMFS believes providing a list of all potential sounds sources within the Technical Guidance is unnecessary and would limit the document's utility (e.g., if there

was a new source that was not specifically listed).

Comment 22: Multiple commenters remarked that the Guidance's definitions of "non-impulsive" and "impulsive" sounds are vague (i.e., NMFS does not define what is meant by "high peak sound pressure level" or "rapid rise time") and do not objectively distinguish between these two types of sound. The commenters recommended that clear, technical definitions be included. Further, commenters noted that impulsive sounds become increasingly continuous with distance, due to multipath arrivals and other factors, and may have continuous components even at short distances due to reverberation and requested NMFS also consider waveform data at the location of the marine mammal to categorize sound sources.

Response: The Technical Guidance relied on defining sound sources based on previously established definitions and standards (i.e., American National Standards Institute (ANSI)). NMFS categorized sound sources as impulsive or non-impulsive based on temporal characteristics of the sound at the source. The definition of an impulsive sound source in the Technical Guidance relates specifically to noise-induced hearing loss and specifies the physical characteristics of an impulsive sound source, which likely gives impulsive sounds a higher potential to cause auditory injury than non-impulsive sounds. Unfortunately, these standards do not provide quantitative definitions for terms like "high" peak sound pressure level and "rapid" rise time, especially in the context of underwater sources.

NMFS acknowledges that sound propagation is complex and the physical property of sounds change as they travel through the environment. The July 2015 Draft Guidance proposed a methodology for examining when impulsive sounds are less likely to possess the physical characteristics that make them more injurious (i.e., peak sound pressure level and pulse duration). This proposed methodology underwent an independent peer review (Guidance's third peer review). However, based on comments received during the public comment period for the 2015 Draft Guidance, NMFS decided the proposed methodology would benefit from by further research, removed the proposed methodology from main Guidance document, and highlighted it in the Research Recommendations, Appendix B. Included in the Technical Guidance's Research Recommendations is a call to identify sound characteristics associated with injury, which may allow for more

detailed definitions in future iterations of this Guidance.

Comment 23: One commenter suggested that the Guidance definition of impulsive sound sources as those with signals less than one second in duration could possibly capture sources that are not truly impulsive and recommended that impulsive sources be defined as those which exceed some threshold of impulse, defined as "the time integral of a force over the time that the force is applied (ANSI 1994)." Another commenter suggested characterizing impulsive sources based on metrics which consider rise time, crest factor, or the signal kurtosis (i.e., statistical quantity that represents the impulsiveness "peakedness" of the event). A follow-up comment acknowledged that kurtosis in the time domain may not be practical and suggested considering kurtosis in the frequency domain.

Response: The terms impulsive and non-impulsive as defined in the Technical Guidance are based on several ANSI standards. If action proponents are unclear which category their source might fit, they may contact NMFS for further discussion. NMFS acknowledges that the additional factors suggested by the commenters could be useful for defining source types. However, these are not currently commonly used descriptors by action proponents or those conducting marine mammal noise-induced hearing loss studies (i.e., data are not typically collected and published using these metrics), and would not be easily implementable at this time. Additional metrics can be considered as more data become available in a broader array of metrics. A better understanding of appropriate metrics has been identified as an area for recommended research in Appendix B of the Technical Guidance. In regards to using kurtosis in the frequency domain, NMFS re-examined this metric based on the comment received. However, upon evaluation, it was determined that this metric is still not currently practical to implement.

Comment 24: The Commission recommended that the 2015 Finneran Technical Report definitions of impulsive and non-impulsive sounds be adopted by NMFS and used in all contexts, including MMPA Level B behavioral harassment.

Response: The Technical Guidance definitions of impulsive and non-impulsive sounds comply with ANSI definitions and were subject to independent peer review (third peer review). These specific definitions were chosen to capture those physical characteristics that make a sound more

or less injurious in terms of noiseinduced hearing loss. The Technical Guidance does not address direct behavioral impacts from sound and so does not adopt definitions that bear on behavior. Classification of sound sources in terms of behavioral harassment will be examined when we develop guidance for these types of impacts.

Comment 25: Multiple commenters expressed concern that seismic waterguns produce higher frequency sounds than seismic airguns and should not be used to set thresholds for airguns.

Response: NMFS established Technical Guidance for all impulsive sounds based on the currently available data, which may not include every potential sound source to which a marine mammal could be exposed. Watergun data were used to represent airguns, as well as impact pile driving for most hearing groups. However it should be noted that the HF cetacean TTS onset impulsive thresholds are derived directly from data obtained from a harbor porpoise exposed to a single airgun. Incorporating marine mammal auditory weighting functions into exposure models allows for the consideration that airguns predominantly produce lower frequencies compared to waterguns.

Comment 26: A group of commenters expressed concern the Guidance will restrict the use of marine vibrators, which are designed to be more environmentally friendly by avoiding the generation of sound in the "best hearing" range of most marine animals, and generate a significantly lower overall sound pressure level throughout the frequency band relative to seismic airguns.

Response: The Technical Guidance does not restrict or allow any activity. It sets out science-based thresholds for the onset of auditory impacts based on our evaluation and synthesis of available data. Decisions about various sound-generating activities are outside the scope of the Technical Guidance.

Comment 27: A commenter noted that when considering sound source characterization, recording equipment can be limited in bandwidth and dynamic range (i.e., equipment may not be able to accurately characterize the sound source).

Response: NMFS agrees that fully characterizing the complete spectrum of a sound source, within the hearing ranges of marine mammals, is essential to accurately assess potential impacts, as is ensuring that sources meet manufacturer specifications (i.e., sometimes sources are capable of producing sounds outside their

specified bands, which have the potential to fall within the hearing range of marine mammals; Deng et al., 2014; Hastie et al., 2014). This factor is important in considering the potential of a sound source to impact a specific hearing group, and text addressing this point has been added to the Technical Guidance.

Comment 28: One commenter remarked that the Guidance was unclear whether NMFS will require sound source verification (SSV), associated with the application of the Guidance's acoustic thresholds. The comment noted that conducting a SSV poses a complicated and unnecessary burden on operations because the results are highly variable due to constantly changing conditions in the environment.

Response: The Technical Guidance does not impose any such requirements. NMFS has added text to the introduction of the Technical Guidance to clarify this point.

Metrics

Comment 29: One commenter recommended additional clarification on various sound metrics to prevent confusion between the peak sound pressure level (PK) used in the current Guidance and maximum RMS SPL used to describe prior NMFS thresholds.

Response: NMFS agrees and added clarification to the Technical Guidance to distinguish between metrics used in this document and those associated with previous thresholds, as well as including definitions of these metrics in the Glossary (Appendix E).

Comment 30: One commenter requested clarity on the definition of "peak pressure" used in the Guidance, which the commenter assumes to be the equivalent of a "zero-to-peak" value. This commenter further indicated that the Guidance has been inconsistent in converting between "peak-to-peak" and RMS values to "zero-to-peak" values.

Response: NMFS has defined peak sound pressure level in the Glossary (Appendix E) and has clarified the definition in the Technical Guidance to indicate a zero-to-peak value. NOAA disagrees that there are inconsistencies in the Technical Guidance because there have been no conversions made between zero-to-peak and peak-to-peak sound pressure levels or from RMS sound pressure to any other metric anywhere in this document.

Comment 31: To match what was provided in the Finneran Technical Report (Appendix A of July 2015 Draft Guidance), the Commission and some other commenters recommended that NMFS only provide dual metrics for PTS onset for impulsive sources (i.e.,

remove peak pressure metric threshold for non-impulsive sources). Conversely, a commenter was not supportive of removing the peak pressure thresholds for non-impulsive sources, as was suggested in the 2016 Proposed Changes document. Finally, there was some confusion as to how and when the PK threshold needs to be considered based on the updates in the 2016 Proposed Changes document.

Response: Upon further evaluation, NMFS agrees and has removed the PK thresholds for non-impulsive source in the Technical Guidance, since it is highly unlikely that the dominant metric for non-impulsive sources will be the peak sound pressure level. However, the Technical Guidance caveats that if a non-impulsive sound has the potential of exceeding the PK threshold associated with impulsive sources, these thresholds should still be considered. Thus, in the Technical Guidance, there remain dual criteria associated with impulsive sources (i.e., applicant should consider whichever threshold results in the largest effect distance (isopleth)).

Comment 32: A few commenters remarked SEL_{cum} is not a standardized acoustic notation and that the Guidance should adhere to existing standards in terms of terminology, definitions, symbols, and acronyms in order to promote clarity and reduce confusion. It was also recommended that NMFS work with standards-setting bodies to develop a consistent system of notation for marine bioacoustics applications (e.g., ANSI or International Organization for Standardization (ISO)).

Response: NMFS acknowledges that neither the 2013 nor the 2015 Draft Guidance documents consistently used notations complying with available standards. The final Technical Guidance has been revised to better reflect ANSI standards (e.g., terminology, abbreviation, and symbols). Further, NMFS is aware of the work of ISO 18405 to develop standards specifically for underwater acoustics and will reevaluate the Guidance's notations in future updates once the ISO work becomes finalized.

Comment 33: One commenter noted an inconsistency in the Guidance with both PK and SEL_{cum} acoustic thresholds being derived from the same study. The commenter noted that if the energy from a transmission does not cause an impact at a given frequency because of an animal's reduced sensitivity (or capability) to hear that signal, then the ability to be impacted by the PK should also be reduced for that frequency.

Response: NMFS does not agree there is an inconsistency in how data were assessed. Data from Lucke *et al.* (2009)

were used to derive both thresholds for HF cetaceans exposed to impulsive sources. For MF cetaceans, both thresholds come from belugas exposed to waterguns (Finneran et al., 2002). For both the Lucke et al. (2009) and Finneran et al. (2002) study, TTS onset was recorded in multiple metrics, with two of these metrics (i.e., PK and SEL_{cum}) directly used in the Technical Guidance. NMFS disagrees that auditory weighting functions are appropriate for use with the PK metric, as direct mechanical damage associated with sounds having high peak sound pressures typically does not strictly reflect the frequencies an individual species hears best (i.e., why PK thresholds should be considered unweighted/flat-weighted within the entire frequency band of a hearing group).

Comment 34: Multiple commenters noted that the SEL_{cum} metric within the Guidance is used under the assumption that a low amplitude/long signal having an equal SEL_{cum}, as a high amplitude/ short signal, will have the same effects on the auditory system (i.e., the Equal Energy Hypothesis (EEH)). A commenter further stated that the EEH may be correct in certain conditions, but that an increasing body of evidence indicates that the EEH does not hold true for most marine mammal sound exposures. It was suggested that as more data become available, NMFS should perform more analyses to determine what model or equation best fits the EEH and revise the acoustic thresholds to more accurately reflect the potential for TTS changes with duration and amplitude.

Response: NMFS agrees that EEH may not be valid for all exposure situations. However, the Technical Guidance provides acoustic thresholds in the SEL_{cum} metric, based on the belief that the EEH is the best means of incorporating this metric (also recommended by Southall et al., 2007). NMFS maintains that despite the shortcomings, having a metric that includes the duration of exposure is critical for predicting effects of noise on marine mammal hearing. The evaluation of appropriate metrics and EEH has specifically been identified as an area where more research is needed (Guidance Appendix B).

Comment 35: One commenter indicated since "SEL" is the accumulated acoustic energy in a signal and cumulative by definition, whether calculated over one second or a single pulse event, the Guidance's use of "SEL_{cum}" to describe cumulative sound exposure is unnecessary. The commenter suggested NMFS should simply use the abbreviation "SEL".

Response: NMFS agrees that the SEL implies accumulation. The ANSI definition indicates that accumulation occurs over a stated time interval, which is typically referenced to one second. In order to clarify that the duration of accumulation in the Guidance is not one second (i.e., 24 hours), NMFS chose to use the notation SEL_{cum}.

Use of Data From Captive Marine Mammals

Comment 36: Multiple commenters indicated that the use of data from captive individuals was a poor proxy (e.g., over-estimate TTS onset or hearing thresholds, may be habituated or have different survival tactics) for their freeranging counterparts and suggested that data from captive bottlenose dolphins be adjusted to be more representative.

Response: NMFS acknowledges that captive individuals may be habituated to their test environment, making them less than ideal proxies for their freeranging counterparts for studying behavioral reactions to noise. However, we believe habituation has minimal effects on testing auditory capabilities and the impacts of noise on hearing, which is the focus of this Technical Guidance.

For example, NMFS notes that data from Castellote et al. (2014), from freeranging belugas in Alaska, indicate of the seven healthy individuals tested (3 females/4 males; 1 subadult/6 adults), all had hearing abilities "similar to those of belugas measured in zoological settings." Thus, from this one study, it appears that for baseline hearing measurements, captive individuals might be an appropriate surrogate for free-ranging animals. However, this is currently the only study of its kind, and more research is needed to examine if this trend applies to other species (see Appendix B: Research Recommendations).

NMFS also finds an adjustment to bottlenose dolphin data is unnecessary. The Technical Guidance methodology for deriving marine mammal auditory weighting functions incorporates data from a multitude of species (~20 species), beyond just bottlenose dolphins, and is considered representative based on the best available science.

Comment 37: Several commenters expressed concern over the ages of many of the captive individuals used in TTS studies as not being representative (e.g., thresholds obtained from younger bottlenose dolphin in Johnson 1968 are on average 10 dB lower than from older individuals) and considers them sources of uncertainty. Many commenters suggested that data from older

individuals should either be adjusted or excluded from consideration.

Response: NMFS disagrees that data from older individuals needs to be excluded or adjusted and notes that Houser and Finneran (2006) did a comprehensive study on the hearing sensitivity of the Navy bottlenose dolphin population (i.e., tested 42 individuals from age 4 to 47 years; 28 males/14 females) and found that highfrequency hearing loss typically began between the ages of 20 and 30 years. For example, at frequencies where this species is most susceptible to noiseinduced hearing loss (i.e., 10 to 30 kilohertz (kHz)), these are the frequencies where there is the lowest variability in mean thresholds between individuals of different ages. Additionally, for harbor seals, similar levels of TTS onset were found in Kastelein et al. (2012a) for individuals of 4 to 5 years of age compared to the individual from in Kastak et al. (2005), which was 14 years old. For belugas similar levels of TTS were measured in Popov et al. (2014) for an individual 2 years old compared to those used in Schlundt et al. (2000), which were 20 to 22 years old or 29 to 31 years old. Further, Houser and Finneran 2006

attribute the lower thresholds recorded by the individual from Johnson (1968) to differences in methodology (i.e., Johnson (1968) used behavioral protocol to test hearing versus electrophysiological methodology by Houser and Finneran (2006)). The Technical Guidance relies primarily on behavioral data associated with hearing and threshold shift measurements, as opposed to those obtained via other means (e.g., auditory evoked potentials (AEP)) because we consider these data to be most representative of hearing ability and noise-induced hearing loss, which further eliminates the need for any adjustment.

Comment 38: One commenter indicated that studies show that marine mammals tend to avoid disruptive sound sources, which could significantly diminish the potential for noise-induced hearing loss. Therefore, the commenter suggests that the data collected in laboratory experiments are likely to result in overestimates of exposure because the subjects are exposed to longer and louder sounds than they would be in the natural environment.

Response: NMFS agrees that when considering exposure durations for animals under realistic exposure conditions, generally, it is predicted that most individuals will only be in the closest ranges to a sound source/activity for a minimal amount of time (e.g.,

animals are capable of moving horizontally and vertically in the water column to reduce exposure, and/or individuals are exposed to mobile sources). Thus, using laboratory data from animals exposed to unusually long, continuous durations of sound (i.e., animals cannot leave exposure scenario and the level during exposure remains constant) may not best reflect scenarios expected to be encountered by wild individuals, when exposed to sound over long periods of time. However, measurements of TTS from laboratory studies are the only data currently available, and they remain informative regarding sound exposure that may impact marine mammal hearing. Appendix B of the Guidance recommends future TTS studies to address exposures animals are likely to receive in the natural environment and provide more representative results.

Marine Mammal Hearing Ranges

Comment 39: One commenter noted that the establishment of hearing groups is fundamentally flawed because it is based on the assumption that similar exposures will result in similar effects in all group members. The commenter believes it is important to consider species differences in behavior (e.g., movement away from the noise source) when calculating cumulative exposure associated with PTS onset.

Response: NMFS agrees that marine mammal behavioral responses could result in differences in noise exposures and accumulation scenarios (i.e., SEL_{cum}). However, NMFS disagrees that such responses necessarily indicate that hearing physiology is dissimilar or that levels causing noise-induced threshold shifts are dissimilar between species within a hearing group. Further, differences in behavioral responses to sound will be considered in the development of behavioral effects thresholds.

Comment 40: One commenter indicated that the method for determining the limits of the functional hearing ranges was not clearly indicated in the Guidance and suggests that NMFS should indicate how the limits were obtained for each group. Another commenter indicated that the term "functional hearing range" is intended to convey the range over which the majority of the species' hearing ability is found. However, there are at least two examples of a species' ability to hear a signal outside its functional hearing range (i.e., false killer whale and Risso's dolphin (Au et al., 1997)).

Response: Based on the revised methodology for establishing marine mammal auditory weighting functions

(Appendix A), NMFS has replaced the concept of functional hearing range with the establishment of what the Technical Guidance terms "generalized hearing range" for each hearing group. The latter is recommended for consideration associated with flat weighting for PK thresholds and when determining general risk of auditory impacts from noise. The generalized hearing ranges were chosen based on the approximate 65 dB threshold from the normalized composite audiogram. NMFS believes that outside the generalized hearing range, the risk of auditory impacts from sounds (i.e., TTS or PTS) is considered to be either zero or very low (the exception would be if a sound above/ below this range was determined to have the potential to cause physical injury, i.e., lung or gastrointestinal tract injury from explosives) and added additional information to clarify this in the Technical Guidance.

NMFS is aware of the Au et al. (1997) paper, which examines the effect of the 75 Hz acoustic thermometry of ocean climate (ATOC) signal on hearing sensitivity of a single false killer whale and single Risso's dolphin, both midfrequency (MF) cetaceans. Hearing thresholds for both species, from this study, were 139 dB or higher (false killer whale: Thomas et al., 1988; Risso's dolphin: Nachtigall et al., 1995). Thus, this ATOC signal is considered beyond the generalized hearing range of MF cetaceans.

Comment 41: Several commenters questioned the justification used to support the PW and OW pinnipeds' upper hearing limit in the Technical Guidance. The commenters noted that newer studies have consistently shown that 75 kHz is a more reasonable upper cutoff for PW pinnipeds underwater. These commenters recommended that NMFS choose the median value, not the most conservative value, for the PW pinniped upper hearing range limit. For OW pinnipeds, the 2013 Draft Guidance does not clearly explain why 40 kHz was selected as a high-frequency cut-off for OW pinnipeds instead of 50 kHz reported in Finneran and Jenkins (2012).

Response: As indicated in the previous comment/response, NMFS has provided generalized hearing ranges by marine mammal hearing group. The generalized hearing ranges are supported by available pinniped audiogram data that were used to derive the composite audiogram for this group (Terhune 1988; Kastak and Schusterman 1999; Kastelein et al., 2009; Reichmuth et al., 2013; Sills et al., 2014; and Sills et al., 2015). The generalized frequency ranges are intended to be broad enough to encompass the hearing range of the

entire hearing group (i.e., choice of using 65 dB threshold compared to 60 dB threshold typically used to define human and other terrestrial mammal hearing ranges). Thus, NMFS disagrees that using a median is preferred. For PW and OW pinnipeds, the upper range based in the finalized Technical Guidance is 86 kHz and 39 kHz, respectively.

Comment 42: One commenter noted that current ESA and MMPA analyses are based on data collected while monitoring previous activities, with little of that data having been analyzed by hearing group. The commenter suggested that until more data are available, it will be difficult to find data upon which to base the analyses.

Response: NMFS disagrees that it will be difficult to complete analyses and believes that hearing group data and marine mammal auditory weighting functions provided in the Technical Guidance are based on the best available science and can be applied to any source. Additionally, the Technical Guidance states that the application of marine mammal auditory weighting functions should be completed after data collection (i.e., auditory weighting functions should not be applied beforehand), with the total spectrum of sound preserved for later analysis (i.e., if weighting functions are updated or if there is interest in additional species, data can still be used).

General Auditory Weighting Functions

Comment 43: NMFS' exclusion of AEP data in establishing marine mammal composite audiograms and auditory weighting functions was criticized by several commenters. These commenters noted that by including AEP datasets, the statistical power of the assessment would be improved.

Response: In deriving marine mammal composite audiograms, NMFS established an informal data hierarchy in terms of assessing these types of data. Specifically, audiograms obtained via behavioral methodology provide the most representative presentation (most sensitive) on hearing ability, followed by AEP data, lastly by mathematical models for species where no data are available (i.e., low-frequency or LF cetaceans). Thus, the highest quality data available for a specific hearing group should be used, which for all hearing groups, except LF cetaceans, is behavioral. Additional clarifying text on this informal data hierarchy has been provided in the Technical Guidance.

It also should be noted that marine mammal AEP audiograms have been based almost exclusively on measurements of the auditory brainstem response, and thus do not take into account contributions to hearing from higher centers of the brain and auditory nervous system, and no means have been established for "correcting" AEP data so that they may be more comparable to those obtained via behavioral methods. AEP thresholds are typically elevated compared to behavioral thresholds in a frequencydependent manner, especially at lower frequencies (e.g., Szymanski et al., 1999; Yuen et al., 2005; Houser and Finneran 2006); therefore including the lowfrequency AEP data in the composite audiogram would cause an artificial increase in audiogram low-frequency slope and cause the resulting weighting function to be more narrow at low frequencies.

Despite not directly including AEP audiograms in the development of a hearing groups' composite audiogram, these data were evaluated to ensure species were placed within the appropriate hearing group and to ensure that a species for which only AEP data were available were within the bounds of the composite audiogram for that hearing group. Further, AEP TTS data are presented within the Guidance for comparative purposes alongside TTS data collected by behavioral methods illustrating that the AEP TTS data are within the bounds (the majority of the time above) of those collected by behavioral methods (i.e., Figures A18

and A19).

Comment 44: One commenter remarked that the Guidance may change as improved information becomes available, which means that auditory weighting functions may also change. The commenter suggested that NMFS develop a mechanism for allowing updates until a widely-accepted weighting procedure for marine mammals is standardized by expert consensus (e.g., through the ANSI or ISO standardization processes).

Response: NMFS agrees that as additional data become available, the auditory weighting functions, among other factors, may require modification. For that reason, NMFS has added specifications to the Technical Guidance indicating that auditory weighting functions should be applied after data are collected (i.e., during data collection, the complete spectrum of sound should be collected) to ensure they are available for re-analysis if updated weighting functions become available. The Technical Guidance also establishes protocols for evaluating new data and updating the document.

Comment 45: Multiple commenters noted that each of Guidance's hearing groups contains species whose sound production and regions of best hearing sensitivity do not overlap to a high degree. A few commenters further added that applying results from one or two aging bottlenose dolphins to all members of a hearing group is inadequate.

Response: The auditory weighting functions are meant to assess risk of noise-induced hearing loss and not necessarily encompass the entire range of best hearing for every species within the hearing group. NMFS' use of auditory weighting functions is consistent with how weighting functions are used in human noise standards, which is to assess the overall hazard of noise on hearing. Specifically, the human auditory weighting function provides a "rating that indicates the injurious effects of noise on human hearing" (OSHA 2013). While these weighting functions are based on regions of equal loudness and best hearing, they are meant to reflect the susceptibility of the ear to noiseinduced threshold shifts, and as such, the region of enhanced susceptibility to noise exposure may not perfectly mirror a species' region of best hearing (e.g., TTS data from bottlenose dolphin, belugas, and Yangtze finless porpoise support this).

Further, updated methodology in the July 2015 revised Draft Guidance used composite audiograms based on multiple species to derive marine mammal auditory weighting functions. Thus, data from more than just bottlenose dolphins were used to derive these functions (i.e., MF cetacean composite audiograms are derived using data from eight different species).

As for how animal age could impact hearing susceptibility, please see Response to Comment 37.

Comment 46: Multiple commenters expressed concern that the Guidance's marine mammal auditory weighting functions are invalid, since they are based on assumptions that have not been subject to uncertainty analysis for frequencies below 3 kHz.

Response: NMFS disagrees that there is greater uncertainty for frequencies below 3 kHz, since audiogram data were collected for frequencies below 3 kHz for a multitude of species in the MF and HF cetacean and PW and OW pinniped hearing groups (e.g., see Figure A5 in Technical Guidance). Further, low-frequency data from the composite audiogram is used to directly determine the slope of the weighting function.

Comment 47: A commenter requested clarification on what NMFS intended by the term "smaller isopleth" in discussing the effects marine mammal

auditory weighting functions have on exposure modeling results.

Response: The Technical Guidance thresholds associated with a hearing group themselves do not change depending on how much a sound may overlap a group's most susceptible frequency range. Instead, how weighting functions affect exposure modeling/ analysis is related to the size of the isopleth (area) associated with the threshold based on how susceptible that particular hearing group is to the particular sound being modeled. For example, a hearing group could have different size isopleths associated with the same threshold, if one sound was within its most susceptible frequency range and the other was not (i.e., sound in the most susceptible hearing range will result in larger isopleth compared to sound outside the most susceptible hearing range). We have provided additional text in the Technical Guidance to clarify this concept.

Comment 48: One commenter expressed concern as to the practicality of obtaining and maintaining modeled sound field results for broadband sources (e.g., airguns or impact pile drivers) in order for weighting functions (current or revised) to be applied at a later date.

Response: The Technical Guidance recommends that marine mammal auditory weighting functions be applied after sound field measurements have been obtained (i.e., post-processing; auditory weighting functions should not be applied beforehand), with the total spectrum of sound preserved for later analysis (i.e., if weighting functions are updated or if there is interest in additional species, data can still be used). This recommendation applies to actual field measurements and not modeling results. The final Technical Guidance includes additional text to clarify this point.

Uncertainty and Statistical Analyses Associated With Auditory Weighting Functions

Comment 49: Several commenters expressed concern about uncertainty in the development of the marine mammal auditory weighting functions and acoustic thresholds, especially because of the reliance on mean and median values without reporting variation (i.e., methodology does not account for variability/confidence intervals associated with small sample sizes). Alternative methodologies to account for uncertainty were suggested for consideration (e.g., inverse Bayesian formulations with Markov-chain Monte Carlo and Metropolis-Hastings sampling methods; Wright 2015; Potential

Biological Removal (PBR); human noise standards (NIOSH 1998)).

Further, Wright (2015) claimed that inconsistencies within the methodology used to establish the auditory weighting functions and acoustic thresholds contributed to uncertainty; namely, that: (a) The hearing threshold (audiogram)to-TTS onset component, on a per individual basis, is neglected (recommends calculating audiogram-to-TTS onset for each individual); (b) it is inappropriate for non-adjusted (nonnormalized) TTS onset data points for individuals to be fit to composite audiograms; and (c) there is a discrepancy between the frequency of best sensitivity for the composite audiogram and exposure function, which results in the weighting/exposure function gain parameters (i.e., parameters " \vec{K} " and "C") underestimating TTS onset.

Finally, it was requested that NMFS (1) provide the underlying data used to derive the weighting functions so that uncertainty and statistical analyses can be evaluated by those outside NMFS and (2) delay the Guidance's finalization until this outside process can be completed.

Response: NMFS acknowledges the small sample size associated with the available marine mammal data used to derive weighting functions and thresholds presents challenges. However, the Technical Guidance's methodology is designed to predict the mostly likely (realistic) outcome using the central tendencies (means/median) associated with the best available science. The intent is not to predict the worst-case-scenario by relying on the lowest limits for every possible step in the methodology (i.e., Technical Guidance is for accurately predicting exposures and not for establishing "safe limits," where there is limited to no risk). Despite not using statistical methodology to report variability, Appendix A provides the full suite of available data for consideration and comparison to the values used in the Technical Guidance (e.g., Figures A5 and A6 for audiogram data and Figures A18-A20 for TTS data). With respect to data used to derive composite audiograms, auditory thresholds are typically defined by the 50 percent detection threshold (ANSI 2009), and equal loudness contours used to derive human weighting functions are derived using averages (e.g., Fletcher and Munson 1933), as opposed to relying on the lowest value (i.e., there is a precedence for using medians/means). Additionally, it is important to remember that the derived weighting functions are based on more than the

just the composite audiogram (*i.e.*, the audiogram shapes are adjusted to best fit the existing TTS data) resulting in a function that is always broader than the composite audiogram (*e.g.*, Figure A17).

Human noise risk assessments (NIOSH 1998) are not equivalent (or applicable) to thresholds provided in the Technical Guidance, since they are used to predict hearing loss based on a daily 8-h exposure over 40 years (i.e., current marine mammal TTS are only available to predict exposure periods of 24 h or less and cannot be used to assess or predict risk associated with a lifetime of exposure; See Response to Comment 79) and are based on larger sample sizes of human listeners (e.g., NIOSH 1972 and 1997 risk assessments were based on a sample size of 1,172 people). As pointed out in Wright 2015, NIOSH criteria provide a 95 percent confidence interval for their human noise standards but also allows for an excess risk of material hearing impairment, defined as an average threshold elevation for both ears that exceeds 25 dB, of eight percent (i.e., human noise standards limits do allow for some risk; risk is not zero percent and specifically that eight percent of the population is still capable of developing noise-induced hearing loss exceeding 25 dB when exposed to the 85 dB NIOSH level). For how the Technical Guidance's TTS thresholds encompass available data, see Response to Comment 72 and Appendix A, Figures A18–A20, which provide all available marine mammal TTS data collected via both behavioral and AEP techniques). Additionally, methodology associated with the calculation of PBR (i.e., use of twentieth percentile) was based on simulations specific to a particular dataset (Wade 1998) and is not applicable to the Technical Guidance.

With respect to specific comments made in Wright (2015), NMFS disagrees there are inconsistencies in the methodology in the Technical Guidance. Specifically related to the assertion in part (a) of the comment that NMFS neglected the hearing threshold (audiogram)-to-TTS onset component: In re-examining available data sets, in terms of offset between hearing threshold and TTS onset, only six individuals (three MF cetacean, one OW pinniped, and two PW pinnipeds) have measurements available for both hearing threshold and TTS onset. Differences in TTS onset at frequency of best hearing (from the exposure function) and threshold at frequency of best hearing (from the composite audiogram) are reflected by hearing group in the Technical Guidance in Table A7 (Appendix A, "Difference" column).

Unfortunately, comparisons between the difference hearing thresholds and TTS onset from the same individual to differences depicted in Table A7 are difficult, since none of the individual TTS data occur in the frequency of best hearing. However, TTS onset (SEL_{cum} metric) predicted from the exposure function is within 1 dB or lower compared to TTS onset based on these five individuals. Further, this specific recommendation from Wright (2015), to consider data from individual audiograms, counters other recommendations made elsewhere in that paper that data from the same species should be considered correlated and combined to reduce issues associated pseudoreplication (See Response to Comments 53).

As for non-adjusted TTS data points being fit to normalized composite audiograms (point b), the Guidance's methodology examines the best fit of TTS data points to *both* original (non-normalized) and normalized composite audiogram data to establish the "delta T" parameter (*i.e.*, both non-normalized and normalized data are used to derive delta T). Additionally, the "K" parameter is derived using the original (non-normalized) audiogram data and is defined to minimize the square error between the exposure function and TTS data for each hearing group.

As to point (c), NMFS acknowledges that there is a shift (discrepancy) in frequency between the best sensitivity in terms of the composite audiogram and resulting exposure function for a hearing group, but disagrees that this leads to an underestimation of TTS onset. Any difference in minimum value between the exposure function and audiogram is an outcome of the fitting process used to fit the exposure function to the available TTS data, and thus, reflects the underlying TTS data. This shift in minimal value results in an identical (PW and OW pinnipeds) or lower TTS onset threshold (MF and HF cetaceans) than predicted by considering the composite audiogram alone (See Table A7 vs. A8 in Technical Guidance). Further, the "C" parameter results in a minimal adjustment to the final TTS onset threshold (maximum 1 dB; See Table A8 in Appendix A).

Finally, NMFS believes it is unnecessary to provide underlying datasets associated with the Technical Guidance and delay publication, since the majority of the underlying data (with a few exceptions) are published and freely available.

Comment 50: Commenters indicated that sound reception is an essential ability of marine mammals, particularly cetaceans, for survival, and these

commenters, citing Nowacek *et al.* (2007), indicated that PTS can lead in many cases to mortality of individuals which may have serious consequences for the survival of populations.

Response: NMFS agrees that the ability to accurately interpret the surrounding environment via hearing is essential for marine mammals. However, NMFS' review of Nowacek et al. (2007) as well as all other available information did not locate any statements that PTS can result in mortality.

Comment 51: Some commenters recommended that audiograms from individuals of the same species should be treated as correlated in the determination of composite audiograms. Further, in order to determine a conservative representative sensitivity for each hearing group, the highest measured sensitivity, lowest threshold (behavioral or AEP), per frequency per species should be assessed. Commenters indicated that this would be a more cautionary approach than relying on the mean.

Response: NMFS does not disagree that audiograms from individuals of the same species may be correlated but disagrees with the recommendation to collapse available audiograms, so that there is only one per species. Employing this recommendation would further reduce already limited data sets (see Response to Comment 53 regarding pseudoreplication recommending a similar procedure and similar issue with data limitations) For NMFS' response relating to the use of AEP data, see Response to Comment 43, and for our response regarding relying on the lowest threshold, see Response to Comment 49. NMFS believes that the Guidance's current approach maximizes the use of the best available science.

That said, based on this comment, NMFS re-evaluated AEP data available for consideration in the development of composite audiograms. The inclusion of AEP resulted in only minimal changes to the composite audiogram (*i.e.*, majority of AEP audiogram data had equal, if not higher thresholds, than those collected by behavioral methods, which would only result in a less conservative composite audiogram).

Comment 52: Based on Wright 2015, commenters recommended that NMFS develop marine mammal auditory weighting functions based on envelope functions, which incorporate all available audiogram points.

Additionally, these same commenters objected to NMFS' comparison between the Guidance's weighting functions and inverted audiograms (i.e., Guidance's weighting functions are broader than

inverted audiograms that have been suggested). The commenters stressed that inverted audiograms have only been recommended for individual species and not entire hearing groups.

Response: NMFS disagrees with this recommendation (See Response to Comment 49). As far as comparing the Technical Guidance's weighting functions to inverted audiograms, NMFS agrees that the comparison to inverse audiograms may not have been applicable and removed it from the Technical Guidance. Nevertheless, the point that the Technical Guidance auditory weighting functions are broader than the corresponding hearing group's composite audiogram, as well as any audiogram associated with an individual species, is still valid.

Comment 53: Pseudoreplication was highlighted as a significant deficiency of the Guidance by several commenters. It was recommended that NMFS evaluate TTS on a species-by-species basis, rather than on an individual basis.

Response: NMFS understands the concerns regarding pseudoreplication. However, marine mammal hearing and noise-induced hearing loss data are limited, not only in the number of species but also in the number of individuals available. Unfortunately, any means of minimizing pseudoreplication would further reduce these already limited data sets. Specifically, with marine mammal behavioral TTS studies, behaviorallyderived data are only available for two MF cetacean species (i.e., bottlenose dolphin, beluga) and two PW pinniped species (i.e., harbor seal and northern elephant seal), with OW pinnipeds and HF cetaceans only having behaviorallyderived data from one species. Thus, NMFS believes that the current approach makes the best use of the given data (See Response to Comment 72 for more information on the inclusion of available TTS data). Appropriate means of reducing pseudoreplication may be considered in the future, if more data become available.

Comment 54: Several commenters requested that a list of data gaps and research recommendations should be included in the Guidance to inform funding groups and the research community of critical data needs.

Response: NMFS agrees and has identified several data gaps and added a Research Recommendations Appendix (B) to the Technical Guidance.

Low-Frequency Cetacean Hearing and Auditory Weighting Functions

Comment 55: Several commenters questioned the justification for

expanding the upper hearing limit of LF cetaceans beyond that proposed in Southall *et al.* (2007) in the 2013 Draft Guidance (*i.e.*, 22 kHz to 30 kHz).

Response: NMFS has replaced the use of functional hearing range with generalized hearing range, which is derived based upon more consistent methodology (See Response to Comment 40).

Comment 56: One commenter indicated that recent data suggest that within the LF cetacean hearing group, new divisions are appropriate to consider (e.g., Ultra Low: blue and fin whales; Low: bowhead and right whales; Low to Mid: humpback and gray whales; and Mid: minke whale groups).

Response: NMFS acknowledges that as more data become available, marine mammal hearing ranges may warrant modification, or that it may be appropriate to divide LF cetaceans into subdivisions. However, NMFS does not believe there currently are enough data to support further LF cetacean divisions and subsequent auditory weighting functions, especially since so little direct information on hearing is available for this hearing group.

Comment 57: Several commenters questioned the sufficiency of data to support the LF cetacean auditory weighting function provided in various versions of the Draft Guidance. Some recommended using the M-weighting function provided by Southall et al. (2007) until more data could be collected or developing a LF cetacean weighting function based on the known low-frequency vocal range of this hearing group, ensuring that the weighting function encompasses ultralow-frequencies (i.e., <30 Hz) used by blue and fin whales. One commenter further suggested that the LF cetacean weighting function be flat down to 0 Hz to ensure low-frequency sound does not compromise critical communication signals.

Counter to those recommendations, other commenters expressed concern that the low-frequency slope parameter ("a" parameter) of the LF weighting function (i.e., 20 dB/decade) was not scientifically supportable and should be more reflective of mammalian data (30) to 40 dB/decade). Furthermore, the selection of this parameter was criticized because it resulted in an exposure function that predicts an unrealistically low-frequency hearing (80 dB threshold above best hearing occurring well below 1 Hz; e.g., only a 26 dB weighting function amplitude at 10 Hz), which is not reflective of what is known about other low-frequency specialist mammals, like humans and

kangaroo rats. Additionally, these same commenters commended NMFS for not using vocalizations, especially frequencies associated with blue and fin whales, as a direct means for deriving the LF cetacean predicted audiogram.

Finally, NMFS received a comment from a group of subject matter experts offering information on ambient noise levels below 2 kHz from Clark and Ellison (2004) as additional scientific justification for the LF cetacean weighting function contained in the March 2016 Proposed Changes.

Response: NMFS acknowledges the limited data predicting LF cetacean hearing sensitivity but disagrees that utilizing the M-weighting functions from Southall et al. (2007) or creating a weighting function that is flat to 0 Hz reflects the best available science. Via the Technical Guidance public comment and peer review processes, NMFS determined that the methodology in the March 2016 Proposed Changes document best reflects the currently available data for deriving marine mammal auditory weighting/exposure functions, including those methods to derive surrogate parameters for LF cetaceans.

Regarding the appropriateness of using vocal range to establish weighting functions, see Response to Comment 45. As for the frequencies used by fin and blue whales, NMFS acknowledges that the weighting function amplitude is >-16 dB at frequencies below 30 Hz. However, predicted hearing sensitivity for LF cetaceans based on ambient noise levels from Clark and Ellison (2004) offer additional scientific support to NMFS' weighting function below 2 kHz (for direct comparison to the 2016 LF cetacean weighting function see: https:// www.regulations.gov/ #!documentDetail;D=NOAA-NMFS-2013-0177-0155). Additionally, Cranford and Krysl (2015) predicted that since low-frequency sound propagates further than those containing higher frequencies, this might explain the potential mismatch between the frequencies associated with best hearing and vocalizations for LF cetaceans. Furthermore, creating a weighting function to ensure communication signals are not compromised is beyond the scope of this document (the Technical Guidance weighting functions are meant to reflect a hearing group's susceptibility to noise-induced hearing loss).

As for the low-frequency slope associated with the LF cetacean weighting function, NMFS believes it is reflective of currently available predictive data for this hearing group. For example, predictive audiograms

based on anatomical modeling for minke whale (Tubelli et al., 2012), fin whale (Cranford and Krysl 2015), and humpback whale (Houser et al., 2001) all indicate this hearing group may have a shallower low-frequency slope compared to other terrestrial and marine mammals. Specifically, Tubelli et al. (2012) offers that the "extra" 20 dB difference in the low-frequency slope between other cetaceans (HF and MF cetaceans) may be a result of the inner ear anatomy of this hearing group (i.e., open auditory bulla and the resulting pressure differences along the "glove finger"). Finally, ambient noise levels with slopes ~20 dB/decade support the predicted low-frequency slope for this hearing group (Wenz 1962).

Comment 58: Multiple commenters indicated the LF cetacean exposure function's "K" parameter, which the commenters classified as a metric of dynamic range, was arbitrary and inappropriately based on data from a beluga and a harbor porpoise for

impulsive sounds.

Response: NMFS disagrees with the commenters' classification of the exposure function's "K" parameter as a metric of dynamic range and the criticism. This parameter is set to match the weighted threshold for TTS or PTS onset based on available data in the SEL_{cum} metric (i.e., NMFS' dynamic range methodology is for deriving PK thresholds; See Response to Comment 87). NMFS agrees that for impulsive sounds, TTS data are extremely limited (i.e., beluga data from Finneran et al. (2002) and harbor porpoise data from Lucke et al. (2009). Nevertheless, the methodology for establishing a surrogate value for this parameter for hearing groups where no data are available is consistent with the derivation of other surrogate parameters within the Technical Guidance.

Comment 59: Numerous commenters, including the Commission, identified an inconsistency in how NMFS derived the " F_2 " parameter, which predicts the high-frequency portion of the composite audiogram for LF cetaceans. Specifically, this parameter was adjusted to achieve a threshold at 30 kHz of 40 dB relative to the lowest threshold. However, in earlier discussions of the low-frequency parameter " F_I ," the March 2016 Proposed Changes document mentioned predictive modeling of LF cetacean hearing indicating 40 dB of best sensitivity occurring at ~25 kHz (i.e., not 30 kHz). Commenters were unclear if this was an error or if 30 kHz was chosen deliberately and if so, why.

Response: NMFŠ acknowledges the potential for confusion and chose to

adjust the " F_2 " parameter to achieve a threshold value at 30 kHz of 40 dB relative to the lowest threshold as a means to account for uncertainty associated with this hearing group and to avoid too gradual of a cutoff at the high-frequency end (*i.e.*, decision to adjust parameter at 30 kHz vs. 25 kHz). Additional text was added to the final Technical Guidance for more clarity on this decision.

Comment 60: Numerous commenters criticized the potential for "takes"/isopleths/mitigation ranges to increase dramatically based on updated weighting functions/thresholds for LF cetacean hearing group (i.e., comparison between 2015 Draft Guidance and 2016 Proposed Changes document).

Response: NMFS acknowledges that the LF cetacean predicted weighting function and PTS onset thresholds in the 2016 Proposed Changes document/ Technical Guidance are more conservative than those presented in the 2015 Draft Guidance. However, in our judgement, the changes reflect the best available science and account for uncertainty associated with this particular hearing group where data are limited. In response to how the Technical Guidance could impact mitigation ranges, see Response to Comment 11.

Mid- and High-Frequency Cetacean Hearing and Auditory Weighting Functions

Comment 61: Multiple commenters indicated that the Guidance's auditory weighting functions do not represent the hearing sensitivities of all included species, indicating that bottlenose dolphins are not appropriate surrogates for killer whales or sperm whales, which are known to have regions of greatest hearing sensitivities at much lower frequencies, and that harbor porpoises and finless porpoise may not represent the auditory ability of Irrawaddy, Ganges River, Commerson's, and Peale's dolphins.

Response: See Response to Comment 45. In the Guidance, a broader range of species were considered in the development of the MF auditory weighting function via the composite audiogram. Specifically, for MF cetaceans, the composite audiograms are derived from data compiled from eight species (bottlenose dolphins, beluga, false killer whale, Risso's dolphin, striped dolphin, and tucuxi) and 22 individuals of these species, of which only six individuals are bottlenose dolphins. Further, two individuals of these are killer whales, which from these available audiogram data indicate thresholds consistent with other MF

cetaceans (i.e., current audiograms do not indicate this species has better lowfrequency hearing than other MF cetaceans). Currently, there are no direct measurements available on sperm whale hearing (only an incomplete audiogram exists for a stranded sperm whale neonate from Ridgway and Carder (2001)). NMFS considers sperm whale placement within MF cetaceans appropriate based on Ketten (2000), which classified sperm whales as having Type I cochlea, similar to other MF cetaceans and considers the MF cetacean auditory weighting function representative of all species within this hearing group based on the best available science.

For HF cetaceans, composite audiograms are derived from more limited data (i.e., four individuals from two species: harbor porpoise and Amazon River dolphin; AEP data are only available for Yangtze finless porpoise). Thus, it is unclear how these two species represent others in this hearing group, since no other data are available (i.e., no data on hearing ability of Irrawaddy, Ganges River, Commerson's and Peale's dolphins). The need for additional audiograms, particularly from the HF cetacean hearing group was added as a Research Recommendation (Appendix B) in the Technical Guidance.

Comment 62: One commenter noticed an error in the audiograms used to construct the composite audiogram for HF cetacean in the July 2015 Draft Guidance. They indicated that the harbor porpoise audiogram by Kastelein et al. (2002), was later revised due to a problem with the analysis of the sound stimuli, with the correct audiogram found in Kastelein et al. (2010). Thus, it is recommended that NMFS use the 2010 data, instead of the 2002 data.

Response: NMFS re-evaluated the data used to construct the composite audiogram for HF cetaceans and confirmed the assertion made by the commenter that the wrong data set was initially used. This error has been corrected for in the final Technical Guidance.

Comment 63: Several commenters, including the Commission, were in support of moving the white-beaked dolphin from MF cetaceans to HF cetaceans.

However, numerous other commenters indicated that moving this species to a new hearing group was not scientifically supported. The Navy specifically recommended that this species remain in the MF cetacean hearing group based upon the following scientific support: (1) A hearing threshold comparison between white-

beaked dolphin (Nachtigall et al., 2008), bottlenose dolphin (Johnson 1967), and harbor porpoise (Kastelein et al., 2002; Kastelein et al., 2010) indicating whitebeaked dolphin do not have significantly better high-frequency hearing than the bottlenose dolphin (for figure depicting comparison see: https:// www.regulations.gov/#!document Detail;D=NOAA-NMFS-2013-0177-0152); (2) white-beaked dolphin echolocation are more similar to those of bottlenose dolphins (i.e., resembling broadband, exponentially-damped sinusoids containing only a few cycles; Au 1980; Rasmussen and Miller 2002) in contrast to echolocation emissions for harbor porpoises and other species placed into the HF cetacean hearing group (e.g., Cephalorhynchus sp., Lagenorhynchus australis) (i.e., more narrowband, longer in duration, and contain mostly high-frequency energy; Tougaard and Kyhn 2010); and (3) Ketten's (2000) categorization of the cochlea of white-beaked dolphin and bottlenose dolphin as "Type II," while the harbor porpoise cochlea is categorized as "Type I" (i.e., reinforcing the idea that the white-beaked dolphin is acoustically more-closely related to the bottlenose dolphin than to porpoises).

Response: Upon re-evaluation, NMFS concurs that based on currently available data, it is more appropriate for the white-beaked dolphin to remain in the MF cetacean hearing group. The scientific support to move this species from MF to HF cetaceans is not to the level of that of two other members of the genus Lagenorhynchus Peale's and hourglass dolphins. (Note: In the Navy's justification above, Ketten (2000) did not analyze white-beaked dolphin cochlea but instead Pacific and Atlantic white-sided dolphins (also members of the genus Lagenorhynchus)).

Comment 64: The Commission supported NMFS' decision to include the newly published audiogram of a harbor porpoise (Kastelein et al., 2015) in the March 2016 Proposed Changes document. However, other commenters indicated that NMFS provided incomplete information on this dataset making it impossible to conduct a meaningful comparison to the July 2015 Draft Guidance.

Response: NMFS disagrees that incomplete information was provided in the March 2016 Proposed Changes document associated with the addition of a newly published harbor porpoise audiogram (Kastelein et al., 2015). The addition of this audiogram did not change the fundamental methodology associated with the Guidance (i.e., Appendix A), rather it only added a

newly available dataset, as will be the case as new data become available in the future.

Pinniped Hearing and Auditory Weighting Functions

Comment 65: NMFS received a comment indicating that there are not enough data to establish two separate weighting functions for pinnipeds.

Response: NMFS disagrees. There are audiogram data available from three species (eight individuals) of OW pinnipeds and four species (eight individuals) of PW pinnipeds. Further, based on NMFS' review of the literature, phocid species have consistently demonstrated an extended frequency range of hearing compared to otariids, especially in the higher frequency range. This is believed to be because phocid ears are anatomically distinct from otariid ears in that phocids have larger, more dense middle ear ossicles, inflated auditory bulla, and larger portions of the inner ear (i.e., tympanic membrane, oval window, and round window), which make them more adapted for underwater hearing. If one examines the composite audiograms for these two pinniped groups, distinct differences appear, supporting NMFS' decision to establish two distinct pinniped hearing groups.

Comment 66: Numerous commenters questioned the justification for the removal of some of the pinniped datasets based on non-representative hearing in the March 2016 Proposed Changes document. The commenters noted that masking is a common issue with obtaining audiogram data for animals in captivity and indicated that NMFS must provide a specific explanation for why these particular datasets contain unique masking problems that are unlike the other datasets used in the Guidance. An additional commenter requested NMFS provide the exact procedures as to how and why it removed unrepresentative or outlier data from its datasets and consider that one reason for unrepresentative data is due to exposure to anthropogenic sound. Other commenters, including the Commission, were in favor of removing these

Response: Decisions to exclude data were based on comparison of the individual published audiograms and ambient noise characteristics with those for other individuals of the same or closely related species. The most common reasons for excluding an individual's data were abnormal audiograms featuring high-frequency hearing loss (typically seen in older animals) or "notches" in the audiogram,

or data collected in the presence of relatively high ambient noise which resulted in elevated thresholds. Excluding these data ensured that the composite audiograms were not artificially elevated, which could result in unrealistically high impact thresholds. NMFS disagrees that previous exposure to anthropogenic sources is the basis for deeming the datasets unrepresentative, since currently available audiograms are derived from captive individuals (i.e., there is no indication that anthropogenic sound in captivity is directly impacting auditory thresholds, other than via possible masking).

Comment 67: NMFS received several comments indicating that the proposed changes to the PW pinniped "a" parameter, which defines the slope of the low-frequency portion of the weighting function, were arbitrary and unsupported. Additionally, a commenter noted an inconsistency in this parameter (i.e., "a" parameter value provided did not seem to match what was depicted on the PW pinniped weighting function). Finally, the commenters criticized that the March 2016 Proposed Changes document illustrated (Figure PC5) that the PW exposure functions was only based on one data point.

Response: The PW pinniped "a" parameter is directly derived from PW pinniped behavioral audiograms (8 individuals of 4 species). Additionally, the 2016 Proposed Changes document removed unrepresentative datasets, which resulted in a steeper slope ("a" = 1.0) compared to the 2015 Draft Guidance ("a" = 0.8).

Upon re-evaluation, NMFS agrees that there was a slight discrepancy with the "a" parameter depicted in the weighting function provided for PW pinnipeds in the March 2016 Proposed Changes document. This has been remedied with the correct value portrayed for this hearing group's auditory weighting function.

Finally, the March 2016 Proposed Changes document (Figure PC5) illustrates available TTS data for all hearing groups. NMFS agrees that data are limited particularly for PW pinnipeds (i.e., two TTS onset data points). Nevertheless, it should be noted that the exposure/weighting functions are not merely based on TTS onset data but also incorporate available audiogram data each for hearing group.

Comment 68: A commenter questioned if there was an error in Appendix A, specifically with the bestfit parameters associated with the derivation of the composite audiogram (original and normalized data) for PW

pinnipeds in Table A4. These tables indicate an unusually high " F_1 " value (excess of 300 kHz) and an anomalous " T_0 " value of negative decibels.

Response: Upon re-evaluation, NMFS determined that the best-fit parameters for PW are not anomalous or in error. These parameters mentioned by the commenter are merely fitting parameters for equation 9 in Appendix A and do not directly correspond to a particular feature of the audiogram (i.e., F_1 does not represent the frequency at which the audiogram reaches a specific value). The value for F_1 influences the frequency at which thresholds begin to plateau near the best sensitivity. Very large values for F_1 (and the accompanying small value for T_0) simply reflect little or no plateau in the thresholds in the region of best sensitivity. In many respects, the specific numeric values applied to Equation 9 in Appendix A of Technical Guidance are not key; what matters are the resulting shapes of the composite audiograms and how well they match the underlying threshold data.

Comment 69: One commenter suggested that the two species of PW pinnipeds (i.e., harbor seal and northern elephant seal) mentioned in the Guidance are commonly found in close proximity to human population centers and are not good proxies for Arctic and Antarctic seals.

Response: The Technical Guidance relies on more data than from harbor seal and northern elephant seal. Additionally data from two Arctic species (spotted seal from Sills et al. (2014) and ringed seal from Sills et al. (2015)) were used to derive composite audiogram for PW pinnipeds. Thus, data from four different PW pinniped species were used to derive composite audiograms for this hearing group. NMFS believes currently available data are representative of all PW pinnipeds, including polar species.

Application of Auditory Weighting **Functions**

Comment 70: One commenter requested that NMFS provide additional clarification as how the auditory weighting functions were applied to the data used to develop acoustic thresholds (e.g., were the auditory weighting functions applied to the entire raw data before calculating the SEL_{cum}) and examples of software that could be used to apply these weighting functions.

Response: Marine mammal auditory weighting were directly incorporated in the derivation of thresholds associated with non-impulsive sounds and then were directly applied in the derivation of impulsive thresholds, since only limited data are available (Details in

Appendix A). Section 2.2.4 of the Technical Guidance (Main Document) provides more detail on how to implement/apply these weighting functions. For a source consisting of a single tone, the application of auditory weighting functions is a straight forward process (i.e., only single frequency to consider). For broadband sounds, the application is more complicated (i.e., must consider multiple frequencies), which is why NMFS included alternative weighting factor adjustments for when frequency weighting functions cannot be fully incorporated (Appendix D).

Comment 71: One commenter noted that the LF cetacean acoustic thresholds do not appear to be adjusted based on the LF cetacean auditory weighting functions and asked whether the threshold for LF cetaceans exposed to an airgun/watergun with most of its energy in their primary hearing band as measured in the experiment should be adjusted.

Response: Marine mammal TTS data for impulsive sources exist only for two hearing groups (i.e., MF and HF cetaceans). For other groups, alternative methodology was developed using MF and HF cetaceans as surrogate data and assuming the relationship between impulsive and non-impulsive thresholds is conserved among hearing groups (i.e., methodology resulted in a TTS onset threshold for impulsive sources that is 11 dB lower than the TTS threshold onset for non-impulsive sources). NMFS disagrees that any adjustment needs to be made to the LF cetacean acoustic thresholds. Weighting functions are also implemented in exposure modeling, which will take into account whether or not a sound falls within a hearing group's most susceptible frequency range.

Comment 72: A few commenters indicated that Tougaard et al. (2013) note that auditory weighing functions cannot themselves be "conservative" if applied in establishing and then implementing acoustic thresholds. To achieve a conservative approach, the commenters suggested the application of a more tailored function at the acoustic threshold determination stage in combination with a wider and more energy-inclusive function at the implementation stage. The commenters suggested that NMFS use a function normalized to a lower level (e.g., -3dB) for establishing acoustic thresholds, while using functions normalized to a higher level (e.g., 0 dB) for estimating the number of "takes" when implementing these thresholds. The commenters provided the example that JASCO Applied Sciences typically

incorporates a 3-dB precautionary adjustment in their propagation modeling to account for uncertainty.

Response: The Technical Guidance explains that auditory weighting functions are considered within both the data evaluation and implementation processes, as pointed out by Tougaard et al. (2013) (now published Tougaard et al., 2015). NMFS acknowledges that adjustments during the data evaluation process that result in a lower threshold could potentially translate to smaller isopleths, if a source has energy in frequencies outside a hearing groups most susceptible hearing range (i.e., weighting functions are essentially filters; their application results either in the same size or in smaller isopleths or the same or lower thresholds). Tougaard et al. (2015) provide some important factors for consideration when applying weighting functions in both the context of data evaluation and implementation. However, NMFS does not find it appropriate to normalize the Technical Guidance's acoustic thresholds, as suggested by the commenters, as there are no data to support doing so. Further, several conservative assumptions were applied to the derivation of acoustic thresholds to account for uncertainty and limited data (see Response to Comment 77). Finally, NMFS' application of auditory weighting functions is consistent with what has been done for humans (i.e., A-weighted thresholds used in conjunction with Aweighting during implementation).

As for the 3-dB adjustment JASCO Applied Sciences makes to the results of their propagation models, this adjustment is based on their best fit analysis, where 90 percent of all their measured values fall within 3 dB of the mean level (e.g., see any recent SSV reports from JASCO Applied Sciences, like Beland et al. (2013), for more details). NMFS used this same premise to re-examine the TTS onset thresholds for non-impulsive sources for data collected via both the preferred behavioral technique as well as AEP methodology, the next tier in our data hierarchy (the same analysis could not be done for impulsive sources, where data are limited to two studies). It was found that for all hearing groups, except PW pinnipeds, the TTS onset thresholds encompassed more than 90 percent of available TTS data (MF cetaceans, only two points below the onset threshold, with maximum point only 2 dB below), and in some situations 100 percent of TTS data (i.e., OW and HF cetaceans; although both these groups are data limited). For PW, which are also data limited, only one of the five available data points was below the TTS onset

threshold (i.e., 1 dB below the threshold). Thus, NMFS believes any further adjustments to the thresholds are unnecessary and that they provide realistic predictions, based on currently available data, of noise-induced hearing loss in marine mammals.

Temporary Threshold Shifts

Comment 73: One commenter cautioned that a 6 dB threshold shift may be appropriate for testing TTS but should not be confused with the level that is biologically important (e.g., 6 dB corresponds to a roughly 8-fold decrease in the volume in which biologically significant sounds can be detected through passive listening).

Response: The Technical Guidance considers a threshold shift of 6 dB the minimum threshold shift clearly larger than any day-to-day or session-tosession variation in a subject's normal hearing ability and is typically the minimum amount of threshold shift that can be differentiated in most experimental conditions (Schlundt et al., 2000; Finneran et al., 2000; Finneran et al., 2002). Similarly, for humans, NIOSH (1998) regards the range of audiometric testing variability to be approximately 5 dB. Because the Technical Guidance does not address the biological significance of passive listening, NMFS has set the onset of TTS at the lowest level that exceeds recorded variation and could be considered biologically significant.

Comment 74: One commenter noted that the Guidance appeared to use temporary threshold shift (TTS) when it may mean threshold shift (TS) and suggested that NMFS use terms consistently and clearly.

Another commenter requested the Guidance make clear that a threshold shift is a symptom of noise exposure rather than an impact (i.e., a manifestation of an anatomical alteration that deters or eliminates auditory responses). The commenter emphasized that impairments arise from other acoustic features associated with what the ear receives (i.e., not necessarily characteristics associated with the source), and there are multiple components to any received sound (e.g., received level, timing, intensity, sensitivity, time course, recovery period), all of which may act singly or in concert to impact an ear at any frequency and for any species, whether in air or water. As such, the commenter suggested the Guidance include a brief statement indicating the choice of using a threshold shift to assess the effects of noise on hearing is one driven by practicality (i.e., Guidance does not address all critical features associated

with impacts from sound, but there is an awareness and expectation that other features require investigation and that these may ultimately alter the thresholds according to their interplay and relative potential for harm).

Response: NMFS has revised the Technical Guidance to clearly distinguish between a threshold shift (temporary or permanent) as a term which indicates the increase in threshold of audibility (i.e., 6 dB for onset of TTS and 40 dB for onset of PTS) versus the exposure level (i.e., acoustic threshold) associated with that shift.

NMFS agrees that a threshold shift is a "symptom" rather than an "impact." However, in the context of the Technical Guidance and in terms of how the acoustic thresholds will be used, the term/concept of "impact" is one that readers of the document will be more familiar with. NMFS also agrees that features of the signal at the receiver are most important, but are often most difficult to determine. The Technical Guidance includes more information explaining when choices are based on considerations of practicality because of complexity and makes various research recommendations to address these issues (Appendix B).

Comment 75: Several commenters requested clarification on the application of TTS onset acoustic thresholds presented in the Guidance under NMFS' relevant statutes, including the Commission, which recommended all applicants be required to use the Guidance's TTS onset thresholds. The Commission requested further clarification on how the Guidance's TTS thresholds are to be implemented in conjunction with NMFS' generic RMS SPL 120/160 dB behavioral thresholds.

Response: The Technical Guidance sets forth the levels at which TTS and PTS onset are likely to occur. In this Federal Register Notice (Regulatory Context), we describe our current agency practice for assessing take and refer readers to that section (this information previously appeared in the Draft Guidance Regulatory Context section). In short, PTS onset is treated as Level A harassment under the MMPA and harm under the ESA (as well as injury under NMSA as administered by NOS' National Marine Sanctuary Program), and NMFS recommends using the Technical Guidance to estimate take from PTS exposures in regulatory compliance documents.

Regarding TTS, with the exception of underwater explosives (see Regulatory Context), NMFS does not currently recommend calculations of TTS exposures separate from assessments of Level B harassment or ESA harassment using the prior existing thresholds for enumerating behavioral takes. NMFS is in the process of evaluating behavioral effects thresholds and intends to develop related guidance for use in its regulatory processes. Because the effects in consideration when TTS is incurred are behavioral and temporary in nature, much like behavioral responses, we intend to address those effects in the context of regulatory compliance at that time.

Comment 76: Multiple commenters indicated an inconsistency in the Guidance in the characterization of TTS among NOAA's various statutes (i.e., NMFS collectively does not consider TTS an auditory injury, but TTS is considered injury under the broad definition of the NMSA) and suggested NOAA implement a consistent regulatory interpretation of the term injure when addressing acoustic exposures on marine mammals.

Response: The Guidance is a technical document that compiles, interprets, and synthesizes the scientific literature, to produce updated, scientifically-based, impact thresholds for assessing the effects of noise on hearing. Although these changes may necessitate new methodologies for calculating impacts, the application of the thresholds under applicable statutes remains consistent with past and current NMFS practice. See Regulatory Context section in this Federal Register Notice. That information was moved out of the main body of the Guidance to emphasize the distinction between the scientific exercise of developing updated thresholds, which is science-based, and the application of thresholds in the regulatory arena, which is also informed by policy and legal considerations.

Comment 77: Multiple commenters recommended that NMFS consider threshold shifts requiring extended recovery periods (e.g., in excess of 24 hours), as well as nerve and other related damage, to be included in the definition of injury. The commenters expressed concern that NMFS did not consider the results of Kujawa and Liberman (2009) and Lin et al. (2011), and suggested the Guidance state that the PTS acoustic thresholds will be conservatively revised in the future to reflect any new evidence showing correlations of injurious effects of TTS below these new acoustic thresholds.

Response: NMFS recognizes this is an area where additional study is needed. NMFS has included several conservative assumptions in its protocol for examining marine mammal hearing loss data (e.g., using a 6 dB threshold

shift to represent TTS onset, not directly accounting for exposure levels that did not result in threshold shifts, assuming there is no recovery with the 24-h baseline accumulation period or between intermittent exposures, etc.).

The Technical Guidance includes information from Kujawa and Liberman (2009) and Lin et al. (2011) as a way to illustrate the complexity associated with noise-induced hearing loss and as an area where more research is needed (Appendix B). NMFS finds that these studies would be informative for use as qualitative considerations within the comprehensive effects analysis. NMFS acknowledges the complexity of sound exposure on the nervous system, and will re-examine this issue as more data become available.

Comment 78: One commenter indicated that in Germany, TTS is considered the onset of injury. The commenter suggested that since many countries may adopt this Guidance rather than developing their own, NMFS make clear that choosing PTS as onset for injury is based on U.S. legal considerations.

Response: This Federal Register Notice contains a section explaining the current U.S. regulatory context for using the acoustic thresholds contained in the Technical Guidance.

Comment 79: Several commenters indicated that chronic, repeated exposures to levels capable of inducing TTS can lead to PTS and recommended that NMFS consider cumulative effects of all anthropogenic sound sources in terms of long-term exposure in the development of the Guidance's acoustic thresholds, as well as within the context of NEPA. Specifically, it was suggested that, apart from the accumulation time applied to any single activity (i.e., acoustic thresholds), NMFS add repeated, intermittent exposure to multiple acoustic activities to its table of "qualitative factors for consideration."

Response: NMFS acknowledges that cumulative effects and long-term exposure of noise are important considerations in understanding the impacts of sound on marine mammals and that repeated exposures initially resulting in TTS have the potential to result in PTS. However, they are beyond the scope of this document, in terms of developing quantitative acoustic thresholds and are being considered by other mechanisms within or supported by NOAA (e.g., NOAA Ocean Noise Strategy and CetSound Projects; National Research Council's Ocean Studies Board's Cumulative Effects of Human Activities on Marine Mammal Populations Study). The Technical Guidance focuses on acute exposures to

noise and threshold shifts associated with these types of exposures. Additionally, the TTS data currently available for marine mammals only support deriving thresholds for these types of short-term exposures, rather than long-term/chronic exposure. Having data to address more realistic exposure scenarios, including repeated exposures, have been identified within our Research Recommendation Appendix (Appendix B).

NMFS has added cumulative exposures to its recommended qualitative factors to consider within a comprehensive effects analysis. The discussion of qualitative factors has been moved from the main Guidance document to Appendix B (See Response to Comment 130).

Comment 80: One commenter recommended that since seismic activities do not cause PTS and TTS "during realistic field conditions," there is no need to apply the new PTS and TTS acoustic thresholds levels in the Guidance to these activities.

Response: NMFS notes that the only marine mammal TTS data available are from laboratory studies, and that there are no TTS data available for any sound source in more realistic field conditions. Nevertheless, marine mammal laboratory studies offer vital information on exposure situations that can result in noise-induced threshold shifts, and NMFS used this information to establish acoustic thresholds for free-ranging animals exposed to anthropogenic sound sources in their natural environment. NMFS is not aware of any evidence to indicate that seismic sound sources should be treated differently than any other anthropogenic sound

Uncertainty and Statistical Analyses Associated With Temporary Threshold Shift Data

Comment 81: Several commenters suggested that where a potential for uncertainty exists NMFS should proceed cautiously and consider adjustments to thresholds that are most protective of the animals. One commenter specifically urged NMFS to consider the precautionary principle within the Guidance and NOAA's need to comply with its own statutes.

Response: The Technical Guidance identifies areas of uncertainty and data limitations (Appendix A) and has made several conservative assumptions to account for this (e.g., defining TTS onset as the level just above where individual variability in hearing occurs, not accounting for exposures where TTS onset did not occur, etc.). See Response to Comment 49 for more details on the

issue of uncertainty. Additionally, a Research Recommendations section has been added to identify data gaps (Appendix B). As more data become available, NMFS can explore more sophisticated means of analysis.

As previously indicated, the acoustic thresholds do not represent the entirety of an effects analysis, but rather serve as one tool to help evaluate the effects of a proposed action and make findings required by NOAA's various statutes. Further, other measures can be employed to account for uncertainty beyond considerations within the Technical Guidance (e.g., mitigation/ monitoring requirements).

Comment 82: Multiple commenters recommended that the procedures for establishing acoustic thresholds be revised to use the lowest available value or correction factor to account for the full representation of the distribution of TTS/PTS onset in a population rather than using the median value if five or more data points are available. Specifically, commenters expressed concern that NMFS is producing a threshold closer to the population mean (i.e., the point at which the first "take" is estimated to occur is roughly 50 percent of any given population will have already experienced a threshold shift) by relying on the median value. These commenters suggested that NMFS investigate statistical methods that deal with probabilities and distributions (e.g., Bayesian statistics), which particularly account for individual variability and uncertainty over the mean of threshold shift onset. These commenters further indicated that these statistical methods or a simple less precise alternative where the lowest reported TTS onset value was always selected (instead of the median) would likely provide a more appropriate estimation of TTS/PTS onset for a given proportion of the population.

Contrary to the comments above, another commenter cautioned against relying on the lowest onset with limited data because these data could be outliers and result in overly conservative acoustic thresholds. The commenter further indicated that overly conservative thresholds could result in unrealistic exposure estimates and suggested NMFS' protocol be modified to examine the distribution of the data and make a reasoned decision about whether the lowest threshold might be an outlier and whether (and how) it should be included in the determination of a threshold.

Response: NMFS incorporated several conservative assumptions into the derivation of the acoustic thresholds to account for uncertainty and variability

(see Response to Comment 77). The comment's reference to use of a median value if five or more data points are available refers to proposed methodology from the 2013 Draft Guidance. The 2015 Draft Guidance contained updated methodology for deriving TTS/PTS onset acoustic thresholds which better account for available marine mammal data (see Response to Comment 72).

NMFS used the best available science to develop the Technical Guidance. As more data are collected, NMFS will be better able to identify outliers (e.g., one individual has an unusually high or low threshold or testing procedures led to flawed results) and consider necessary adjustments (i.e., removal of an outlier datum).

Comment 83: Multiple commenters expressed concern associated with the Guidance's low acoustic thresholds for the HF cetacean hearing group. Specifically, the commenters indicated that for impulsive sound, the thresholds are based on data from a single study involving a single animal (harbor porpoise) (Lucke et al., 2009), and for non-impulsive sound, the threshold is based on a single study involving only two animals (Popov et al., 2011). The commenters remarked that both studies have potential biases and uncertainty and urged NMFS to allow for flexibility in the implementation of acoustic thresholds in future regulatory processes.

Response: NMFS acknowledges that, for most hearing groups, data are available only from a limited number of species and a limited number of individuals within that species. The need for more data from all species is highlighted in the newly added Research Recommendation section of the Technical Guidance (Appendix B).

In addition, new data have become available since the NMFS received this comment during the first public comment period. As indicated in the Technical Guidance, the acoustic threshold (SEL_{cum} metric) for HF cetaceans exposed to non-impulsive sound was derived using data from three studies (i.e., Kastelein et al., 2012, Kastelein et al., 2014a, and Kastelein et al., 2014b, not Popov et al., 2011a, which did not derive TTS onset and relied on AEP methodology). These new studies support results from Lucke et al. 2009 indicating that harbor porpoises have a lower TTS onset than other cetaceans (i.e., reason for separating MF and HF cetaceans into separate hearing

NMFS recognizes that acoustic thresholds for HF cetaceans, which are based exclusively from harbor porpoise data, are much lower than other hearing groups, and therefore some additional considerations may be warranted on a case-by-case basis. However, it also should be noted that auditory weighting functions should be considered when evaluating impacts of sound on HF cetaceans, which are most susceptible to injury from higher frequency sounds (e.g., 25 to 60 kHz).

Comment 84: Multiple commenters recommended a precautionary approach (i.e., more conservative thresholds) when applying the Guidance to activities and species in the Arctic.

Response: NMFS recognizes that marine mammals in the Arctic are experiencing increasing pressures from human activities (e.g., climate change, increased commercial activities). However, NMFS does not find that there are data to indicate greater susceptibility of Arctic species to noise-induced hearing loss compared to non-Arctic species. Data from two Arctic species (spotted seal from Sills et al., 2014 and ringed seal from Sills et al., 2015) were used to derive composite audiograms for PW pinnipeds. Additionally, measured underwater hearing of two captive spotted seals (Sills et al., 2014) and two captive ringed seals (Sills et al., 2015) found these species' hearing abilities are comparable to harbor seals. Thus, harbor seals (i.e., only phocid with TTS data are available) are believed to be an appropriate surrogate for ice seal species.

Further, audiogram data from belugas (n=9; more individuals of this species than any other) were specifically used to derive composite audiograms for MF cetaceans. In addition, recent data from Castellote et al. (2014), from freeranging belugas in Alaska, indicate of the seven individuals tested (3 females/ 4 males; 1 subadult/6 adults), all had hearing abilities "similar to those of belugas measured in zoological settings." Thus, from this study, it appears that for baseline hearing measurements, captive individuals are an appropriate surrogate for free-ranging animals. The Technical Guidance also incorporates TTS data (i.e., TTS onset and TTS growth rate) are available from four individual belugas (e.g., Schlundt et al., 2000; Popov et al., 2014)

Thus, data from Arctic species are directly incorporated into numerous aspects of the Technical Guidance's methodology. These data indicate additional conservative adjustments in determining thresholds unnecessary. Precautionary adjustments may be made elsewhere (e.g., applied in a specific regulatory context of fully evaluating effects, authorizing, and developing mitigation for an action).

Cetacean Temporary Threshold Shift Data

Comment 85: There was concerned expressed that the low TTS onset thresholds for HF cetaceans exposed to impulsive sources results from a AEP study, opposed to one using behavioral methods, and that this violates the methodology of only using behavioral data stipulated in Appendix A of the Guidance. Contrary to this comment, multiple commenters advocated for the inclusion of TTS data derived using AEPs into the Guidance's methodology.

Response: As mentioned in earlier, NMFS established an informal data hierarchy in consideration of the development of the Technical Guidance's composite audiograms and acoustic thresholds (see Response to Comment 43), with the bestrepresentative data being used over other sources. In the case of deriving TTS acoustic thresholds for HF cetaceans, only one dataset is currently available (Lucke et al., 2009), which relies on AEP measurements. Appendix A specifically addresses this issue: "Note that the data from Lucke et al. (2009) are based on AEP measurements and may thus under-estimate TTS onset; however, they are used here because of the very limited nature of the impulse TTS data for marine mammals and the likelihood that the high-frequency cetaceans are more susceptible than the mid-frequency cetaceans (i.e., use of the mid-frequency cetacean value is not appropriate).

There have been limited comparisons of TTS data collected via behavioral versus AEP methods for any marine mammals, especially marine mammals. There is only one available marine mammal study (Finneran et al., 2007) that found threshold shifts of 40 to 45 dB associated with AEP methods and 19 to 33 dB thresholds shifts measured via behavioral methods. These two methodologies do not provide the same results (i.e., AEP methods consistently produce higher thresholds compared to behavioral techniques), and there is currently no accurate means available to "correct" AEP data so that it can be more comparable to those obtained via behavioral techniques.

Comment 86: One commenter requested the Guidance provide additional clarification on the TTS PK acoustic threshold of 224 dB for MF cetaceans and suggested a 226 dB value be used instead, as is cited in Finneran et al. (2002).

Response: NMFS notes the Guidance's MF cetacean TTS onset PK threshold is based on the pressure levels originally expressed as pounds per square inch

(psi) presented in Finneran *et al.* (2002). This value was then converted from psi to peak pressure levels (*i.e.*, 23 psi is equivalent to PK 224 dB). The PK 226 dB, referred to by the commenter, was a peak-to-peak pressure level and not a peak pressure level (*i.e.*, different metric), which was why it was not directly applied to the Technical Guidance.

Comment 87: The Commission recommended that instead of using the MF cetaceans' PK thresholds as surrogates for other hearing groups where no data are available that NMFS consider dynamic range (i.e., difference between threshold at frequency of best hearing sensitivity and peak pressure threshold) for deriving peak pressure thresholds, as has been used for humans (e.g., 140 dB from Occupational Safety and Health Administration, OSHA). The Commission specifically suggested NMFS apply the measured dynamic range from HF cetaceans to the derive thresholds for LF cetaceans, PW pinnipeds, and OW pinnipeds.

Contrary to the Commission's recommendation, several commenters criticized NMFS' use of dynamic range to predict PK thresholds. Specifically, commenters questioned NMFS use of onset TTS to define dynamic range, since the onset of TTS is not equivalent to the threshold of pain and therefore overly conservative (i.e., different between TTS onset and PTS is approximately 40 dB). Additionally, these commenters indicated that dynamic range data are available for both pinniped hearing groups (Kastak et al., 2005) and should be used instead of surrogate data from MF and HF cetaceans.

Additionally, one group of commenters requested NMFS provide more information on why the median dynamic range for MF and HF cetaceans was used as a surrogate for LF cetaceans.

Response: NMFS evaluated the Commission's recommendation of an alternative methodology for deriving PK thresholds using dynamic range and determined that it is a more valid approach to approximating PK thresholds for hearing groups where no data exist. However, NMFS determined that using the dynamic range for HF cetaceans for other hearing groups was not appropriate and instead used the median of the dynamic range from both MF and HF cetaceans to derive PK thresholds for PW and OW pinnipeds and LF cetaceans.

As for comments criticizing the Technical Guidance's methodology for establishing PK thresholds based on dynamic range, NMFS notes that "dynamic range" can have many connotations. In the Technical Guidance, we relate hearing threshold and TTS onset levels, and therefore define dynamic range based on hearing threshold and TTS onset. Furthermore, NMFS does consider a 40 dB threshold shift to represent the PTS onset and uses this value to approximate PTS onset thresholds from available TTS onset data (i.e., TTS growth rate data). NMFS re-evaluated data within Kastak et al. (2005) to consider for establishing PK pressure thresholds for pinnipeds, rather than using surrogate MF and HF cetacean data. Within this publication, NMFS could not find any information on dynamic range for pinnipeds or any other publication that provides impulsive data for pinnipeds. Therefore, dynamic range cannot be directly calculated for pinnipeds and surrogate data had to be used.

As for the request for more information on why a surrogate dynamic range from MF and HF cetacean data was used for LF cetaceans, NMFS relied on the methodology used in other situations to derive surrogate values for species groups where data do not exist (i.e., use data from other hearing groups, assuming groups where data are not available fall within the bounds of existing marine mammal data). Until data become available for these hearing groups, NMFS believes this method is an appropriate means of deriving surrogate values.

Comment 88: Multiple commenters expressed concern that the Guidance excludes studies in which TTS was not induced, and that, as a result, the acoustic thresholds could represent exposure scenarios that will not necessarily result in TTS under all conditions. The commenters suggested that Guidance's thresholds should only be used to estimate the number of animals that could potentially experience TTS (i.e., acoustic exposure levels describe potential and not actual TTS onset for all exposure scenarios) and that exposures not inducing TTS be directly included and used to develop the Guidance's acoustic thresholds. The commenters stressed that this distinction is important because the Draft Guidance defines TTS, not "potential TTS," as Level B harassment and that how Level B harassment is estimated has important relevance to the "small numbers" and "negligible impact" determinations that must be made in support of MMPA incidental take authorizations.

Response: The Technical Guidance itself does not rely upon or address regulatory practice or interpretations. The section of the Draft Guidance that

discussed application of thresholds in the regulatory context for informational purposes has been more appropriately placed in this Federal Register Notice (see Regulatory Context). However, to account for uncertainty and limited data, the Technical Guidance used a conservative protocol to estimate the onset of TTS (see Response to Comment 77). NMFS agrees that exposure scenarios where TTS could not be induced are not directly accounted for in the development of the quantitative acoustic thresholds. Nevertheless, in some situations, studies where TTS could not be induced are used to evaluate (cross-check) the Guidance thresholds (e.g., HF cetacean pile driving data; MF cetacean seismic airgun data, MF cetacean explosion simulator data). As more data become available, NMFS may explore alternative means of deriving acoustic thresholds (e.g., protocol that directly accounts for scenarios when threshold shifts do and do not occur).

Comment 89: The Commission indicated that TTS data have not been collected for either HF or MF cetaceans below 1 kHz. Further, they recommend that measurements of TTS frequencies lower than 1 kHz and TTS measurements associated with exposure to multiple pulses/hammers strikes be added the Guidance's Research Recommendations (Appendix B).

Response: Although limited, TTS data have been collected at frequencies below 1 kHz for HF and MF cetaceans. Finneran et al. (2015) exposed bottlenose dolphins (MF cetaceans) to multiple impulses from seismic airguns measured TTS at a range of frequencies (0.5 to 64 kHz) for three individuals (see Figure 6 in Finneran et al., 2015b). Additionally, Kastelein et al. (2015) exposed a harbor porpoise (HF cetacean) to playbacks of offshore pile driving and measured TTS at a range of frequencies from 0.5 to 125 kHz. Finally, Kastelein et al. (2014) exposed harbor porpoise (HF cetaceans) to 1 to 2 kHz sonar sweeps and measured TTS at 1.5 kHz. NMFS agrees with the Commission's recommendations for additional research and has added them to Appendix B of the Guidance (i.e., Sound Exposure to More Realistic Scenarios).

Pinniped Temporary Threshold Shift Data

Comment 90: One commenter remarked that pinnipeds are likely to be less sensitive to noise compared to cetaceans and expressed concern that the Guidance's extrapolations using cetaceans as surrogates for pinnipeds may be flawed. Given the current lack of information, the commenter

suggested the highest threshold values from any of the cetacean hearing groups (and not any higher) be used to establish the underwater acoustic thresholds for pinnipeds.

Response: In establishing the pinniped thresholds, NMFS used the best available data (i.e., non-impulsive TTS thresholds are based on measurements collected from three individual harbor seals and a single California sea lion) and acknowledges that in some situations where no pinniped data were available, cetacean data were used as surrogate data to derive acoustic thresholds for pinnipeds. As an example, for PK thresholds, data from MF cetaceans and HF cetaceans were used to determine an appropriate dynamic range for pinnipeds, but this surrogate dynamic range was then combined with direct data on hearing thresholds from pinnipeds to derive these thresholds (i.e., combination of pinniped and other marine mammal data). As more direct pinniped data become available, NMFS will re-evaluate these acoustic thresholds. This has specifically been identified as a data gap within the Research Recommendation Appendix (Appendix B) of the Technical Guidance.

Comment 91: A commenter expressed concern that the thresholds for OW pinnipeds were much higher than other hearing groups, especially that the SEL_{cum} thresholds are not much lower than the PK threshold. It was indicated that these values appear anomalous and should be verified.

Response: NMFS re-evaluated the data used to derive the OW pinniped acoustic thresholds. There are only limited data available for this hearing group, with TTS onset thresholds for non-impulsive sources coming from a single California sea lion. This threshold is 18 dB higher than that for PW pinnipeds and at least 20+ dB higher than the thresholds for the cetacean hearing group. Additionally, with the updated methodology to estimate PK thresholds using dynamic range (2016 Proposed Changes document), the OW pinniped PK thresholds have increased by 2 dB compared to the thresholds in the 2015 Draft Guidance. Due to lack of data for OW pinnipeds, surrogate datasets or methodologies to approximate TTS onset for impulsive sounds and PTS onset levels had to be used. These approximations build upon the one data set available for OW pinnipeds. Thus, all the resulting thresholds are higher than those of other hearing groups. This has been highlighted within the Technical

Guidance's Appendix B: Research Recommendations.

Alternative Acoustic Thresholds (Optional Means To Incorporate Weighting Functions)

Comment 92: One commenter suggested that there is no justification or explanation for the process for alternative acoustic thresholds within the 2015 Draft Guidance and that attempts to compare the results of using these alternative thresholds seem to produce conservative (i.e., higher) levels of exposure when compared to the thresholds the encompass the full auditory weighting function.

Response: Based on public comment, NMFS re-evaluated its proposed alternative acoustic thresholds and replaced this methodology with optional weighting factor adjustments (WFAs) that more realistically incorporate marine mammal auditory weighting functions for all hearing groups (not just HF and MF cetaceans) and allow for all action proponents to use the same acoustic thresholds.

NMFS has included additional explanation in the final Technical Guidance's Appendix D. For situations where the full auditory weighting functions cannot be incorporated, updated weighting factor adjustments are provided, which are based on broader, simpler consideration of weighting functions (i.e., relies on using a single frequency that best represents where a particular sound has energy). Incorporating optional WFAs should result in similar if not identical isopleths for narrowband sources and slightly more conservative isopleths (albeit more realistic than the previous alternative threshold methodology) for broadband sources compared to those action proponents that can fully incorporate the Technical Guidance's auditory weighting functions.

Comment 93: The Commission questioned the utility of two sets of thresholds in the Guidance (i.e., weighted and unweighted), noting that if an action proponent can calculate or determine the isopleths (distances) to the relevant thresholds (weighted or unweighted) then that same action proponent should be able to apply the auditory weighting functions. The Commission suggested that NMFS require action proponents to use the best available science, including auditory weighting functions and relevant weighted thresholds, rather than give action proponents the choice of using unweighted thresholds.

Response: NMFS notes that the updated optional WFAs, which replace the Draft Guidance alternative

thresholds, are provided for action proponents unable to fully incorporate auditory weighting functions. This is because, especially for broadband sources (which most anthropogenic sources are), this incorporation is not a simple calculation (*i.e.*, it depends upon the spectrum of the source). NMFS regards the practicality of applying more complex, updated thresholds an important consideration. This is why NMFS has provided the simpler optional WFA approach, which allows action proponents to apply weighting in a simpler manner (i.e., most appropriate single frequency). The use of WFAs results in all action proponents using on the same thresholds.

Comment 94: Several commenters suggested that the Guidance provide clear direction on which thresholds should be used and under what specific circumstances. Further, multiple commenters noted that the Guidance's alternative thresholds (updated WFAs in final Technical Guidance) represent a simple and conservative way to present the thresholds and recommended that they be applied to all action proponents. Doing so, the commenters suggested, would simplify implementation for all authorization action proponents, as well as those processing and reviewing the applications, including the associated public comment by increasing transparency and reducing application processing time.

Response: As indicated in the Response to the previous comment, alternative thresholds have been removed from the final Technical Guidance, such that all action proponents are using identical thresholds, regardless of their ability to incorporated marine mammal weighting functions. NMFS appreciates the need for clarity and has included more information in the final Technical Guidance's Appendix D regarding when optional WFAs should be used. Specifically, text has been added to indicate that NMFS recognizes that the implementation of marine mammal auditory weighting functions represents a new and complicating factor for consideration, which may extend beyond the capabilities of some action proponents and that NMFS has developed optional WFAs for those who cannot fully apply weighting functions associated with the SEL_{cum} metric. Action proponents are encouraged to incorporate as many factors, like full auditory weighting functions, into their exposure models as possible.

Comment 95: One commenter suggested that NMFS include a more detailed definition of the term "narrowband," one that includes

explanatory text with regard to the derivation, terms and application within the Guidance. Additionally, it was pointed out that NMFS is incorrect to assume that narrowband sources will precisely adhere to manufacture specifications and that harmonics or subharmonics are unusual occurrences with these sources.

Response: NMFS agrees and has included additional clarification in the Technical Guidance regarding the derivation and application of WFAs in Appendix D (see Response to Comment 70). The term "bandwidth" is defined in the Glossary (Appendix E). Additionally, based on this comment, NMFS has revised the Technical Guidance to indicate harmonics and sub-harmonics are almost always present and should be considered when evaluating a source. The terms "harmonics" and "sub-harmonics" have also been added to the Glossary (Appendix E) of the Technical Guidance.

24-Hour Accumulation Period

Comment 96: One commenter suggested the Guidance's SEL_{cum} metric should require that the accumulation period be based on the time an animal is or could be exposed to the sound and not necessarily the time the noise

Along these same lines, the Commission noted that the accumulation period should account for the biology, ecology, and ecological setting (e.g., semi-enclosed bay, steepsided underwater canyon) of the affected animals and recommended that for activities that last at least 24 hours, NMFS consult with scientists and acousticians regarding the applicability of an accumulation time for species that occur in a confined or small geographic area during an extended period of time and for activities that may affect resident populations or marine mammals involved in certain behavior states (e.g., feeding, breeding/nursing, socializing). Several other commenters provided similar examples and made similar recommendations.

Response: NMFS agrees that the accumulation time associated with SEL_{cum} metric should be based on the time the animal is exposed, but notes that this can be exceedingly difficult if not impossible or practical to determine (i.e., an animal's movement can vary over space and time).

Further, NMFS acknowledges for exposure scenarios that occur in confined geographic areas with resident populations, case-specific modifications can be made, if appropriate, to the accumulation period to capture the

potential for extended exposure periods for these populations. Various factors could be considered, including consulting with scientists, if appropriate.

Comment 97: One commenter expressed concern that implementing a fixed accumulation period that is not based on physiology could have unintended consequences. The commenter provided the example of when an operation lasts for more than 24 hours, the use of a fixed 24-h accumulation period may result in animals being "taken" multiple times and that this may skew the risk assessment.

Response: The Technical Guidance focuses on predicting onset of PTS and TTS, including consideration of energy accumulation. In the regulatory context, NMFS acknowledges that the application of the updated acoustic thresholds for quantifying take could result in scenarios where an animal could be "taken" on multiple days (i.e., a stationary source near resident animals; mobile source continuing over multiple days), but this is no different from how take calculations are done under the current thresholds, nor should it skew the broader effects analysis. Ultimately, other factors would have to be taken into consideration within a comprehensive effect analysis, including if the same animals are exposed or "taken" on multiple days.

Comment 98: Several commenters recommended that the accumulation period encompass the entire duration of an activity and suggested NMFS revise the Technical Guidance to allow for the option of SEL_{cum} modeling for the duration of the activity, in order to allow action proponents the ability to utilize the approach with the smallest estimated number of marine mammal

exposures.

Response: NMFS determined the data currently available for deriving acoustic thresholds do not support an accumulation period beyond 24 hours (e.g., available marine mammal TTS data are only available for shorter duration exposures). Further, a key consideration in accurately accumulating exposure beyond the recommended 24-h period is the ability to accurately predict the location of the receiver relative to the source. Again, the understanding of marine mammal distribution and movement, especially during periods of sound exposure, is limited. These data limitations hamper the ability to make realistic exposure predictions for longer duration exposures. However, NMFS acknowledges that there may be specific exposure situations where this

accumulation period requires adjustment and will work with action proponents to make these adjustments (e.g., a resident population found in a small and/or confined area; continuous stationery activity nearby an area where marine mammals congregate, like a pinniped pupping beach). Finally, NMFS recommends use of the approach that produces the most accurate results for an activity (i.e., not necessarily the one that produces the smallest or largest number of exposures).

Comment 99: Multiple commenters requested clarification as to whether the Guidance accounts for the accumulation of sound from multiple activities in the same area and multiple sources/phases associated with a single activity. The commenters requested that an alternative method/metric be developed for multiple sources active in the same area at the same time (i.e., to better address cumulative exposure associated with the entire soundscape). Specifically, the Commission recommended that NMFS require action proponents use the Guidance thresholds for determining the relevant isopleths associated with activities that use multiple sound sources in the same area during the same timeframe (e.g., multibeam echosounders and subbottom profilers simultaneously with airguns during a seismic survey, various types of sonar and/or impulsive sources used simultaneously during a military exercise), rather than requiring action proponents to apply the thresholds to discrete sources used during a specific

Response: The Technical Guidance recommends application of the SEL_{cum} metric to assess the impacts of noise on hearing for individual activities/sources. Because current data available for deriving acoustic thresholds are based on exposure to only a single source, this metric is not intended for accumulating sound exposure from multiple activities occurring within the same area or over the same time or for multiple sources within a single activity. Currently, NMFS is unaware of alternative metrics available to assess the impacts of noise on hearing from multiple sound sources. As more data become available, NMFS can re-evaluate the use of this metric for application of exposure from multiple activities occurring in space and time. In other contexts, such as masking, which is expected to occur at much lower levels and much more likely to result from the contributions of multiple sources, NMFS is supporting efforts to better assess the impact of multiple sound sources on marine mammals (e.g., NOAA Ocean Noise Strategy and CetSound Projects; National Research

Council's Ocean Studies Board's Cumulative Effects of Human Activities on Marine Mammal Populations Study).

Comment 100: The Commission requested that NMFS provide additional guidance on how action proponents unable to incorporate moving sources should determine the total ensonified area (and consequently the number of "takes") and recommended that action proponents unable to model moving receivers and/or sources determined the total ensonified area based on a model accumulating the energy for 24 hours and then multiplying that ensonified area by the marine mammal density to determine the total number of "takes." The Commission's approach does not assume a constant distance from the source, but rather a total ensonified area associated with activity lasting 24 hours (or less if appropriate) and a uniform density.

Response: Instead of the approach recommended by the Commission, NMFS created a simple User Spreadsheet (released with Technical Guidance) to aid action proponents in determining the isopleth associated with their particular activity, if they are unable to employ more sophisticated modeling techniques. The updated simple methodology is based on the concept of "safe distance" presented in Sivle et al. (2014) for moving sources, with more details presented in Appendix D of the Guidance. The "safe distance" is equivalent to isopleths applicants have calculated in the past, with area and marine mammal exposures calculated by the same means (i.e., multiply isopleth times marine mammal density) applicants have used with NMFS' current thresholds (e.g., generic RMS SPL 180/190 dB).

Comment 101: One commenter requested clarification on several questions related to the modeling of exposures using more and less sophisticated methods: (1) Must a model be able to incorporate the movement of both the source and the receivers or at least the receiver? (2) How will NMFS determine whether an action proponent has the ability to model moving receivers or not? (3) What will be the difference between an action proponent employing more sophisticated modeling capabilities versus those with less sophisticated capabilities?

Response: An action proponent is responsible for determining their own modeling capabilities and, depending on the source and/or receiver, this might include movement or not in order to recreate the most realistic sourcereceiver separation (i.e., variation in spacing between source and receiver over space and time). While NMFS does

not require any particular models be used, they do evaluate the appropriateness of models and associated methodologies used in estimating acoustic exposures on a caseby-case basis in the context of a proposed activity. NMFS has provided an optional User Spreadsheet for action proponents unable to employ more sophisticated modeling on their own. Generally speaking, because it intentionally includes multiple conservative assumptions, we expect the simple, alternative method generally will result in higher estimates of PTSlevel exposure (which in turn will translate into higher take estimates). A comprehensive effects analysis for an action would take into consideration the fact that the alternative method results in overestimates.

Comment 102: Several commenters indicated that the Guidance needs to better address the potential of noiseinduced hearing loss from more continuous sources that operate 24 hours a day for multiple days (e.g., renewable energy wind farms/tidal operations; communication/navigation beacons). Additionally, a commenter urged NMFS to consider complementary devices operating synchronously in arrays as a continuous sound source, rather than discrete sources. This same commenter requested consideration for continuous noise sources having the potential to displace an animal from critical feeding habitat.

Response: In U.S. waters, NMFS is aware of very few sources with the potential of operating continuously (i.e., 24 hours a day, 7 days a week, yearround). However, renewable energy platforms have the capabilities for these types of continuous operations. NMFS acknowledges that continuous operations can result in higher potential for exposure accumulation, but the majority of renewable energy operations produce relatively low levels of sound (i.e., close to ambient, especially in environments conducive to wave or tidal devices; e.g., Coping et al., 2014; Schuster et al., 2015) that even over an accumulation period of 24-h are unlikely to exceed the PTS onset thresholds. As for the operation of communication/navigation beacons, these types of sources have a multitude of characteristics (e.g., source level, duty cycle, frequency band, beam width/ orientation) but generally have relatively short pulse lengths and produce higher frequencies (i.e., greater ability for sound to attenuate) reducing the likelihood of exposure resulting in cumulative effects. Finally, regarding the comment about displacing an animal from critical feeding habitat, the

Technical Guidance focuses on the effects of noise on marine mammal hearing and does not address displacement.

As previously addressed in a prior comment, because a sound operates 24-h a day does not necessarily mean a receiver is exposed to that source for that entire period (i.e., marine mammals are capable of moving vertically or horizontally in the water column) or that it is exposed to levels capable of inducing noise induced threshold shifts. In other words, having an accurate understanding of the spatial and temporal overlap between a source and receiver is important in being able to accurately predict exposures.

Recovery

Comment 103: Multiple commenters recommended that the Guidance consider data on marine mammal recovery from noise exposure.

Specifically, one commenter suggested the use of a "leaky-integrator model" that accumulates sound energy and account for potential physiological recovery in a time-dependent manner (described by a time constant). The commenter indicated that the value of the time constant(s) is not known but could be conservatively estimated.

Contrary to this comment, another commenter cautioned that recovery times have generally been measured only during quiet periods within laboratory settings and that in the open ocean, it is likely that free-ranging animals will be exposed to sound during the recovery period.

Response: Recovery is an important consideration in assessing the effects of noise on marine mammals, and the Technical Guidance includes general information on recovery. We also agree recovery in the open ocean is more complex than measured in a laboratory setting. Currently, there are not enough data to directly take recovery into consideration in the development of acoustic thresholds (and this is specifically identified as a research recommendation in Appendix B), including the integration of a "leaky-integrator model." As more data become available, NMFS can re-evaluate this issue. NMFS has provided additional text in the Technical Guidance to address why recovery was not directly considered in a quantitative manner. NMFS has also provided more clarification in the text regarding recovery and the Technical Guidance baseline accumulation period.

Comment 104: One commenter suggested that the Guidance's accumulation period be "reset" to zero only when there has been a sufficiently

long silent period (*i.e.*, not automatically after 24 hours). The commenter referred to NMFS' interim injury impact pile driving criteria for fishes, which assumes that accumulation from zero occurs only after a recovery period of 12 hours without sound exposure.

Response: NMFS' interim injury criteria for fishes pertain to smaller pile driving activities (i.e., primarily associated with construction) that only occur during daylight hours, where resetting the accumulation period and allowing for a 12-h recovery period is possible. However, some activities covered by the scope of this Technical Guidance continue for longer than 24 hours (e.g., seismic survey) and only resetting the accumulation after a sufficiently long silent period (i.e., 12 to 24 hours) is not feasible. The data currently available for deriving acoustic thresholds do not support an accumulation period beyond 24 hours, and accumulating over the entire activity duration (i.e., beyond 24 hours) could result in unrealistic exposure results (e.g., difficult to predict the temporal and spatial variability of a receivers over multiple days; see Response to Comment 79).

Comment 105: One commenter noted that if TTS and/or PTS are caused by build-up of free radicals in the hair cell synapses (e.g., McFadden et al., 2005), then exposure over extended periods must take the clearance rate of the free radicals into consideration. The commenter indicated that a 24-h period might be a reasonable approach based on human audiometry but that given the absence of sufficient marine mammal data, it may be necessary to consider SEL_{cum} over periods of greater than 24 hours in situations where sources are loudest (e.g., large seismic airgun surveys) and propagation loss is lowest.

Response: NMFS acknowledges there are a multitude of factors that affect recovery from noise-induced hearing loss, including clearance of free radicals, making recovery complex. Further, there is a lack of data, especially for marine mammals. That said, NMFS acknowledges there may be some situations where the accumulation period needs to be extended beyond 24 hours depending on case-specific scenarios. However, these should be exceptions and not the norm (i.e., proposed accumulations periods represent the typical exposure scenario; see Response to Comment 79).

Comment 106: Multiple commenters expressed concern that several of the recovery time lengths in the marine mammal TTS literature have been reported to exceed 24 hours and indicate the Guidance's acoustic thresholds may not be sufficiently conservative. Further, several commenters requested that NMFS consider recovery in terms of exposure to other stressors, since these stressors may exacerbate threshold shifts and/or recovery.

Response: NMFS acknowledges that recovery from noise exposure is extremely complex and depends on a multitude of factors, which is why recovery was not directly integrated into the Technical Guidance's recommended accumulation period or into the acoustic thresholds. As NMFS notes in the Technical Guidance, threshold shifts on the order of the established PTS onset (i.e., 40 dB) recorded in marine mammal laboratory studies have still resulted in recovery. Additionally, NMFS has made several conservative assumptions in the development of its acoustic thresholds (see Response to Comment 77). NMFS has added a research recommendation relating to examining noise under realistic exposure scenarios, including consideration of other stressors.

Comment 107: Several commenters suggested that the accumulation period allow for the consideration of periods of reduced or no sound (e.g., power-downs and line turns during seismic activities).

Response: NMFS agrees that power-downs associated with line turns (not associated with mitigation, which can be unpredictable) should be accounted for in modeling, particularly with the accumulation period (*i.e.*, total exposure period within a 24-h period, excluding periods when there is no exposure).

Appendix D: Alternative Methodology (Formerly Identified as the User Guide)

Comment 108: Several commenters indicated that the Guidance should not be finalized until the public has been given the opportunity to evaluate NMFS' user tools (i.e., having these tools is necessary to perform a thorough analysis of the Guidance).

Response: NMFS disagrees. See Response to Comment 3.

Comment 109: It was suggested by a commenter that an alternative method is unnecessary, as it is unlikely animals will remain close enough to a source to exceed the Guidance's SEL_{cum} thresholds (i.e., PK is anticipated to be the dominant metric, resulting in the largest isopleth for most, if not all situations).

Response: NMFS disagrees that the PK should be assumed to be the threshold resulting in the most conservative (i.e., largest) isopleth for most sources. Furthermore, as a result of public comment, NMFS decided to remove the PK thresholds for non-

impulsive sounds. For impulsive sounds, NMFS recommends an action proponent fully evaluate their sound source to determine which metric would be dominant. NMFS agrees it may be unlikely that animals would remain close to a source for extended periods of time in most exposure situations. However, predicting animal movement and distribution, especially during sound exposure scenarios, is difficult. Finally, NMFS recognizes that in updating our acoustic thresholds to reflect the best available science, they have become more complex. Thus, Appendix D provides a set of tools, examples, and weighting factor adjustments to allow action proponents with different levels of exposure modeling capabilities to reasonably approximate PTS onset, using the updated acoustic thresholds, for all sound sources.

Comment 110: Several commenters requested NMFS explain how the SEL_{cum} acoustic threshold should be used to determine if an auditory impact would occur. Commenters recommended more guidance on how this would be implemented for a couple of example projects (*i.e.* stationary source such as pile driving, and moving source such as seismic).

Response: Due to the diverse array of potential sound sources, it is impractical for NMFS to provide specific, detailed example calculations within the Technical Guidance. However, NMFS is providing a simple optional User Spreadsheet to aid action proponents unable to perform more sophisticated exposure modeling. This spreadsheet specifically provides a means of applying the Technical Guidance's thresholds and simplified weighting (WFAs) and calculates isopleths associated with thresholds expressed as SEL_{cum}. Thus, example calculations can be completed by using the optional User Spreadsheet. Those using more sophisticated models (e.g., animats) would presumably have some other means of accounting for cumulative exposure, like an "acoustic dosimeter," and would not necessarily need to determine a SEL_{cum} threshold distance (see Response to Comment

Comment 111: Concern was expressed by several commenters that the alternative methodology provided in Appendix D would limit flexibility to assess the impacts of noise on marine mammal hearing.

Response: Action proponents are not obligated to use the alternative methodology and may perform more sophisticated modeling or consider additional action- or location-specific

factors, if able. Thus, action proponents are given flexibility in terms of their exposure modeling.

Comment 112: Several commenters were concerned that the highly technical nature of the Guidance does not lend itself to direct and consistent application, particularly by non-experts and indicated that alternative methodology could result in more restrictive acoustic criteria for the smaller action proponents.

Response: NMFS has produced an associated simple optional User Spreadsheet that has been finalized with the Technical Guidance to assist stakeholders in applying the updated acoustic thresholds associated with the more complex SEL_{cum} thresholds, including tools to help those that cannot incorporate more complicated auditory weighting functions (see Response to Comments 70 and 100).

NMFS acknowledges that less sophisticated exposure models may result in higher exposure estimates because these models do not incorporate as many factors as more sophisticated models. Action proponents are encouraged to incorporate as many appropriate factors into their modeling as possible. An action proponent is not obligated to use the simpler tools provided by NMFS, if they can provide equally or more realistic exposure modeling on their own.

Comment 113: One commenter noted that the NMFS' West Coast Region provides a SEL_{cum} calculator for estimating impacts to fishes during impact pile driving, including the incorporation of an "effective quiet" value, and requested a similar calculator be provided for marine mammals. The commenter recommended a consistent process for accumulating energy and assessing impacts to all species under NMFS' purview.

Response: The Technical Guidance provides a similar $\operatorname{SEL_{cum}}$ calculator for marine mammals, but effective quiet will not be directly incorporated into the marine mammal calculator because NMFS determined there are not enough data at this time to do so. NMFS believes it is consistent in how it assesses acoustic impacts for the various species under its jurisdiction but, there may be exceptions that depend on various factors (e.g., species-specific considerations, data availability, etc.).

Model Specifications

Comment 114: Multiple commenters indicated that the Guidance suggests that a variety of model approaches could be employed in applying the Guidance's acoustic thresholds. Instead, the commenters suggested that NMFS

recommended standardized computer models or modeling requirements, which would allow regulators, industry, and the public to run repeatable analysis to verify acoustic data based on NMFS' recommendations. The commenters expressed concern that it is likely that both the current range of modeling vendor choices and their capacity will be inadequate to fulfill the agency's requirements, which could lead to unwarranted permitting delays or costs, and suggested a transition period to necessitate the expansion of the pool of adequate modeling expertise and vendors. Finally, a commenter recommended that NMFS undertake model validation/verification as part of the process of developing the final acoustic criteria.

Response: Providing standard computer models for analysis or modeling requirements associated with the application of the Technical Guidance's acoustic thresholds and/or auditory weighting functions, as well as model validation/verification, is beyond the scope of this exercise. The adequacy of models will depend on a multitude of factors, including the activity (source) and potential receivers. Because the updated acoustic thresholds are more complex, simpler alternatives have been provided (e.g., User Spreadsheet with weighting factor adjustments for those unable to fully incorporate auditory weighting functions), which can be used until the pool of adequate modeling expertise is expanded. Further, NMFS recognizes there will be a transition period before the Guidance is fully used. (See previous section in this Notice on Transitioning to the Technical Guidance).

Comment 115: The Commission recommended that the Guidance provide specifications necessary to perform exposure modeling. They indicate that it is NMFS' responsibility, as a regulatory agency, to make required findings and direct action proponents to the appropriate types of models, including inputs and appropriate factors to be considered within those models.

Response: NMFS does not currently provide modeling specifications and has no current plans to do so. NMFS will provide some technical assistance to prospective applicants who request it and will continue to evaluate the models that are used in submitted compliance documents to ensure they are adequate and appropriate.

Comment 116: The Commission commented on the two alternative models (i.e., one for moving sources and one for stationary sources) provided in the 2015 Draft Guidance Appendix D. Specifically, the Commission requested

that more information be provided whether the 3–D "safe distance" methodology of Sivle *et al.* (2014) for moving sources is applicable to NMFS' 2–D application specified in the Guidance. The Commission requests this aspect be submitted for peer review.

BOEM expressed concern that the methodology of Sivle *et al.* (2014) is not appropriate for directional sources or for receivers that are not at the same depth as the source (*e.g.*, sperm whales). The Guidance states that this methodology is independent of exposure duration, and BOEM states this is inconsistent with the document's recommendation of a 24-h baseline accumulation period. Further, BOEM recommended that this method include a representative depth typical of the species being modeled.

Response: NMFS reiterates that the two models referred by the Commission are alternative methods. Action proponents are not obligated to use these methods. Although Sivle *et al.* (2014) accounted for the depth of herring to determine the percent of the winter and summer populations exceeding the "safe distance" associated with exposure to naval sonar, the calculation of "safe distance" (i.e., equations in the Technical Guidance) makes minimal assumptions associated with the receiver (i.e., the receiver is stationary and does not exhibit avoidance or attraction to the source) and does not directly account for receiver depth or density. It only provides the distance from the source (i.e., isopleth) beyond which a threshold is exceeded. Thus, NMFS believes that this methodology is appropriate for 2-D applications. NMFS has added information about the assumptions associated with the receiver within the Technical Guidance for clarity. NMFS does not believe additional peer review is need for this aspect of the Technical Guidance because the methodology (Sivle et al., 2014) has already undergone peer review as part of its publication in ICES Journal of Marine Science.

Addressing concerns raised by BOEM. it is correct that the methods of Sivle et al. (2014) may not be representative for directional sources and are likely to result in more conservative exposures (i.e., model does not account for source directivity and isopleths produced assume an omnidirectional source; meaning that it produces an isopleth equal in all directions). However for directional sources, the source level parameter associated with this methodology assumes the values provided are those relating to the direction producing the maximum level. Again, this optional methodology does

not make any assumptions about the depth of the receiver: it only provides an isopleth associated with a particular acoustic threshold. It is possible that the depth of the receiver can accounted for in terms of depth-dependent density (i.e., percentage of time species is located at a particular depth). However, accounting for specific characteristics associated with the receiver (e.g., depth distribution, density, behavioral response, etc.) is beyond the scope of this document.

Finally, the reason this optional methodology is independent of exposure duration is because it only considers one pass of the source relative to receiver, with the closest points of approach incurring the greatest accumulation (i.e., once the source moves past the closest point of approach accumulation is only further reduced as the source moves farther and farther away). Accumulating past the recommended 24-h accumulation period does not result in the addition of any significant amount to the cumulative sound exposure of the receiver. The model can be adjusted to account for shorter accumulation periods. However, the equations become more complex and more difficult to implement.

Comment 117: Several commenters expressed concerns over a potential short-coming associated with the optional "safe distance" method (Sivle et al., 2014) accounting for cumulative exposure for moving sources, specifically its ability to allow only for the inclusion of spherical spreading as a propagation model. It was suggested that other propagation models, especially those more conservative spreading models associated with shallow water, need to be incorporated into this methodology. Related to this, BOEM indicated that the Guidance's "source factor" definitions closely resembled cylindrical spreading (10TL/10), rather than spherical spreading (10TL/20) and expressed a concern over whether Mean Squared Pressure (MSP) or Equivalent Plane Wave Intensity (EPWI) terms were used, and that the terms "S," " S_E ," and " E_0 " in the Guidance appear to have similar units, but they do not.

Additionally, these commenters provided an example to assess the appropriateness of the "safe distance" methodology by examining the modeled radii from four parallel passes, within a 24-h period, from a 3300 cubic inch airgun. Based on their modeling, it was suggested that NMFS lower thresholds for LF cetacean and PW pinnipeds, raise thresholds for HF cetaceans, and adjust the same distance methodology to

account for the number of passes within an area during a 24-h period. There was no detail provided by the commenter on what these adjustments should be.

Response: NMFS acknowledges the concerns and potential limitations of the optional "safe distance" methodology but believes other assumptions associated with this methodology ensure as a whole it remains precautionary. The incorporation of other types of spreading models results in a more complicated equation making the methodology less easy to implement. However, many mobile sources, like seismic airguns or sonar, produce sound that is highly-directional (i.e., most of time sound source is directed to the ocean floor, with less sound propagating horizontally, compared to the vertical direction), and directionality is not accounted for with this methodology (see Response to previous comment). Additionally, many higher-frequency sounds, like sonar, are also attenuated by absorption, which is also not taken into account in this methodology. Thus, there are other considerations beyond spherical spreading, including other conservative factors (i.e., simplified incorporation of auditory weighting factors, the receiver does not avoid the source, etc.) to consider when assessing whether the use of this optional methodology will result in a potential underestimate of exposure. Thus, despite these simple assumptions, NMFS believes the optional "safe distance" approach offers a better approximation of the sourcereceiver distance over space and time for various mobile sources than choosing a set accumulation period for all sources, which assumes a fixed source-receiver distance over that time, and encourages the development/ validation of alternative models, including the assessment optional models provided in the Technical Guidance (see Appendix B: Research Recommendations).

As for BOEM's comments regarding MSP vs. EPWI terms, by following ANSI definitions within the Guidance, NMFS is implicitly using MSP terms. The term "source factor" within the Guidance is based on a source level being defined as pressure squared, which why it may appear to resemble cylindrical spreading, rather than spherical spreading. This additional information was added to provide clarity. BOEM is correct that the terms "S," " S_E ," and " E_0 " that appear in the Technical Guidance do not have identical units. NMFS understands the potential confusion, since this information was not included in the 2015 July Draft Guidance. A section has been added in

Appendix D providing these units in the Technical Guidance (*i.e.*, See section 3.2.1.1 Linear Equivalents).

In response to the commenter's modeled example, NMFS disagrees with the appropriateness of this comparison. One of the assumptions associated with the optional "safe distance" methodology is that the source moves at a constant speed and in a constant direction. Thus, this model is not sophisticated enough to account for situations for multiple passes and should not be used for these situations (i.e., NMFS would recommend an action proponent in this situation to find a more appropriate means of modeling exposure, or work with NMFS to determine if the "safe distance" methodology can be appropriately modified to account for multiple passes from a source). Thus, it is not unexpected that there are several discrepancies between the commenter's modeled isopleths and those provided by the "safe distance" method, including the use of different weighting functions and thresholds, by the commenter, compared to those in the Technical Guidance. NMFS believes the Technical Guidance represents the best available science and disagrees that adjustments to the document's acoustic thresholds is supported.

Technical Guidance Implementation and Regulatory Context

Comment 118: One commenter recommended that the Guidance solely focus on providing the technical basis for acoustic thresholds (i.e., best available science) rather than containing substantial implementation language in the document. The commenter indicated that limiting the purpose of the Guidance to solely providing technical background would allow flexibility to incorporate new technologies and information as they become available.

Response: NMFS agrees and revised the title of the Guidance to reflect its technical, scientific nature. The Technical Guidance is a compilation, interpretation, and synthesis of the available literature. Application of the updated acoustic thresholds remains consistent with current NMFS practice. That information on regulatory context has been moved to this Notice. Any changes to application in the regulatory context are separate from the basis for updating the thresholds themselves, where advances in scientific knowledge are the drivers.

Comment 119: One commenter requested the Technical Guidance provide a brief reference to its use in the

current 14-question MMPA incidental take application.

Response: The Technical Guidance is a compilation, interpretation, and synthesis of the scientific literature on the impacts of sound on marine mammal hearing. There is no change to the use of thresholds in the regulatory context. No specific reference is required in our implementing regulations.

Comment 120: One commenter noted that the MMPA mandates that "Level A" harassment includes not only the actual or likely onset of injury, but also the potential for injury and that the ESA definition of "harm" encompasses temporary injuries or impairments that impact essential behavior. The commenter expressed concern that setting the threshold for "Level A" harassment under the MMPA and "harm" under the ESA at the actual onset of injury is inconsistent with the statutory mandates, which seek to protect against the risk of, or potential for, injury and recommended that NMFS must set a protective threshold in order to comply with its statutory mandates (i.e., one that interprets the existing literature conservatively enough to reflect the potentiality of harm).

Response: The Technical Guidance auditory impact thresholds were based on scientifically-based judgments, including accounting for uncertainty and variability, developed to stand independent of interpretations of statutory terms such as "take," "harm," and "harassment." At the same time, the thresholds were designed for use in NMFS' regulatory analyses.

NMFS incorporated several conservative assumptions in the development of the PTS onset thresholds to account for the potential for PTS onset (see Response to Comment 77). Further, there are several examples of marine mammal exposure exceeding the Guidance's PTS thresholds, where recovery has occurred (see recent review in Finneran 2015).

Comment 121: Several commenters provided examples of how the weighting function and thresholds compare to data collected in the field during SSV measurements (e.g., seismic and impact piled driving). The commenters' analysis operated on the assumption that the weighting functions and thresholds should provide equal results when compared to the weighting functions and thresholds in Southall et al. (2007), and argued that results stemming from the Guidance "did not yield the most reliable or cautionary results." In one example, it is stated that these comparisons are "at odds with the

reports of the sensitivity of beaked whales to pulsed sounds."

Response: NMFS appreciates the commenter's efforts to provide examples and comparisons using the Technical Guidance. However, we disagree that the Technical Guidance must yield similar results to those provided in Southall et al. (2007), since available data and methodology has significantly evolved since 2007. For example, marine mammal weighting functions (M-weighting) from Southall et al. (2007) were derived in a more simplistic manner than the updated methodology provided in Appendix A, which directly uses audiogram and TTS data to derive weighting functions. Thus, the Southall et al. (2007) M-weighting functions are broader than those provided in the Technical Guidance and would inherently result in larger, more conservative isopleths. Although the isopleths derived using the Technical Guidance results are smaller in comparison to those from Southall *et al.* (2007), they are not necessarily unreliable.

In addition, NMFS is aware that the Southall et al. (2007) panel is in the process of updating its paper. It is anticipated that their proposed weighting functions will not be as broad (most susceptible frequency range) as their original M-weighting functions (i.e., they will be more aligned with those presented in the Technical Guidance). Regarding beaked whale sensitivity, NMFS agrees these species are often classified as a "particularly sensitive" group, but in the context of behavioral responses. The Technical Guidance does not pertain to behavioral responses, only effects of noise on hearing. The assumption that this enhanced sensitivity carries over to hearing and susceptibility to noiseinduced hearing loss is currently unsupported by beaked whale AEP measurements (e.g., Finneran et al., 2009; Pacini et al.. 2011) or transmission pathway modeling (e.g., Cranford et al., 2008).

Comment 122: Several commenters remarked that the Guidance does not explain the anticipated impact of the acoustic thresholds on the regulated community. Because the Guidance will be applied in a range of regulatory actions, it was recommended that NMFS undertake a study comparing the assessment approach described in the Guidance with the current assessment methods to demonstrate the regulatory implications of the proposed acoustic thresholds.

Response: The Technical Guidance represents the culmination of a robust assessment of the scientific literature to derive updated, science-based auditory impact thresholds for marine mammals. The overall assessment approach in the regulatory context has not changed from current agency practice.

The acoustic thresholds presented in the Technical Guidance use different metrics compared to the current thresholds. In some situations, depending on the sound source, species of interest, and duration of exposure, application of the updated acoustic thresholds may result in greater estimates of PTS (and therefore more "takes") than under the existing thresholds, while in other situations the opposite result may occur. Examining all possible scenarios associated with the wide range of potential activities is not feasible.

Comment 123: Multiple commenters expressed concern that the Guidance will unnecessarily result in an increased burden to action proponents during the permitting process and would lead to an increased number of shutdowns or longer survey duration, with increased costs and safety risks.

Response: NMFS recognizes the advancing science on auditory impacts has led to more complex set of thresholds and methodology for evaluating impacts and has provided a simplified alternative methodology to alleviate some of the burden associated with applying the more complex acoustic thresholds and auditory weighting functions.

In terms of effects on activities themselves, the Guidance does not address consequences for mitigation requirements in a regulatory context. This will depend on the particular aspects of an action, taking into account the comprehensive effects analysis and regulatory considerations. NMFS notes that there are no requirements that mitigation measures directly correspond to acoustic thresholds (See Response to Comment 11).

Comment 124: One commenter expressed concern that applying the alternative methods provided in the Guidance could result in unrealistically high exposure estimates. The commenter recommended that the Guidance include more explanation to inform action proponents about the potential costs, benefits, and consequences of methodologies that directly use auditory weighting functions and those that do not (alternative methods).

Response: NMFS notes it will be an action proponent's decision as to how they model and estimate their potential impacts to marine mammals. Analyzing the potential cost/benefits of the methodologies applied is beyond the

scope of the document and will vary depending on the activity/sound source and species impacted. The optional WFAs provided in the Technical Guidance should assist action proponents with incorporating auditory weighting functions and should provide very similar (if not identical) results for narrow-band sources and larger isopleths for broadband sources, depending on how much information the action proponent can provide regarding the frequency composition of their source (i.e., can provide the 95 percent frequency contour percentile or rely on the more conservative default WFA values).

Comment 125: Multiple commenters requested more information on how NMFS will transition from previously applied thresholds to the acoustic thresholds provided in the Guidance (e.g., how will it affect applications/consultations completed, in process and beyond) and expressed concerned over the potential for delays and NMFS' time requirements to process permits based on the Guidance.

Further, one commenter remarked that NMFS' intention to update the acoustic thresholds based on newly available information is valid from a scientific point of view, but from a practical aspect could be confusing, could promote regulatory uncertainty, and has the potential to affect permitting timelines. The commenter indicated that planning for certain activities can take multiple years to complete, with the introduction of additional uncertainty potentially adversely affecting the ability of action proponents to plan for and comply with the Guidance.

Similarly, several commenters requested clarification as to how the Guidance would be implemented in (a) the context of a five-year incidental take regulation (ITR) (with specific take authorizations by letters of authorization (LOA)) and (b) when numerous IHAs are issued for a given area in the absence of an ITR. Specifically, a commenter asked if different methods will be used to estimate the amount of authorized incidental "take" in each of these contexts and how, if at all, will authorized "take" be allocated over certain periods of time in one or both of these contexts?

Response: NMFS acknowledges there will be some lag between updates in the best available information and the ability to incorporate that new information into ongoing processes. We refer readers to the section of this Notice addressing Transitioning to the

Technical Guidance for more information.

Comment 126: One commenter suggested that the Guidance provides an opportunity for NMFS to clarify its policy on "takes" vs. "animals taken." The commenter indicated that just because an animal is "exposed" to a sound source does not necessarily equate to a "take" or an impact as defined in the MMPA and provided the following example with migratory (e.g., 50 takes with individuals being taken once) vs. resident species (e.g., 50 takes with ten individuals being taken five time each). Similarly, a commenter requested that NMFS should clarify that, in estimating numbers of auditory impacts for management purposes, take numbers will be calculated for each day of exposure and then added to obtain the total estimate. For example, assuming an equal daily risk of eight exposures that exceed PTS thresholds for some species over a 10-day piledriving project, the total potential PTSlevel take would be 80 animals. The Navy has long employed this method of calculation, but its use by other applicants (e.g., seismic operators) has been inconsistent. Notably, this method would not account for multiple takes of individual marine mammals and the cumulative impact on hearing that would result from those takes.

Response: The Technical Guidance is designed for assessing the impact of underwater noise on marine mammal hearing by providing scientificallybased auditory weighting functions and acoustic thresholds. It does not address how to calculate takes in various situations. Those considerations are case-specific and based on multiple considerations, including spatial and temporal overlap between the sound source and a receiver). Moreover, factors like whether a marine mammal species or stock is migratory or resident (among numerous other factors), are considered within a broader comprehensive effects analysis when such information is available.

Comment 127: The Commission commented that the Guidance states that an alternative approach may be proposed (by federal agencies or other action proponents) and used if casespecific information or data indicate that the alternative approach is likely to produce a more accurate estimate of Level A Harassment, harm, or auditory injury for the proposed activities. Such a proposed alternative approach may be used if NMFS determines that the approach satisfies the requirements of the applicable statutes and regulations. The Commission noted that NMFS has not provided any criteria under which

such an exception could be invoked and is allowing action proponents to waive the Guidance's acoustic thresholds. The Commission does not support this approach and recommends that NMFS require all action proponents to implement the final acoustic thresholds until such time that they are amended or revised by NMFS.

Similar to the Commission's concerns, another commenter indicated any alternative approach must be at least as protective as methods prescribed in the Guidance, which have at least undergone peer review and public notice and comment. Alternatively, the commenter suggested that more conservative approaches should be used if a project's circumstances require a lower threshold for "take" based on specific factors, such as geographic region, oceanographic conditions, low abundance, species site fidelity, prey impacts or cumulative impacts.

Contrary to the comments above, a few commenters indicated that they welcome the opportunity for action proponents to propose alternative approaches to those presented in the Guidance. The commenters noted that this flexibility will enable innovation within the bounds of regulatory compliance and that are appropriate and justified (e.g., there are many ways to estimate potential exposures of marine mammals to various sound levels).

Response: The Technical Guidance is not a regulation or rule. It does not create or confer any rights for or on any person, or operate to bind the public. However, it is NMFS' assessment of the best available information for determining auditory impacts from exposure to anthropogenic sound and it has undergone extensive peer and public review. With that in mind, NMFS agrees with the comment that any alternative approach should be peer reviewed before it is used instead of the updated thresholds in the Technical Guidance (or the alternative methodology). With that addition to NMFS' statement in the Draft Guidance, an alternative approach that has undergone independent peer review may be proposed if in NMFS' view it "is likely to produce an equally or more accurate estimate of auditory impacts for the project being evaluated, if NMFS determines the approach satisfies the requirements of the applicable statutes and regulations." NMFS believes this sets a fairly high bar as to what type of data/alternative approach would justify a departure from the Guidance's auditory weighting functions and/or acoustic thresholds, especially in terms of the HISA standards to which this Guidance adheres. Additionally, action

proponents are afforded flexibility for factors beyond the Guidance's auditory weighting functions and/or acoustic thresholds (e.g., propagation modeling, exposure modeling) as a means to accurately predict and assess the effects of noise on marine mammals.

Comment 128: Multiple commenters requested flexibility associated with the accumulation period, especially for projects with a stationary source and for action proponents with limited ability to conduct detailed modeling (e.g., pile driving projects). The commenters recommended that NMFS allow for the flexibility to make project-specific adjustments based on physical or biological factors associated with the activity.

Response: NMFS acknowledges that all action proponents may not have the same level capabilities to apply the Technical Guidance and has provided an optional User Spreadsheet for action proponents that wish to avail themselves of it. Additionally, NMFS recognizes there may be some situations where project-specific modification may be necessary (i.e., action proponent should contact NMFS to discuss project-specific issues that are beyond scope of Technical Guidance).

Comment 129: One commenter expressed concern that the updated acoustic thresholds could underestimate instances of PTS/TTS from permitted activities because marine mammals can be elusive and observations from protected species observers are few in relation to the estimated abundance. Similarly, one commenter asked how the acoustic thresholds would be used to calculate "take" after an activity is completed.

Response: The acoustic thresholds are just one tool used to predict "take" calculations. Other factors (e.g., sound propagation or marine mammal density/occurrence) contribute to these calculations though they are beyond the scope of the Technical Guidance. NMFS notes that the Technical Guidance's intended purpose is as a tool for predicting potential impacts of noise on hearing before an activity occurs (and perhaps afterward).

Comment 130: The Commission requested clarification on how and when action proponents should use the qualitative factors identified within the Guidance and expressed concern that these factors could be used to allow for a reduction in "take" estimates based on subjective judgments rather than best available science. The Commission recommended that NMFS remove the list of qualitative factors listed and incorporate it by reference in the text and not allow action proponents to use

those factors to modify isopleths or numbers of "takes" resulting from the quantitative thresholds.

Response: NMFS' intent of providing qualitative factors for consideration was to acknowledge that when additional data may become available in the future; these additional factors may be incorporated with quantitative PTS onset thresholds. At this time, however, it is not NMFS' intent for these factors to reduce quantitative exposure estimates based on subjective judgment. The Technical Guidance acknowledges that these factors are important for consideration within the comprehensive effects analysis on a qualitative basis. To avoid confusion, NMFS removed the list of qualitative factors from the threshold tables and placed this information in Appendix B: Research Recommendations.

Miscellaneous Issues

Comment 131: One commenter requested clarification was on how much an acoustic threshold would need to change to update the Technical Guidance and suggested updates only occur when thresholds change by at least 5 dB.

Response: NMFS has provided a procedure and timeline for updating the Guidance (Section III of main Guidance

document) and will evaluate new studies as they become available, including in the context of existing data, before determining the impact to the acoustic thresholds.

Comment 132: One commenter recommended the Guidance include a table indicating a species' hearing ability, sound production characteristics, and genetic relatedness to other species in order to determine when there are enough individuals of a particular species or genus to warrant species- or genus-specific acoustic thresholds, rather than relying on hearing group thresholds.

Response: NMFS has used the best available science to support the division marine mammals into five hearing groups, including the derivation of composite audiograms based on available hearing data, and declines to include the requested table as it goes beyond the scope of the Technical Guidance. As science progresses (i.e., more data on hearing, sound production, genetics become available), NMFS will determine if further refinements of hearing groups and their associated auditory thresholds are needed.

Comment 133: Several commenters requested that additional terms be better

defined in the Guidance (e.g., isopleth, narrowband, roll-off, equal latency).

Response: NMFS has added and defined these terms in the Glossary (Appendix E) and/or provided more clarification within the Technical Guidance.

Comment 134: A few commenters suggested improvements to the Guidance, including technical editing, literature citation verification, and the inclusion of more plain language.

Response: NMFS has verified that all references used in the Technical Guidance appear in the Literature Cited section and has included more plain language, when possible. However, NMFS notes this is a highly technical document, with most of the terms not easily subjected to plain language revisions without altering the accepted meaning of those terms. Additionally, definitions for technical terms used in this document are defined in the Glossary (Appendix E).

Dated: July 29, 2016.

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[FR Doc. 2016-18462 Filed 8-3-16; 8:45 am]

BILLING CODE 3510-22-P