ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 211

[EPA–HQ–OAR–2003–0024; FRL–8934–9]

RIN 2060–A025

Product Noise Labeling Hearing Protection Devices

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: By this action the Environmental Protection Agency proposes to revise the Noise Labeling Standards for Hearing Protection Devices (HPD). These standards have not been amended since 1979 and technologies have evolved and improved in the interim. The proposed revisions provide manufacturers with newly developed testing methodologies that are the most appropriate to assess and label hearing protection devices, and to allow legitimate hearing protection products to be sold as such in U.S. markets. In particular, this action should result in the availability of a new generation of significantly improved devices that are precluded from entering the marketplace as ''hearing protectors'' by the 1979 regulation. Finally, the Agency is mindful of the relatively large percentage of small entities that comprise the HPD industry. In recognition of the evolutionary changes in marketing and selling products brought about by the internet, and in order to minimize the potential economic burden on manufacturers that sell their products ''exclusively'' over the internet, the Agency is proposing to allow ''electronic labeling'' as a means for certain manufacturers (as defined in subpart B) to comply with the labeling requirements of this proposed rule.

DATES: *Comments.* Written comments must be received on or before September 4, 2009.

Public Hearing. If requested by August 17, 2009 the EPA will hold a public hearing on August 25, 2009. If a public hearing is held, anyone that would like to speak at the hearing should notify the EPA by August 18, 2009.

ADDRESSES: Submit your comments, identified by docket ID number EPA–HQ–OAR–2003–0024, by one of the following methods:

- *www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *E-mail: a-and-r-docket@epa.gov.*
- *Fax:* (202) 566–1741.
- *Mail:* EPA Labeling Regulation, Docket Number EPA–HQ–OAR–2003–0024, Environmental Protection Agency, EPA Docket Center, Mailcode 6102T, 1200 Pennsylvania Ave., NW., Washington, DC 20460.
- *Hand Delivery:* EPA Docket Center, Public Reading Room, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC 20460. Such deliveries are only accepted during the Docket's normal hours of operation (Monday through Friday, from 8:30 a.m. to 4:30 p.m.), excluding legal holidays and special arrangement should be made for deliveries of boxed information. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Air Docket is (202) 566–1742.

Instructions: Direct your comments to Docket ID Number EPA–HQ–OAR–2003–0024. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through www.regulations.gov or e-mail. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through www.regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name or other content information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defect or viruses. For additional information about EPA's public docket, visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

Docket: All documents in the docket are listed in the www.regulations.gov index. Although listed in the index, some information is not publicly available, e.g., confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in www.regulations.gov or in hard copy at the EPA Air Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Air Docket is (202) 566–1742.

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SUPPLEMENTARY INFORMATION: *Outline.* The information presented in this preamble is organized as follows:

I. Noise Control Act Authorities

In the Noise Control Act of 1972 (42 U.S.C. 4907), hereinafter ''the Act'', the Congress declared that it is the ''policy of the United States to promote an environment for all Americans free from noise that jeopardizes their health and welfare.'' Congress further declared that one purpose of this Act is ''* * * to authorize the establishment of Federal noise emission standards for products distributed in commerce, and to provide information to the public respecting the noise emission and noise reduction characteristics of such products.''

Section 8 (Labeling) of the Act states that ''the Administrator (of the Environmental Protection Agency) shall, by regulation, designate any product (or class thereof)—(1) which emits noise capable of adversely affecting the public health or welfare; or (2) which is sold wholly or in part on the basis of its effectiveness in reducing noise.'' Further, of direct relevance to this proposal, it provides that ''the Administrator shall by regulation require that notice be given to the

prospective user of the level of the noise the product emits, or of its effectiveness in reducing noise, as the case may be. Such regulations shall specify (1) whether such notice shall be affixed to the product or to the outside of its container, or to both, at the time of its sale to the ultimate purchaser or whether such notice shall be given to the prospective user in some other manner, (2) the form of the notice, and (3) the methods and units of measurement to be used'' [in developing the required information notice].''

II. Introduction

EPA has issued rules, found at 40 CFR Part 211, subpart B, which implement section 8 of the Act. EPA issued these rules in 1979 (44 FR 56120). These rules require manufacturers of hearing protection devices (HPD), that are entered into commerce in the United States, to provide the prospective user with information regarding the products' effectiveness in reducing the level of noise (unwanted sound) entering a user's ears. The regulation requires that such information be presented at the time of its sale to the ultimate purchaser on a label(s) that is readily visible at the point of purchase or distribution to users.

Since 1979, the demand for hearing protector devices has increased dramatically due, in part, to an increased awareness of hearing loss in the workplace and the increased stringency of occupation and health regulations at the federal and state levels. The Agency estimates the current *legal* hearing protector market to be approximately four (4) billion units annually, comprised of about 2.1 billion units sold to industrial users and an estimated 1.9 billion sold to military and commercial users.

As a result of an increased demand for more effective products, significant technological changes have occurred in the design, performance and comfort of hearing protectors with the resultant introduction of new products that, unfortunately, are not amenable to the current regulatory testing and rating schemes. These products include special purpose ''passive'' (non-electronic aided) devices, custom molded and tuned devices, electronic noise reduction devices, sound restoration devices and combination hearing protector (communication headset). Other changes that have occurred in the hearing protector industry include the consolidation of U.S. and foreign manufacturers, and an increasing number of foreign-made products finding their way into U.S. commerce that are not in compliance with the existing rule.

Today's proposal reflects these technological advances and specifies the new and revised test methods to determine product effectiveness; the mathematical process to determine a numeric effectiveness rating(s) (i.e., Noise Reduction Rating (NRR)); the required graphic and textual information for the required labels; the introduction of electronic labeling for organizations that sell their hearing protectors exclusively via the internet; and future compliance testing to assure the continuous accuracy of product effectiveness and label information. EPA's overall objectives remain, as they were 30 years ago:

(1) Provide accurate and understandable information to hearing protector purchasers, users, and hearing conservation professionals regarding the acoustic performance of hearing protection products in specific noise environments so that meaningful product comparisons, with respect to the reduction of sound entering a user's ears, can be made as part of a product purchase or use decision.

(2) Provide such information with minimal Federal involvement by ensuring the labeling requirements are structured to minimize administrative, economic, and technical impacts on manufacturers, distributors, and other interested parties.

(3) Promote improvements in hearing protector design, performance, and user acceptability.

(4) Promote public awareness of potential damage to hearing that can result from unprotected exposure to high intensity sound.

III. Background

Since EPA's promulgation of the 1979 regulation, the federal government, universities and industry have conducted research on the effectiveness of hearing protection devices when used in ''real world'' settings. Professional and trade organizations, manufacturers and other federal agencies have presented their concerns to the EPA on a number of significant issues including the currently required test method, the required Noise Reduction Rating (NRR), and the required textual information on labels. All interested parties generally agree that the existing regulation needs to be revised to address new technology products, related test methodologies, and current user needs.

In response, EPA gave notice via the Agency's Web site and by written invitation to interested parties to participate in a workshop at EPA headquarters in Washington, DC on March 27–28, 2003. The EPA sought detailed technical concerns, new information and recommendations relevant to the current federal labeling requirements for hearing protection devices, with particular emphasis in the following areas:

(1) Product Label

- Primary label information and format
- Supporting information
- Label size and placement

(2) New Hearing Protector Technologies

- Sound restoration systems
- Active and passive devices
- Active noise reduction
- Communication headset

(3) Noise Reduction Effectiveness Rating

- Test methodologies
- Passive and active devices
- Effectiveness metric
- Periodic retesting of products

The two-day workshop included presentations of invited papers that provided the historic basis for the current hearing protector regulation; a review of technical revisions to test methods since the 1979 promulgation of the regulation; an analysis of the relationship of the current Noise Reduction Rating (NRR) to current American National Standards Institute (ANSI) and International Standards Organization (ISO) test protocols; and an overview of new hearing protector technologies.

The workshop also included ''break-out'' sessions to address the three major topic areas noted above. The sessions were facilitated by personnel from the National Institute for Safety and Health (NIOSH), and conducted informally without transcript to stimulate the free flow of ideas and exchange of information. However, the session facilitators recorded the essence of the discussions, while preserving the autonomy of the commenters.

All formal presentations are available in EPA Docket Number EPA–HQ–OAR–2003–0024. The docket also contains summaries of each of the breakout sessions and an overall summary that integrates the conclusions and recommendations of the sessions. The proceedings of the workshop, including all presentations and summaries, will be referred to henceforth as ''the report'' or ''the workshop report.'' The report may be found at document number twenty-nine (29) in the above referenced docket.

The workshop presented a number of reasons why the existing regulation should be revised. The most notable are summarized below:

A. Product Applicability

The Agency has been aware of electronic devices such as active noise cancellation, sound restoration, combination communication protectors, that were essentially barred from claiming the acoustic noise reduction benefits attendant to these devices due to the limitations of the federal test procedures designed for non-electronic hearing protectors. Similarly, some protectors that rely upon acoustical and mechanical behavior to increase attenuation were also barred. This is because absent an appropriate measure of the product's noise reduction effectiveness, it cannot be sold as a hearing protection device.

B. Noise Reduction Rating

The most-expressed concern was with the currently-required noise reduction rating (NRR) metric the single-number rating scheme that EPA specified to quantitatively rate the effectiveness (i.e., the sound attenuation or sound reduction) offered by a hearing protection device when used as instructed by its manufacturer. In particular, it was alleged that most purchasers and users of hearing protectors have a limited understanding of the NRR, believing that the higher the numerical rating, the better the product. While technically correct, it was suggested that purchasers or users may select products primarily on the basis of NRR differences as small as 1 decibel (dB), whereas issues of comfort, compatibility with safety equipment, communication needs, and ease of use can be of equal or greater importance to the ultimate user.

Field studies by various researchers,[1] over the past three decades, revealed a relatively poor correlation between the labeled NRR of selected protectors, as determined from testing in accordance with the American National Standards Institute (ANSI) S3.19–1974 test procedure, and the attenuation realized by typical users of these protectors when tested without the benefit of the experimenter fitting the device as required in ANSI S3.19. This difference was more pronounced with earplugs than with earmuffs, where the former device requires specific fitting skills by the user.

Based in large part on these referenced field studies, one Federal agency has made significant modifications to their criteria governing the application of the NRR for determining acceptable employee noise exposure in the work place. The Department of Labor/Occupational Safety and Health Administration (OSHA) has instructed its inspectors to ''derate'' (reduce) a hearing protector's estimated attenuation by 50 percent when assessing the relative effectiveness of hearing protectors in lieu of engineering noise reduction controls.[2]

The National Institute for Occupational Safety and Health (NIOSH) also suggests the derating of protectors in the workplace. However, in contrast to OSHA, they suggest subtracting differing percentages from the labeled NRR for each of the three types of hearing protectors: 25% from the labeled NRR of earmuffs, 50% from the labeled NRR of foam earplugs, and 70% from the NRR of all other earplugs.[3]

In both cases the recommended ''derating'' is based on the agencies' engineering judgment and not controlled scientific determination and consequently could lead to unintended consequence of ''over protection'' that could obscure warning signals or necessary voice communication.

C. Test Methodology

The American National Standards Institute has withdrawn the S3.19–1974 performance test standard (''Method for the Measurement of Real-Ear Protection of Hearing Protectors and Physical Attenuation of Earmuffs''), which is mandated in the current regulation (40 CFR 211 subpart B) and replaced it with ANSI/ASA S12.6–2008, ''Methods for Measuring the Real-Ear Attenuation of Hearing Protectors,'' which is believed to yield data that more closely mirrors the ''real world'' effectiveness of hearing protector devices.

The principal concern with S3.19–1974 is its requirement that testing laboratory personnel (hereinafter the experimenter) physically fit the HPD on the human test subject. The basis for using human test subjects is to address the range of differences in both the external and internal structure of the human ear. Clearly, the original intent of the experimenter fitting the device was to minimize the variability of product effectiveness that could occur due to the user's lack of skill in fitting the device and not that due to the sound reduction effectiveness of the device itself when used as instructed by the manufacturer. However, this procedure can lend itself to experimenter fit adjustments of the product on the test subject to achieve the maximum sound reduction possible without regard for a test subject's comfort or intended fit. Finally, a major deficiency of ANSI S3.19 with regard to current and potential future products is its inability to be used to determine the performance of special devices, such as those utilizing active noise reduction and those used in high level impulsive noise fields.

EPA agrees with interested parties that the current required test methodology, based upon ANSI S3.19–1974, can result in unrealistically high sound reductions that are generally not attainable in real world use. The resultant labeled NRR can lead to product selections that may leave users under-protected and subject to potential hearing damage. Further, the procedure lacks suitability for the testing of other than passive devices. For these reasons, the EPA has concluded, subject to consideration of public comment, that ANSI S 3.19–1974 is no longer appropriate for HPD label requirements.

D. Test Subjects

ANSI S3.19–1974, requires 10 subjects to be tested regardless of the type of protector. Each subject is tested three times and their mean attenuations and standard deviations are determined without averaging the individual subject results. Interested parties have suggested that more test subjects should be utilized for passive insert devices in order to achieve a more statistically accurate representation of the user population. They also proposed that each test subject be required to undergo multiple tests on each product in order to obtain an average fit sound reduction value. They have also suggested that fewer test subjects be required for devices that fit over the user's ears (ear muffs) because such protectors require minimal user skill in obtaining a proper fit.

The EPA favors any changes in the testing protocol that will improve the quality of information that can be provided to the ultimate user of an HPD while offering the potential for reduced testing costs.

E. Compliance Testing

The current regulation was written at a time when, in large part, ear plugs made of wax-impregnated cotton,

[1] The referenced studies can be found in the Federal Docket at *http://www.regulations.gov,* docket number EPA–HQ–OAR–2003–0024.

[2] Occupational Safety and Health Administration (1999). OSHA Technical Manual, Section IV, Appendix IV:C, Methods for Estimating Hearing Protector Attenuation. Washington DC: Office of Science and Technology assessment *http://www.osha.gov/dts/osta/otm/noise/hcp/attenuation_estimation.html.*

[3] National Institute for Occupational Safety and Health (1998). Occupational Noise Exposure, Revised Criteria, 1998. Publication No. 98–126. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health.

silicon, early formulas of polyurethane foam, and earmuffs, were the only types of products on the market. For many reasons, too numerous to detail here, the EPA decided to require compliance testing of a HPD only once prior to its entry into commerce. Further tests are required if (1) a manufacturer modifies the design or changes materials or structure such that the acoustic performance of the product may be degraded; (2) the Administrator has reason to believe the original effectiveness rating is in error, or otherwise requires information pursuant to section 13 of Noise Control Act; or (3) a selective enforcement audit revealed products in non-compliance with their labeled information. With the entry of many new HPD materials, designs, and electronic and mechanical systems, the Agency has become concerned with the adequacy of its present *once in a product lifetime* test requirement.

IV. Product Applicability

This proposed regulation would apply to all devices or materials sold as explicit or implicit ''hearing protection devices'' on the basis of their ability to reduce the level of sound entering the user's ears and thus serve to protect the user's hearing. The proposed regulation also applies to devices whose primary function may not be hearing protection, but which are nonetheless sold in-part as providing protection to the user's hearing.

To the extent that a product manufacturer, importer, packager or any other party introduces into U.S. commerce any product that incorporates an explicit or implicit claim that the product can protect the hearing of the user or stipulates the level of sound reduction offered by such product, then it would be subject to the requirements of this proposed regulation.

The Agency has attempted to establish product definitions on the broadest basis in order to capture all current and future HPD designs and characteristics. The EPA recognizes that by taking this broad approach, certain products presently on the market, that are intended to provide a level of comfort for sleeping, listening to music, restricting the entry of water into ears during swimming or bathing, etc., may be captured as possible hearing protectors. As stated above, this rule does not apply to those devices or materials.

While not necessarily a complete listing, the general categories of hearing protector devices that are subject to this proposed regulation are described below:

(1) *Passive Hearing Protection Device.* A device that relies solely on its structural elements to block or otherwise control the transmission of sound into the ear canal and that does not use electronic circuits or acoustic elements to reduce the entry of external sound.

(2) *Active Hearing Protection Device.* A device that contains electronic components including transducers (i.e. speakers and microphones) to increase or decrease the transmission of sound into the ear canal. Also referred to as an electronic hearing protection device.

(3) *Ear plug.* A hearing protection device that is designed to be inserted into the ear canal and held in place principally by virtue of its fit inside the ear canal.

(4) *Ear muff.* A hearing protection device usually comprised of a headband which applies spring-like force/pressure to two ear cups with soft cushions to seal against the external ear or pinna (supra-aural) or the sides of the head around the pinna (circumaural). The ear cups may also be held in position by attachment arms mounted on a hardhat or hardcap.

(5) *Active Noise Reduction Hearing Protection Device.* A device that uses single or in combination, electrical and structural elements to reduce the sound transmitted to the ear canal through acoustic cancellation of the air-conducted and/or bone-conducted external sound.

(6) *Amplitude Sensitive Hearing Protection Device.* A device that is designed to produce a change in sound attenuation as a function of the external sound level.

(7) *Communication Headset.* A voice communication device (ear plug, ear muff, semi-insert device or helmet) that is designed also to reduce the level of sound at the users' ears by either structural elements and/or electronic means.

(8) *Custom-molded Hearing Protection Device.* A device that is made to conform to a specific person's ears (pinnas) and ear canals.

(9) *Helmet.* A hearing protection device that provides impact protection to the head or skull and that is designed also to reduce the external sound through either structural elements and/or electronic means.

(10) *Semi-insert Device.* An ear plug-like hearing protection device consisting of soft pods or tips that are held in place by a lightweight band. The pods are positioned in the conchae covering the entrances to the ear canals, or fitted to varying depths within the ear canals. Semi-inserts that cap the canal require the force of the band to retain their position and acoustic seal. Semi-inserts that enter the canal behave more like ear plugs; they seal the ear to block noise with or without the application of band force. Also referred to as canal cap or banded hearing protector.

V. Incorporation by Reference

The test methodologies that are being proposed in subpart B rely in whole or in part on established consensus standards of the American National Standards Institute (ANSI) and design standard of the International Electrotechnical Commission (IEC). The version of the standards that are incorporated in the rule remains the applicable standard unless and until the EPA amends the rule to reflect any change in the test procedures. In recognition of the copyrights that protect these standards, the Agency is ''incorporating by reference,'' into subpart B, the following ANSI and IEC standards:

(1) ANSI/ASA S12.6—2008, ''Methods for Measuring the Real-Ear Attenuation of Hearing Protectors''

(2) ANSI S12.42—1995 (R2002), ''Microphone-in-Real-Ear and Acoustic Test Fixture Methods for the Measurement of Insertion Loss of Circumaural Hearing Protection Devices''

(3) ANSI/ASA S12.68—2007, ''Methods of Estimating Effective A-weighted Sound Pressure Levels When Hearing Protectors are Worn''

(4) IEC 60711, ''Occluded-ear simulator for the measurement of earphones coupled to the ear by ear inserts''

VI. Test Methodologies

The EPA has determined, after extensive investigations, multi-laboratory testing and discussions with experts in the field, that the following test methodologies are appropriate for use on the broad spectrum of present and potentially future materials and devices that are sold wholly or in-part on the basis of their ability to reduce the level of sound entering the human ear.

Further, to avoid the potential creation of a technical barrier to U.S. manufacturers' global trade, the Agency has considered foreign testing and labeling standards regarding HPD rating schemes and their relationship to the U.S. Noise Reduction Rating (NRR). In that regard, the Agency has given particular attention to the International Standards Organization (ISO) standard 4869, parts 1 and 2 which describe, for the most part, the European testing and rating methods for HPDs. ISO 4869 part 1 permits subjects to be experienced and trained in proper product use technique.

However, the Agency has concluded that the referenced ISO standards do not add substantively to the intended testing and rating objectives of the proposed regulation over that offered by the selected ANSI standards.

The Agency's consideration of ANSI S12.6–2008 was preceded by considerable debate within the hearing protector device community regarding the qualifications of the human test subjects. ANSI S12.6–2008 offers two significantly different testing protocols, Method A and Method B, as they relate to prior experience of the test subjects and role of the experimenter in the preparation of test subjects prior to product testing. In brief, Method A test subjects are informed and experienced regarding the use of HPDs, based upon detailed instruction and demonstration from the experimenter or from previous HPD use. Method B test subjects are selected principally because of their lack of prior knowledge and experience with HPDs. They are not provided any guidance from the experimenter with regard to product use, beyond that given by the manufacturer's normally provided written instructions. There was no consensus on whether EPA should require Method A or Method B.

A. Method Selection

Several factors must be considered in the selection of testing protocols. First, the measured sound attenuation is the principal determinant of the potential noise reduction rating (effectiveness) of the device. Second, the variability of the rating metric, which is primarily a function of subject selection and training and test laboratory practices, must be accounted for. Third, to the extent possible, the test method should give a measure of product effectiveness under real-world use conditions. Finally, the method should provide a reliable and repeatable means for assessing product performance, with minimal influence and impact of non-product related factors. The competing methods and their differing means to account for user capabilities are presented below.

1. Method A

Supporters of Method A believe it is the appropriate protocol to assess the acoustic performance and sound attenuation capability of an HPD attributes that are a function of product design, materials and construction, rather than user skills. When subjects are trained in the proper use of hearing protectors, they demonstrate higher average attenuation for devices such as earplugs and semi-aural inserts than do ''inexperienced'' subjects. In the EPA-sponsored interlaboratory studies, earmuffs exhibited little change in attenuation between experienced and inexperienced test subjects. However, for earplugs and semi-aural devices, there were marked improvements in attenuation when Method B subjects were given training; attenuation results for foam roll-down earplugs showed significant improvement as a result of correct fit. The range of attenuation results tended to be larger with Method A, but the variability across test subjects was reduced markedly from that of Method B.

Method A is similar to the International Standards Organization (ISO) test standard 4869–1 that permits subjects to be experienced with the use and fitting of protectors. The Occupational Safety and Health Administration (OSHA) and the military require training in the use of hearing protectors, thus supporting the use of Method A that reflects the attenuation obtained by trained users. Supporters also maintain that Method B is an assessment of the product's ergonomics and manufacturers' instructions, but not necessarily the products' noise reduction capabilities. Thus, the use of inexperienced subjects increases the variance of the attenuation data and may serve to mask procedural variances between testing laboratories. Finally, they expressed concern that selection of a Method-B rated protector could result in user over-protection due to the understated attenuation results from inexperienced subjects. This, in turn, can lead to potential safety hazards, particularly in those noise environments that rely on speech communications and audible warning signals.

2. Method B

Supporters of Method B maintained that the use of inexperienced test subjects is a better predictor of the level of sound reduction (attenuation) that might be expected by users in the real world as opposed to the laboratory. Data from field studies show slightly lower real-world attenuation than the laboratory data using Method B, and even studies of well-trained users (as opposed to test subjects) showed results similar to Method B data. Further, it appears that the rank ordering of hearing protector attenuation using Method B correlates well with the data from field studies. While Method-B results exhibited better reproducibility, the measured attenuations were lower. Finally, the variability of the Method-B results was greater than that of Method-A results.

Method B supporters also suggest that the use of subject fit testing methods will eventually lead to protector designs that facilitate the user fitting the protector correctly.

3. Training

Although disagreement exists between Method A and B supporters and parties that will be affected by this revised regulation, there is common agreement that the ultimate effectiveness of a product can only be realized with proper training or, at a minimum, user-friendly instructions. The Department of Defense (DOD) requires that enlisted personnel, officers, and civilians who are exposed to noise receive instruction in the proper use and maintenance of hearing protectors. The OSHA requires that workers involved in a hearing conservation program be instructed about the harmful effects of noise and trained in the proper use of hearing protectors. NIOSH recommends that training is an essential element of every hearing loss prevention program, along with noise control engineering and administrative measures to prevent hearing loss. Finally, the National Hearing Conservation Association (NHCA) recommends that training in the proper use of hearing protectors be provided to noise-exposed persons.

4. Test Protocol Selection

The EPA is proposing to adopt the ANSI S12.6–2008—Method-A testing protocol for all hearing protectors in their ''passive'' mode. EPA believes, subject to consideration of public comment, that Method A is more appropriate to the intent and fulfillment of the hearing protector labeling program objective—*to provide an accurate assessment of the acoustic performance of only the product* (*see* section 8(b) of the Act, authorizing labeling which describes a product's ''effectiveness in reducing noise'').

EPA agrees that Method B can more nearly represent the anticipated protection for uninformed HPD users. But it is not reasonable to assume that HPD users will be typically uninformed, or that they would remain so as they grow accustomed to the use of an HPD. In fact, the federal labeling regulation is but one leg of a three legged stool and is not intended to be all-encompassing in the prevention of hearing damage or loss. The other two legs of a hearing conservation program must include user training and, to the extent possible, engineering controls of noise.

The Agency has several concerns with the use of Method B. First, it believes the concept of ''naïve'' test subjects, as prescribed in ANSI S12.6, is not appropriate for the determination of a

product's acoustical performance, absent human intervention. EPA believes that the naivety of the test subject (hereinafter ''inexperienced'' test subject) disappears (or is at least reduced) once the test subject has completed his or her first series of tests. Consequently, the use of such subjects for multiple testing of similar products is questionable regarding their inexperience. Second, based upon results from an EPA sponsored and NIOSH managed multi-laboratory test [4] of six different products, significant differences in technique between testing laboratories became evident from Method A data. However, such differences appeared to be masked by the large variability between test subjects based upon Method B data. Third, the Agency believes the true potential effectiveness (NRR) of the HPD, when used correctly as instructed by the manufacturer, could be understated because of low attenuation measurements that resulted from improper fit by inexperienced test subjects; this is particularly important with ear insert HPDs.

Further, EPA agrees with supporters of Method A regarding potential over-protection as a result of user selection based on a low Noise Reduction Rating determined from Method B testing. EPA believes the HPD rating should show, within a reasonable range, the sound reduction that users can expect to receive when the device is worn as instructed by the manufacturer. Since EPA cannot regulate human behavior nor provide training in the proper use of HPDs, its only regulatory option is to provide the most accurate product performance information available and rely on training from other entities to assure proper use. It is on the above basis that EPA is proposing to require the use of Method A.

Finally, in the absence of suitable ANSI or other recognized testing standards that address devices that incorporate electronics to enhance their sound reduction (attenuation) performance (i.e., ''active'' mode) or that are intended for use in extremely high impulsive noise environments (levels greater than 140 decibels), the Agency, in collaboration with NIOSH and the U.S. Air Force, has developed test methods for these devices. An explanation of these ''non-consensus standard'' test protocols is given below. The EPA is seeking comment on these new test protocols.

[4] National Institute for Occupational Safety and Health (NIOSH)/EPA Interlab Study Comparison of ANSI S12.6, Method A and B. Refer to the Federal Docket at *http://www.regulations.gov*, docket number EPA–HQ–OAR–2003–0024.

B. Proposed Testing Protocols

1. Passive Noise Reduction Testing

As stated above, EPA is proposing that ANSI 12.6–2008, Method A, Real Ear Attenuation at Threshold (REAT) test protocol be used for the determination of the *passive* noise reduction performance of *all categories* of hearing protector materials and devices. The key elements of the REAT test method includes:

- Subject Selection and Qualification
- Fitting Protocol
- Test Procedure
- Reporting of Test Data

a. Subject Selection and Qualification

The ANSI S12.6–2008 standard specifies test subject requirements for the Method-A protocol. Subjects must have pure-tone air conducted hearing thresholds better than 25 dB HL (Hearing Level) in both ears. Subjects must also demonstrate their proficiency in obtaining a hearing threshold in the test environment with the specific equipment used in the testing laboratory. Proficiency is demonstrated through repeated threshold testing without hearing protectors being worn such that the subject has a range of thresholds that does not exceed a difference of 5 decibels for each test frequency. The Agency believes that subject selection criteria can be used to identify a population of test subjects that produce high attenuations and which have a narrow range of attenuations across subjects. Therefore, the Agency will permit subjects to be rejected for various physical reasons during the pretest process, but they may not be removed from the pool of tested subjects due to their poor attenuation results.

b. Fitting Protocol

Under the 1979 regulation, the fitting protocol requires an experimenter-fit method. The subject serves as an acoustical test fixture capable of providing a response to the test stimulus. The experimenter places the protectors on the subject's head or in the subject's ear canals and prohibits the subject from making any adjustments to the fit of the product. This practice provided a repeatable measurement of the maximum attenuation that a product could achieve for deeply inserted earplugs. For devices such as earmuffs and semi-aural inserts, the ability to achieve a greater attenuation was less susceptible to experimenter manipulation.

The proposed ANSI S12.6–2008 Method-A incorporates specific instructions for the experimenter and limits the interaction between the subject and experimenter once training in the use of the product is completed. The process of defining how a subject should be trained was found to be more complex than defining the process for an inexperienced subject. The Working Group responsible for the development of ANSI S12.6–2008 Method-A settled on an approach that in many ways reflects the reality of how protectors should be issued to noise-exposed persons. The experimenter is allowed to provide training to the subject in how to best fit and use the specific hearing protector. However, once the subject enters the test room, the experimenter is prohibited from providing further instruction. When one considers how protectors are distributed and worn in most settings, if any training is given, it generally is of a short duration and the user must ultimately fit the protector on his/her head or in their ear canals.

c. Test Panel Size

The protocol stipulated in the 1979 regulation specifies that ten subjects are to be tested three times for occluded and unoccluded thresholds and, upon their meeting specified hearing criteria, be selected as the test panel. These requirements were based upon research conducted by the U.S. Air Force and represented the best estimates of variability available in 1979. Since that time, the ANSI S12, Working Group 11 determined that 20 subjects are statistically appropriate for testing ear plugs and semi-aural inserts and 10 subjects are appropriate for ear muffs. The most recent interlaboratory study conducted by EPA and NIOSH found that 20 subjects were adequate for repeatable intra-laboratory tests with both Method-A and Method-B protocols.[5] Section 5.8, ''Number of subjects'', of ANSI S12.6 requires that 10 subjects be tested for earmuffs or helmets and 20 subjects for each test on earplugs or semi-insert devices.

Questions have been raised about the appropriate number of subjects to be used in certain circumstances. It has been suggested that the regulation allow manufacturers to increase the sample size indefinitely, with the proviso they report to EPA the total number of subjects tested for each HPD. The Agency is not opposed to this latter approach provided the test data from *all* subjects is included in the calculations leading to the NRR. However, at this time the EPA is proposing to adopt the

[5] National Institute for Occupational Safety and Health (NIOSH)/EPA Interlab Study Comparison of ANSI S12.6, Method A and B. Refer to the Federal Docket at *http://www.regulations.gov*, docket number EPA–HQ–OAR–2003–0024.

requirements for 10 and 20 test subjects as specified in ANSI S12.6, Section 5.8. The Agency will consider comments on this topic.

d. Test Room Environment

EPA is proposing to change the requirements of the test room environment from those specified in ANSI S3.19–1974. Changes of particular note are the reverberation time of the room and the characterization of the sound field with respect to uniformity and diffusivity; both parameters are more specific under ANSI S12.6–2008. The procedure to determine the occluded and unoccluded thresholds is defined as a modified Bekesy procedure. This procedure was not selected on the basis of superior psychophysical techniques, but was selected by the ANSI S12 Working Group because most of the testing labs used a variant of the method; variation across testing labs could be minimized by standardizing the method.

e. Test Frequencies

The ANSI S3.19–1974 standard required the REAT test include attenuation measurements at 3150 and 6300 Hz. However, later analysis [6] of the added benefit realized by the current NRR due to the inclusion of test frequencies at 3150 and 6300 Hz, revealed differences on the order of 0.1 to 0.3 decibels. NIOSH conducted a similar analysis on 435 devices listed in the NIOSH Compendium [7] of Hearing Protection Devices and confirmed the earlier results. Thus, the voluntary standards community concluded that the small differences in the NRR through the inclusion of these two added test frequencies do not justify the additional time and effort in testing subjects at those frequencies. Consequently, in the recent versions of ANSI S12.6 the requirement to test at 3150 and 6300 Hz has been eliminated for REAT measurements. The Agency concurs with these findings and is proposing to no longer require tests of attenuation at 3150 and 6300 Hz.

f. Computation of the Noise Reduction Rating (NRR)

The 1979 regulation requires the NRR be computed with the mean attenuations and standard deviations from *all* test subjects at each frequency band. The ANSI S12.68–2007 standard requires that data from the individual subjects be used in determining a device's rating across a range of different noise spectra. The inclusion of both subject and spectral variability provides results that are more representative of the product's performance when used by different persons in different types of noise environments.

The Agency is proposing that the ANSI S12.68 methods be used to compute the required NRRs for Passive hearing protectors on the basis that such NRRs provide the best available means of describing product performance that is likely to occur in real-world environments.

2. Active Noise Reduction Testing

Active Noise Reduction (ANR) devices require additional measurements beyond those described above for the passive attenuation methods. An ANR device utilizes electronic circuitry to sample an external sound signal, analyzes the principle acoustic component(s), and then generates a 180 degree out-of-phase signal to be played into the occluded volume (the space under the protector) that, in effect, cancels the external signal that is present under the protector. An error correction microphone in the occluded volume is used to determine the effectiveness of the control, thus allowing adjustment of control parameters to maximize effectiveness.

ANR circuitry has been incorporated in both earplug and earmuff HPDs in several forms; digital or analog controls or a combination of the two have been used. Digital control circuits tend to isolate specific tonal components of the external sound and effect a significant noise reduction. Analog circuits tend to be simpler to implement and have a broader share of the market. The type of control can be feedback, feed forward or a hybrid of the two. In a feedback circuit, the signal must be sampled in the occluded volume and the control is based upon the error correction microphone. In a feed forward circuit, the external microphone is sampled and the control is predicted. The error correction microphone is used to help the circuit determine the effectiveness of the control.

a. Test Method Design Parameters

ANR devices pose a particular problem when attempting to determine a noise reduction rating. The use of a REAT procedure yields an attenuation setting for the device that is biased due to the residual noise produced by the ANR circuitry. When activated, ANR devices tend to produce a small level of electronic noise that is audible in quiet environments. Because REAT testing requires the test subject to identify the presence of a sound produced by electro-mechanical speakers in the test environment, any sound produced by the hearing protector can interfere with the ability to measure near the subject's threshold of hearing, resulting in an inaccurate assessment of the device's active noise reduction performance. An alternative method for determining the noise reduction of the active device is to utilize the Microphone In Real Ear (MIRE) technique where a small microphone is placed in the subject's occluded volume and the insertion loss (the difference in noise level when the device is activated and not activated) is measured. Alternatively, the transmission loss (the difference in noise levels between the external sound field and occluded volume) can be measured. A potential limitation of the MIRE technique is that it underestimates noise reduction at low frequencies when compared to the REAT method.

The use of the MIRE technique for earmuff ANR devices can be readily applied since the occluded volume is sufficiently large that a miniature microphone can be placed completely within the earmuff and positioned in the ear canal without interfering with the seal of the muff cushions to the side of the head. The diameter of the lead wires to the MIRE microphone can be small enough such that no gaps in the seal will be created. Alternatively, the MIRE microphone can be wireless, thus eliminating the need for any wires to exit underneath the cushions of the ear muffs.

In the case of ANR earplugs, the use of a MIRE measurement becomes complicated. Some prototypes rely on a deep-insertion custom-molded earplug that houses the electronic package. For these devices, the occluded volume may only be 0.5 cubic centimeters. Placement of the miniature microphone in the occluded volume could adversely affect the operation of control circuits designed for a specific occluded volume. If the test method uses a probe microphone, then the probe either has to be placed alongside the earplug or must be passed through a sound bore in the device. Placement of a probe microphone alongside the earplug creates a potential leakage path that changes the acoustic impedance of the occluded volume. Requiring a sound bore through the device deprives the manufacturer of critical volume within the device that may be necessary to house additional circuitry. The seal of

[6] Murphy WJ, ''Analysis of the necessity to test at 3150 and 6300 Hz and the effect on the Noise Reduction Rating.''

[7] Franks JR, Graydon PS, Jeng C, Murphy WJ, ''NIOSH Hearing Protector Device Compendium,'' *http://www2d.cdc.gov/hp-devices/hp_srchpg01.asp* (2003). as of July 6, 2008.

the sound bore with the probe tube can also present a sound leakage path.

The Agency has received input from researchers in the field of active noise reduction hearing protection devices and has determined that the method to evaluate ANR noise reduction must include a combination of both the REAT and the MIRE techniques. As stated earlier, every hearing protector manufacturer would be required to conduct a REAT passive measurement and publish a passive NRR. Consequently, a REAT tests would have to be carried out on all ANR devices with their electronic circuitry turned off.

For ANR earplugs, the active contribution would be measured on an acoustic test fixture. The test fixture would include artificial ear canals (tapered cylinder) and ear simulators that approximate the occluded volume and acoustic impedance of the human ear; such devices are commercially available.

For earmuffs, the method uses the same test subjects who participated in the REAT testing. MIRE microphones are mounted on ear plugs underneath both the left and right ear muffs and the microphones are centered in the ear canal flush with the floor of the concha.

To overcome the discrepancy between MIRE and REAT, the MIRE technique would be used to measure the active contribution to the total HPD noise reduction. In both the earmuff and earplug cases, the device would be assessed with the electronics turned on and off in a broadband noise field. The difference between the noise levels measured in the on and off conditions are calculated to estimate the active attenuation contribution. The active contribution is added to the attenuations measured with the REAT method. Together, these attenuations for each subject would be used to estimate the NRR according to the ANSI S12.68–2007 method.

b. Method Requirement

No standardized testing method(s) has yet been developed for determining the peak noise reduction of hearing protection devices. Several organizations have investigated a range of impulse generation techniques. University of Florinapolis, Brazil has a large diameter acoustic shock tube in which a mannequin head can be placed to test the performance of a protector.[8] The Finish Institute of Occupational Health and the Polish Central Institute for Labour Protection have reported the attenuation of hearing protectors exposed to an acoustic shock tube.[9] [10] The French German Research Institute de Saint Louis (ISL) evaluates hearing protector performance with explosives and an anthropometric mannequin with an embedded ear simulator. The US Army has conducted mannequin measurements with explosives and also with an acoustic shock tube. The US Air Force has also evaluated protectors on a mannequin with an explosive impulse source. NIOSH has conducted exposure measurements for gunshots and various occupational impulsive noises and has utilized a mannequin.[11] [12] The use of a mannequin with simulated ears, in place of human test subjects, is essential to avoid the risk of hearing damage at the required high impulse sound levels.

Berger [13] published a review of methods for measuring attenuation of hearing protection devices and has noted that one problem common to many of the artificial ear or head test fixtures available at that time was a lack of isolation of the sensing microphone. The purpose of the mannequin or test fixture is to determine the performance of the air conducted pathway of the device. Berger previously identified that bone conduction of the impulse through the skull was a limiting factor for hearing protector performance. Thus, the test fixture must incorporate isolation of the acoustic sensors from mechanical vibrations that are analogous to that of bone conduction.

Currently there are several mannequins (test fixtures) available for acoustic research as well as other fixtures of varied design that could be potentially used to determine peak sound reduction. Three of the most well-known mannequins are the G.R.A.S. KEMAR (Knowles Electronic Manikin for Acoustic Research), the Bruel and Kjaer HATS (Head and Torso Simulator) and the Head Acoustics RMS fixture. Parmentier et al. reported that the isolation of the KEMAR and the early model of the Head Acoustics fixtures did not achieve sufficient isolation to get below bone conduction.[14] The HATS device suffers from a similar problem as KEMAR; the volume of the head is devoid of any sound or vibration absorbing mass. Parmentier et al. isolated the ear simulator inside a suspended capsule within a relatively solid acrylic body. The additional features were the use of a replaceable ear canal and pinna set which allow both muffs and plugs to be tested. The ISL mannequin has the added benefit of being anthropometrically correct and thus more nearly simulates sound diffraction effects around the head.

a. Test Procedure

The proposed test procedure consists of three parts: calibration, data collection from a hearing protector exposed to the impulse sound source and computation of the of the peak noise reduction.

Calibration is accomplished by simultaneously measuring sound impulses having a peak sound pressure level (SPL) of approximately 150 dBA. The pulse waveforms at both the free-field source location and the impulse acoustic test fixture (IATF), without a protector in place (unoccluded), are recorded. For consistency, five impulses are electronically captured and their waveforms analyzed to obtain the real and imaginary components necessary to calculate an acoustic transfer function. This transfer function will be used to transform the free-field impulse waveforms to their equivalent impulses at the IATF during the conduct of occluded tests. This impulse calibration and transformation is essential to the determination of a hearing protector's effectiveness in high sound level impulse environments.

The second part of the proposed test procedure is the determination of the peak sound reduction provided by a hearing protector for different peak impulse levels. For this part of the procedure, three ranges of impulsive sound levels are required: 130 to 134, 148 to 152 and 166 to 170 dBA peak sound pressure level. The specified ranges of impulse sound levels approximate the peak impulse levels created by a wide variety of everyday sources e.g. pneumatic tools, powder-

[8] Birch RS, Gerges SN, Vergara EF, ''Design of a pulse generator and shock tube for measuring hearing protector attenuation of high-amplitude impulsive noise'' Appl. Acoustics 64:269–286 (2003).

[9] Parmentier G., Dancer A., Buck K., Kronenberger G., Beck C., ''Artificial Head (ATF) for Evaluation of Hearing Protectors'' Acustica,Volume 86 (2000).

[10] Zera J. and Mlynski R. ''Attenuation of high-level impulses by earmuffs'' J. Acoust. Soc. Am. 122:2082–2096 (2007).

[11] Tubbs RL, Murphy WJ, ''Health Hazard Evaluation Report 2002–0131–2898 Fort Collins Police Services, Fort Collins Colorado'' DHHS–CDC–NIOSH, HETA #2002–0131–2898 (2003).

[12] Harney J., King B., Tubbs R., Crouch K., Hayden C., Kardous C., Khan A., Mickelsen L., Willson R., ''Health Hazard Evaluation Report 2000–0191–2960 Immigration and Naturalization Service, National Firearms Unit, Altoona, PA'', DHHS–CDC–NIOSH, HETA #2000–0191–2960 (2005).

[13] Berger, E. ''Methods of measuring the attenuation of hearing protection devices'', J. Acosut. Soc. Am. 79:1655–1687 (1986).

[14] Parmentier, G., Dancer, A., Buck, K., Kronenberger, G., and Beck, C. (2000). ''Artificial Head (ATF) for Evaluation of Hearing Protectors,'' Acta Acustica 86(5), 847–852.

actuated tools, construction equipment, firearms and fireworks.

The hearing protector is installed on the IATF, the particular SPL range is selected and the impulse sound source is activated. The free field and IATF impulse waveforms are electronically captured simultaneously with their respective microphones. The Agency has determined that for each sample type a minimum of five protectors will be tested. Each protector will be removed and refitted on the IATF for testing at each of the three impulse SPL ranges.

The third part of the proposed procedure is the calculation of the impulse sound reduction. The transfer function computed from the calibration waveforms is used to transform the free-field impulses to their counterparts at the location of the IATF microphone, absent the acoustic disturbances that result from the IATF. The transfer function effectively yields a filter that adjusts both the frequency amplitude response and the phase response of the free-field wave to account for differences due to the response of the ear simulator and resonance of the IATF ear canal. The waveforms from the IATF measured underneath the hearing protector and the transformed free-field waveforms are evaluated to identify the maximum peak sound pressures in both pairs of waveforms. The difference in decibels yields the peak reduction for a single trial of a protector and impulse SPL range. Once each of the waveform pairs has been evaluated, the maximum and minimum peak sound reductions across the range of levels would be determined for use in developing the NRRs.

d. Computation of the Noise Reduction Rating (NRR)

Manufacturers of amplitude sensitive devices are required to measure the passive REAT performance levels under the device with the electronics turned on and turned off for all test subjects. For ear muffs and helmets, where it is possible to use the MIRE technique, the levels will be measured for all test subjects. For ear plugs, the testing lab is required to perform repeated placement and replacement fittings of the device on the acoustic test fixture. The laboratory must conduct as many repeated measurements as required for the number of subjects tested.

VII. Noise Reduction Rating Strategies

This proposed regulation sets forth a new rating scheme that, while preserving the current NRR rating metric (e.g. a numeric rating of effectiveness), is expanded to provide the ultimate user and hearing conservation specialist with additional information regarding the potential range of protector effectiveness based on the users' ability to achieve proper fit.

The single number Noise Reduction Rating has been the focus of attention since promulgation of 40 CFR Part 211 subpart B, in 1979. Initial concerns ranged from a lack of understanding of the relationship between NRR and hearing protection, to concerns that such numeric ratings would result in a ''rating war'' within the hearing protector industry. While both situations have occurred intermittently since 1979, the user population has become increasingly informed in the use of the NRR, particularly the hearing conservation community. Manufacturers have concluded, for the most part, that products of like designs are very close in performance. Thus, marketing skills and pricing are the major influences affecting market share.

The EPA has paid considerable attention to the ''user-friendly'' elements of the required label. The Workshop Report served to provide valuable suggestions for improvement. The Agency recognizes that the user community encompasses a wide range of applications from very infrequent use (home shop tools & lawn care) to daily use (workplace). Consequently, a user-friendly label must satisfy the needs and levels of understanding across this broad spectrum of applications. To this end, the Agency is proposing a significant change to the label content and numerical rating scheme, while retaining the now-familiar NRR acronym.

A. HPD Rating Scheme

The significant change in NRR, as proposed here, introduces a *range* of protection rather than a single value as required in the current regulation, in recognition of the fact that users may fit the device differently and thus obtain greater or lesser levels of protection than would be indicated by the single value NRR. The NRR is determined from the results of standardized tests using a representative sampling of human test subjects. The range is anchored by two NRR values that represent the ''lesser'' and ''greater'' levels of protection that a user may expect when the product is used as instructed by the manufacturer. The range of assumed protection is determined from sound attenuation measurements for narrow band noises centered at octave-band center frequencies from 125 to 8000 Hz. The resultant measured attenuations for each test subject are used to develop a statistical rating (20 subjects for all devices except earmuffs and helmets which use 10 subjects). The lesser sound attenuation rating estimates the protection achieved by at least 80 percent of the test subjects (80th percentile). The greater sound attenuation rating estimates the protection achieved by at least 20 percent of the test subjects (20th percentile).

B. Labeled NRR Values

The diversity of hearing protector designs and intended uses is significantly greater today than 30 years ago when HPDs were predominantly passive. Today's devices incorporate specially formulated materials, ergonomic designs, sophisticated electronic circuitry and selective acoustic performance that provide hearing protection in a broad range of noise environments. In order to provide the ultimate user with information that will allow product selection based upon the user's intended noise environment, the EPA has developed three separate NRR labeling schemes as presented below:

1. Passive Hearing Protector: All hearing protectors provide a ''passive'' mode of protection against continuous noise. Therefore, EPA is proposing that the passive effectiveness of all HPDs be tested and rated. The passive mode of operation provides a basis for comparing the effectiveness of all protectors and establishes a benchmark against which other modes of performance (i.e. electronic and mechanically actuated) alter a product's overall effectiveness. The NRR range of protection is depicted by a bar graph with end points representing the lesser and greater levels of protection.

2. Active Noise Reduction (ANR) Hearing Protector: In addition to its passive range of protection, EPA is proposing that active hearing protector devices be tested and rated in their ''active'' mode. The NRR range of protection in the active mode is also depicted by a bar-graph with end points representing the lesser and greater levels of protection. In this case, the label would contain two NRR ranges, one of passive mode operation, the second for active mode operation.

The Agency has been advised by various manufacturers, NIOSH and the U.S. Air Force that the most significant noise reduction offered by ANR devices will be found at lower noise frequencies. On this basis, the Agency is proposing that the active noise reduction rating for both ear muffs and ear plugs be determined for predominantly low frequency noise. The purpose of choosing the low

frequency performance is to allow the end user to understand the potential advantage of the device in a noise field where the ANR device provides its best sound reduction performance. The Agency considered having three ratings for ANR devices (Passive performance, Active with broadband noise, and Active with low frequency noise).

The EPA believes, subject to comment, that the small sound reducing benefit in broadband noise environments detracted from the real benefit afforded by these products—significant low frequency sound protection. Therefore, the Agency is proposing that labels on ANR devices only address their passive and low frequency active performance. If a manufacturer sells a product on the basis of its active noise reduction capability, then such product must be tested accordingly.

3. Impulsive Noise Hearing Protector: In addition to their passive range of protection, hearing protector devices that are intended for use in high-level impulsive noise environments (greater than 140 dBA), must be tested and rated in such noise environments. The label will present two NRR ranges, one for the standard passive low-level noise reduction and a second for the high-level impulsive noise reduction. The impulsive NRR range will represent the lesser and greater levels of assumed protection in such environments. If the device is an active hearing protector, it must be tested and rated in its active mode in the high impulsive noise environment. If a manufacturer sells a product on the basis of its impulsive noise reduction capability, then such product must be tested accordingly.

4. Communication Headsets Incorporating Hearing Protection: Under the proposal, communication headsets would be required to have a Noise Reduction Rating label if the device is sold in whole or in part for the purpose of providing hearing protection. Communication headsets sometimes have a NRR rating but many sold in the United States do not. If a manufacturer sells a product on the basis of its acoustic noise reduction effectiveness then the Agency believes that purchasers and users of these devices are entitled to know the hearing protection that such devices offer, prior to purchase or use. EPA is also proposing that if the device incorporates active noise reduction circuitry, sound restoration circuitry and/or level limiting circuitry (i.e. is not merely a passive HPD), then the appropriate impulse noise reduction and/or active noise reduction test(s) must be conducted. The EPA believes this testing and labeling is particularly important for communication headsets used in the general aviation industry where pilot and ground crew may experience noise exposure for extended periods.

C. Noise Reduction Rating Calculator

The Noise Reduction Rating Calculator (NRRC) is an EPA/NIOSH-designed executable program that will allow manufacturers to calculate their products' NRR's by inputting their HPD attenuation measurements, which are obtained from the testing laboratory. The NRRC will generate a NRR test report. The intent of the NRRC is to afford manufacturers the ability to verify the NRR values from the laboratory test data prior to having their products labeled. This tool is a free downloadable product that will be made available to manufacturers via the EPA Web site. The use of this tool is voluntary and will serve no other purpose than a verification mechanism of the laboratory test results and the labeled NRR values.

VIII. Label Format and Content

The Agency has received a range of comments from interested parties regarding the current required primary and secondary product labels and their content.[15] The comments were relatively narrow in focus with principal attention directed at EPA's mandated statements, their technical accuracy and usefulness to both ultimate users and hearing conservation professionals. The Agency acknowledges that any *mandated* information must accurately reflect the performance and intended use of the product and do so in a manner that is understandable by the ultimate user. To this end the Agency is retaining the requirements set forth in 40 CFR, Part 211, subpart B, but is proposing significant changes to the information content, format, and mandated statements of both the primary and secondary labels.

A. Primary Label

The intent of the primary label is to provide any purchaser or user with readily visible information (on the package exterior) upon which they may make an informed decision regarding the effectiveness of the product relative to their specific hearing protection needs. To this end, the proposed regulation will require a more informative primary label that provides a range of the noise reduction effectiveness as opposed to the single NRR value required currently. The label will identify the protector's intended function (Passive, Active, or Impulsive) and provide the respective range(s) of effectiveness afforded by the product. The range will be presented as a bar graph with endpoints representing the estimated lesser and greater levels of effectiveness. In addition, the primary label will contain an explanation of the product's intended function, use environment, and determination of levels of protection based on the effectiveness rating(s) (NRR). Where appropriate, a caution statement that speaks to the potential unintended use of the product is provided. The label will identify the manufacturer and its relevant contact information, the protector model, and the mandated EPA prohibition and regulatory authorization.

There are a number of products that fit into or over a person's ears to provide, for example, relief from sleep disturbance, prevent water entry during swimming or to enhance the listening quality of music and video dialogue presentations. While not *designed or intended* for use as hearing protection devices, their similarity in appearance to bonafide HPDs may result in their inadvertent purchase or use for hearing protection due to the marketing language on the product label. While these products may offer some level of noise reduction to the user, they are not designed nor intended for the protection of hearing and thus are not subject to this proposed regulation. However, to the extent that a product manufacturer, importer, packager or any other party introduces into U.S. commerce any product that incorporates an explicit or implicit claim that it can protect the hearing of the user, or stipulates the level of acoustic sound reduction offered by it, then such product is subject to the testing and labeling requirements of this proposed regulation.

For companies that sell their products exclusively via the internet, the primary label must be visible to the purchaser at the time of the sale to ensure that the purchaser is fully aware of the product's NRR values. The primary label would replicate the appropriate format, as identified in § 211.204–1, and be automatically downloaded to the purchaser with the sale confirmation document. This proposal implements the requirements of section 8 of the Act that ''the Administrator shall by regulation require that notice be given to the prospective user of the level of the noise the product emits, or of its effectiveness in reducing noise''. This

[15] Reference ''workshop report'' in the Docket at *http://www.regulations.gov*, docket number EPA–HQ–OAR–2003–0024.

authority is not limited by the medium by which HPDs are marketed and sold.

B. Secondary Label

The intent of the secondary label is to provide an in-depth explanation to experienced users and/or hearing conservation professionals of the HPDs functional performance, noise reduction capabilities and, where appropriate, unique features. Consistent with the 1979 regulation, the secondary label is to be located within the individual product packaging or, in the case of bulk packaging, affixed to the exterior of the bulk container. In the case of the newly proposed electronic labeling, the secondary label must be readily viewable on the manufacturer's web-page along with the primary label and be automatically downloaded to the purchaser with the sale confirmation document. The secondary label would include various mandatory data tables, product performance graphics, examples of calculations to determine specific levels of protection and information regarding the products use and limitations.

The Agency is proposing the following product specific information and mandatory statements:

1. All devices (PASSIVE mode): provide the products octave band attenuation and standard deviations and graphical and tabular presentations of the variability of the products NRR for different frequency spectra (Spectral Balance). This information is important to hearing conservation programs where protection is selected to reduce user exposure to particular sounds in the noise environment.

2. All devices (PASSIVE mode): provide the statement ''When this device is used as instructed, the approximate range of noise levels entering a user's ears may be determined by the differences between the lesser and greater NRRs and the A-weighted environmental noise level.''

3. ACTIVE devices: provide the variability of the NRR with spectral balance for the device operating in its PASSIVE and ACTIVE modes (electronics turned on and off).

4. ACTIVE devices: provide the following statement ''When this device is used as instructed and operated in its passive mode, the level of noise entering a person's ears is approximated by the differences between the A-weighted environmental noise level and the lesser and greater PASSIVE NRRs. When this device is operated in its active mode, the level of noise entering a person's ears is approximated by the difference between the A-weighted environmental noise level and the lesser and greater ACTIVE NRRs.''

5. ACTIVE devices: provide the statement ''This device, in its ACTIVE mode, is recommended for use in environmental noise levels from X to Y dBA.'' X and Y are to be designated by the manufacturer since only the manufacturer knows the design limitations of the noise cancellation or sound augmentation of the electronic circuitry incorporated in the device.

6. IMPULSIVE devices: provide a graphical and tabular presentation of the impulsive noise reduction for impulses with peak sound pressure levels that range between 130 and 170 dBA sound pressure level (re 20 μPa). This peak sound pressure range is designated by the testing protocol that is set forth in the proposed regulation. Testing to peak sound pressure levels in excess of 170 dBA would require specialized equipment and testing environment which may not be readily available to commercial testing laboratories.

7. IMPULSIVE devices: provide the statement ''This device is recommended for use in impulsive noise environments having peak levels from 130 to X dBA SPL.'' The Agency acknowledges that products are available for use in impulsive noise environments that exceed the maximum sound pressure level specified in the proposed regulation. Consequently, testing and labeling for levels in excess of the 170 dBA will be allowed provided the manufacturer designates the upper noise limit (X dB) and the test protocol that was used to determine the effectiveness rating (NRR).

8. IMPULSIVE devices: for reasons stated in numbers 6 and 7 above this statement must be provided ''Caution: This device is not intended for use in impulsive noise environments exceeding X dBA peak sound pressure levels (as determined by the manufacturer). Repeated exposures to high peak impulsive sound pressure levels may result in hearing loss.''

9. Devices that have not been tested for impulse noise reduction rating: provide the statement ''The PASSIVE Noise Reduction Rating is based on the attenuation of continuous noise and is not an accurate indicator of the protection attainable against impulsive noise. The IMPULSIVE Noise Reduction Rating is based on the attenuation of high-level impulsive noise and is not an accurate indicator of the protection attainable for continuous noise.''

10. All devices except IMPULSIVE: provide the statement ''Caution: For predominantly low frequency noise environments in which the difference in the measured C-weighted and A-weighted noise levels (dBC–dBA) exceeds 3 dB, the user should refer to the enclosed graph of the variability of noise reduction with noise spectra to determine the level of protection.''

IX. Compliance Requirements

EPA is proposing that all hearing protection devices manufactured after the effective date of this regulation, and meeting the applicability requirements of section IV, must be labeled prior to entry into U.S. commerce. The Noise Reduction Ratings, as determined by the designated test procedure, must be readily visible to the purchaser or the ultimate user, on the exterior of the HPD package, bulk container or at its point of sale. The advent of the internet has introduced a new ''point of sale'' of products to the public. In recognition of this new sales mechanism the EPA is proposing to allow ''electronic labeling'' of hearing protector devices that are sold exclusively via the internet. As noted above, regulating the content of electronic labels is consistent with EPA's broad authority to give users notice of noise levels and HPD effectiveness. Moreover, although the Act's labeling requirements refer to labels being affixed to a product or its container, the requirement that these electronic labels be provided to users at the time of sale is equivalent to labels being affixed to the product—fulfilling the Act's evident purpose of providing users with needed information at the time of sale so as to allow for a considered decision. The proposed electronic labeling must comply with all provisions attendant to both the ''primary'' and ''secondary'' labels.

A. Transition Testing Requirements

The proposed regulation will require testing and labeling procedures significantly different than required by the 1979 regulation. Consequently, after the effective date of this regulation all HPDs must be tested to determine their respective NRRs in accordance with these new test protocols. Testing will be conducted on protectors selected from the product lot (batch) of protectors that are scheduled for entry into commerce on or after the date of the transition test. The manufacturer will be required to submit the test results to the Agency within ten (10) business days of the transition test date. The Agency recognizes that the industry is composed of manufacturers that have single or multiple HPD product lines with various functions that will need to be tested. The Agency identified approximately 1,029 different HPD products currently for sale in the U.S., including 403 models of earplugs or

semi-aural devices, 572 models of earmuffs sold either alone or incorporated into communication headsets and 54 models of active noise reduction devices. Of these 1,029 HPDs, an additional impulse noise reduction test would be required for approximately 156 products.

Based on information obtained from industry sources, the EPA estimates approximately 20 percent of the products will be tested in-house by their respective manufacturers. The approximately 80 percent of remaining products are expected to be tested by two independent testing laboratories and by two manufacturer laboratories that test for fee. Based on information from both in-house and independent testing laboratories, the Agency estimates the testing capacity for a single laboratory to be between 150 and 200 products per year.[16] Assuming there are 1,029 existing HPDs plus an arbitrarily estimated 50 new products to be tested and labeled, the average yearly demand on each of the four testing laboratories would be about 108 products. Consequently, the Agency believes that the available testing laboratories can carry out all required transition testing within thirty (30) months from the effective date of this proposed rule. In addition, we believe that a period of thirty (30) months from the effective date of this proposed rule will provide adequate time for manufacturers to deplete their inventories of product that was tested and labeled pursuant to the 1979 regulation. Since manufacturers have discretion to select the order in which their products are to be tested and labeled, we believe that full compliance with the proposed rule can be achieved within thirty (30) months without any disruption in the availability of any product category.

B. Recurrent Testing Requirements

The current regulation requires that HPDs be tested and rated only once in the lifetime of the product category. While a manufacturer may claim that a specific product has not been changed from its initial design, fabrication/assembly technique or materials, the EPA believes that economic factors associated with any one or combination of these elements can produce changes in product performance.

EPA is proposing to require recurrent testing for all product categories subject to this proposed regulation. The purpose of recurrent testing is to provide a comparison of effectiveness ratings of a product over a period of time and to ensure that product labels accurately reflect current effectiveness. To insure the continuing validity of the effectiveness rating (NRR) and to recognize changes in product design or use, manufacturers will be required to retest their products on a periodic basis and to relabel as necessary. For the purpose of the cost analysis two recurrent testing periods, three and five years were considered.

Relabeling of a protector would be required if the recurrent test yields a lesser and/or greater NRR that is more than 3 dB different from the corresponding transition or new product NRR values given on the product label. The basis for a 3-dB criterion to initiate the relabeling requirement is two fold. First, a 3-dB change in attenuation can either double or halve the effective protection of a device. Second, the variability of the effectiveness rating for earplugs and earmuffs was found to be approximately 3 dB according to the EPA/NIOSH interlaboratory study.[17] To this end the Agency is proposing that all HPDs be retested every five (5) years after the date of their respective transition test and each recurrent test thereafter. Since it is believed that manufacturers will time-stream the testing of their product categories, the first recurrent test could occur as early as approximately sixty-one (61) months and as long as ninety (90) months after the effective date of this proposed regulation.

The Agency believes that linking the recurrent testing to the transition test and subsequent recurrent tests, rather than the effective date of the regulation, will allow manufacturers to stagger their testing and thus minimize testing burdens during any one period of time. For the purpose of recurrent testing, protectors would be selected by the manufacturer from the product lot (batch) of protectors that are scheduled for entry into commerce on the date of the required recurrent test.

C. Product Change Retesting Requirement

The Agency recognized in its current regulation that manufacturers may make product changes to take advantage of new materials, lower cost materials, more efficient manufacturing processes, etc. While the EPA supports any product change that may improve product performance, it has concern that such changes could serve to degrade product performance from its initial state. Therefore, the Agency is proposing to continue the product retest requirement if the manufacturer alters the product design, product materials, manufacturing process or takes any action that may alter the noise reduction performance of the product from its previous test state. Relabeling would be required if the recurrent test yields a lesser and/or greater NRR value(s) that differs by more than 3 dB from the current NRR value(s) given on the product label. The manufacturer will be required to submit the test results to the Agency within ten (10) business days of the change testing date.

D. Compliance Audit Testing

In the 1979 regulation, the EPA defined the basis on which the Administrator may order verification of the claimed performance of a product. Since the Agency is proposing mandatory retesting of all HPDs entering United States commerce, it is anticipated that an administrative order for verification testing will only be required in those cases where there is a reasonable basis to believe a manufacturer (or any party entering HPDs into U.S. commerce) or particular product is not in compliance with all requirements of the proposed rule. In such case, the compliance audit testing requirements of Subpart B, § 211.212 would be ordered by the Administrator. Nothing herein, however, restricts the Administrator's authority under section 13 of the Noise Control Act. [42 U.S.C. 4912]

E. Maintenance of records and submittal of information

The 1979 regulation required manufacturers, which include any party that enters a hearing protection device into commerce in the United States, to establish, maintain and retain adequately organized and indexed records that provide the basis for the claimed NRR values. These records included, in part:

1. Identification and description by category parameters of protectors comprising the manufacturer's product line.

2. A complete record of all noise attenuation tests performed including all individual worksheets, and other documentation relating to each test required by the Federal test procedure.

3. A description of any test procedures, other than those contained in this regulation, used to perform noise attenuation tests on any protector, and the results of those tests.

[16] U.S. Environmental Protection Agency. 2008. Cost Analysis for Proposed Labeling Regulation of Hearing Protection Device Industry. EC/R Inc. Chapel Hill, NC.

[17] National Institute for Occupational Safety and Health (NIOSH)/EPA Interlab Study Comparison of ANSI S12.6, Method A and B. Refer to the Federal Docket at *http://www.regulations.gov*, docket number EPA–HQ–OAR–2003–0024.

4. A record, signed by an authorized representative of the testing laboratory, of any calibration that was performed during testing by the test laboratory.

The manufacturer was able to fulfill this record retention requirement by keeping a copy of the labeling verification report. In addition, the current regulation limited testing to once in a products lifetime unless altered by design, materials or construction. This rather simplistic record keeping scheme was appropriate at a time when protectors were primarily designed as ''passive'' devices, prior to the advent of a plethora of new technology devices that will be available in the marketplace as a result of this proposed regulation.

The Agency has determined that the complexity of device designs, their multi-mode performance and diverse testing protocols dictate the need for periodic retesting as discussed previously. In order to establish reliable baseline performance information for each device against which future performance can be compared, the EPA is proposing the manufacturer provide the Agency with their product test information, according to § 211.209–1, following each required product test. As required by the 1979 regulation, the manufacturer would still retain all required records for a period corresponding to the time interval specified by the *recurrent testing* schedule. Records may be retained as electronic or hard copy or reduced to microfilm, or other forms of data storage depending on the record retention procedures of the manufacturer. The manufacturer must submit to the EPA, in electronic or hardcopy format, a copy of all measurement information, test results and calculated *lesser* and *greater* NRRs obtained from the testing laboratory for each product or product category within ten (10) business days of completion of the required test. These test data would be maintained by EPA in the docket for this regulation and be available for public review.

X. Cost Impact Analysis

As part of EPA's analysis in determining the feasibility and reasonableness of this proposal, EPA has carefully assessed its projected costs. Various Agency, Executive Office and Congressional policies, orders and mandates, respectively, specify the required analyses. The EPA's Economic Analysis Resource Document provides guidance for economic analyses that support rulemaking.[18]

A traditional benefit-cost analysis for HPD labeling is not possible due to the diverse makeup of the user population and its use practices that preclude quantification. Because a major percentage of the 2.1 billion HPDs purchased annually by industry are disposable earplugs (approximately 1.94 billion), the numbers strongly suggest that a ''workplace'' user may dispose of many pairs per day. This user practice does not lend itself to using product sales to quantify the user population that is requisite to a benefit–cost analysis. While the practice of disposal does not extend to the earmuff type HPD or to those HPDs that incorporate electrical or mechanical systems and thus are more costly, a benefit-cost analysis based on this latter user population would not be representative of the principal user population.

Further, while product use inside the workplace may be mandatory in some sectors where they serve as alternatives to engineering solutions to employee noise exposure, HPD use may be voluntary in others; they are totally discretionary in the non-industrial sector, i.e., recreational activities, home workshop, home lawn care, etc.

Finally, because the effectiveness of an HPD depends on the user's ability to ''install'' or fit the product as instructed by the manufacturer, it is difficult to estimate the level of hearing damage or loss avoided through the use of any specific product.

In light of the above impediments to a traditional benefit-cost analysis, the EPA has carried out a cost impact analysis. This analysis indicates that the estimated cost impact of the proposed rule change will be well below the $100 million annual economic impact threshold that would trigger a benefit-cost analysis under Executive Order 12866.

The purpose of this cost impact analysis is to assess the costs which would be imposed by changes to the testing and labeling requirements and to evaluate the impacts of these costs on all parties subject to this regulation with particular emphasis on potential cost impacts on small businesses. The following sections provide a summary profile of the HPD industry and an assessment of those anticipated costs and potential economic impacts that are attendant to the proposed revisions. The detailed cost analysis report, entitled *''Cost Analysis for Proposed Labeling Regulation of the Hearing Protection Device Industry,''*[19] is hereinafter referred to as the cost analysis report.

A. Industry Profile

The direct economic impacts of revisions to the labeling requirements will apply to all HPD manufacturers (as defined in § 211.203 of subpart B) that enter their products into U.S. commerce. Consequently, the potential cost impact could extend to foreign manufacturers that export to the United States, non-manufacturing packagers, and testing laboratories because the revisions include revised or new test methods. The following sections describe HPD products and markets, outline the market structure of this industry, and provide currently available information on HPD sales volumes in the U.S.

1. Markets

The main applications for hearing protection devices are in occupational settings, such as in industrial workplaces, military, law enforcement, forestry and landscaping, by musicians, in home hobby workshops and lawn garden activities and the aviation community. In the industrial workplace HPDs are frequently used in lieu of engineering controls, to comply with maximum employee noise exposure standards set by the OSHA. Absent engineering noise control measures or severe time limitations on employee exposure, there are no substitutes for HPDs to reduce human noise exposure. As stated previously, the Agency determined that the industrial sector purchases approximately 2.1 billion HPDs annually. The breakdown by product type is approximately 1.94 billion disposable earplugs, 155 million reusable earplugs, 2.4 million semi-aural inserts, and 3 million earmuffs. Although a detailed count of hearing protector types and quantities was not possible for the non-industrial sector, including the military and law enforcement, discussions with major U.S. manufacturers suggests this sector accounts for an additional 1.9 billion units annually. Thus, the combined industry and commercial market is estimated at approximately 4 billion units annually.

Within the HPD categories, the choice of an ear plug, ear muff, or semi-aural device is largely dependent on the assumed level of protection, as indicated by the product NRR, cost, personal comfort and, product care

[18] U.S. Environmental Protection Agency. 1999. Economic Analysis Resource Document. RTP, NC: EPA.

[19] The referenced report can be found in the Docket at *http://www.regulations.gov,* docket number EPA–HQ–OAR–2003–0024.

requirements. For the general public the three types of HPDs can be easily substituted depending on user preference. However, for industrial workers the specific characteristics of the noise environment may dictate the appropriate HPD to comply with OSHA exposure requirements.

2. Product Sales Volume

The Frost & Sullivan market research group has estimated total sales of HPDs for the industrial market in the U.S. at $242.9 million.[20] Table A–1 presents the estimated breakdown of the industrial HPD market among earplugs, semi-aural devices, and earmuffs, giving the estimated average wholesale price for each of these product types. As noted, earplugs account for about 75 percent of the industrial market, earmuffs account for about 20 percent and semi-aural devices account for about 5 percent. Frost & Sullivan has estimated the average unit prices of HPDs at $0.06–0.07 for disposable earplugs, $0.36 for reusable earplugs, $5 for semi-aural devices, and $16 for earmuffs.

The Frost & Sullivan estimates do not include military or consumer uses of HPDs; consequently, monetary size of these markets was not available. However, based on limited information the Agency obtained from visits to various HPD manufacturers, it estimates the commercial/military market to be approximately 89 percent of the industrial market. It was not possible to obtain a breakdown of product categories, as in the case of the industrial market. However, the Agency believes that a conservative estimate of the total sales of HPDs for the commercial/military market in the U.S. to be $216.2 million.

Information is not available on the size of the market for active noise reduction (ANR) HPDs or for communication headsets that also serve as HPD's; under the 1979 regulation these products cannot be sold as ''hearing protection devices.'' However, the Agency believes some sales of these devices may be included in the estimate of earmuffs produced for the industrial hearing protection, the music entertainment, and the aviation markets.

TABLE A–1—ESTIMATED SALES OF HPD FOR INDUSTRIAL APPLICATIONS IN 2004[a]

Product type	Total U.S. industrial sales (million $)	Average wholesale price per unit ($)
Disposable earplugs	126.3	0.06–0.07
Reusable earplugs	55.9	0.36
Semi-aural inserts	12.1	5
Earmuffs	48.6	16
Total	242.9	

[a] *Source:* Frost & Sullivan.[3]

3. Industry Categorization

The U.S. Census Bureau compiles economic statistics for manufacturing and trade sectors in the U.S. using the North American Industrial Classification System (NAICS), which has replaced the earlier Standard Industrial Classification (SIC) system. The NAICS and SIC codes can be used to retrieve company financial information from various market databases, such as Dun and Bradstreet and Thomas Register.

The NAICS system includes HPD manufacturing and other personal safety manufacturing under the general miscellaneous manufacturing category 339113, ''Miscellaneous Manufacturing—Surgical Appliance and Supplies Manufacture.'' Specifically, subcategory 3391136 within this category covers ''Personal Industrial and Non-industrial Safety Equipment and Clothing,'' including ''personal noise protector manufacturing.'' Similarly, the SIC system classified HPD manufacturing under category 3842, ''Orthopedic, Prosthetic, and Surgical Appliances and Supplies,'' and subcategory 38423, ''Personal Industrial Safety Devices.''

Most manufacturers of HPDs list the general miscellaneous manufacturing category 339113 as their primary NAICS code. However, some manufacturers also manufacture other products, and determine their primary NAICS on the basis of these other products. For instance, many manufacturers of noise cancellation devices are also manufacturers of other electronic equipment. Similarly, some manufacturers of foam-based earplugs define their NAICS code based on the manufacture of polymer products. Table A–2 lists the various NAICS and SIC codes used by HPD manufacturers and distributors.

TABLE A–2—NAICS AND SIC CODES GIVEN BY MANUFACTURERS AND WHOLESALERS OF HEARING PROTECTION DEVICES[a]

NAICS code	SIC code	Description	Number of companies
Manufacturers			
339113	3842	Surgical Appliance and Supplies Manufacturing	22
334290	3669	Other Communications Equipment Manufacturing	4
334310	3651	Audio and Video Equipment Manufacturing	2
326112	3089	Plastics Packaging Film and Sheet (including Laminated) Manufacturing.	2
325212	2822	Synthetic Rubber Manufacturing	1
334514	3824	Totalizing Fluid Meter and Counting Device Manufacturing.	1
339932	3944	Game, Toy, and Children's Vehicle Manufacturing.	1
334220	3663	Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing.	1
334419	3679	Other Electronic Component Manufacturing	1
339111	3821	Laboratory Apparatus and Furniture Manufacturing.	1
325211	2821	Plastics Material and Resin Manufacturing	1

[20] Frost & Sullivan. 2005. U.S. Markets for Industrial Hearing Protection Products.

TABLE A–2—NAICS AND SIC CODES GIVEN BY MANUFACTURERS AND WHOLESALERS OF HEARING PROTECTION DEVICES [a]—Continued

NAICS code	SIC code	Description	Number of companies
333514	3544	Special Die and Tool, Die Set, Jig, and Fixture Manufacturing.	1
339115	3851	Ophthalmic Goods Manufacturing	1
Wholesalers			
423450	5047	Medical, Dental, and Hospital Equipment and Supplies Merchant Wholesalers.	3
423990	5099	Other Miscellaneous Durable Goods Merchant Wholesalers.	1
423860	5088	Transportation Equipment and Supplies (except Motor Vehicle) Merchant Wholesalers.	1
423840	5085	Industrial Supplies Merchant Wholesalers	1
541710	8731	Research and Development in the Physical, Engineering, and Life Sciences.	1
423	5065	Wholesalers of Electronic Parts and Equipment	1

[a] *Source:* Dunn and Bradstreet database.

4. U.S. Manufacturers

The EPA has identified 96 companies that it believes to be suppliers of HPDs in the U.S. market under their own brand names. Of the 96 companies, 34 produce or sell only one or two products. Another 31 companies produce or sell 3 to 10 products, and the remaining 31 companies produce or sell more than 10 different products. These products may be of the same category, i.e. ear plugs, ear muffs, ANR, or impulsive or encompass all categories. This list was compiled from the NIOSH Hearing Protection Device Compendium,[21] trade association directories and buyer's guides and from market databases. A search of the internet was also conducted to identify companies advertising themselves as manufacturers of HPDs. The International Safety Equipment Association (ISEA) provided the Agency with information regarding private labeling of products from various major HPD manufacturers. A list of these manufacturers is given in the EPA cost analysis report. Most of the manufacturers of HPDs also manufacture other personal safety equipment, such as helmets, respirators, and face shields. Manufacturers of electronic noise cancellation systems generally also manufacture other electronic equipment. Similarly, the manufacturers of communications equipment, which include built-in HPD components, generally also manufacture other electronic equipment such as communications equipment.

Although there are many manufacturers supplying the HPD market in the U.S., available information suggests the industrial HPD market is dominated by a small number of companies. Frost & Sullivan estimates that three companies account for about 78 percent of the industrial HPD market. The Agency was unable to quantify market share for the commercial/military HPD market.

This type of market structure, with a small number of suppliers accounting for most of the industrial HPD market, is termed an oligopoly, where prices generally remain relatively stable. If one of the three major firms drops its price, all other firms will quickly follow suit and equilibrium is re-established without any change in market share. If a firm chooses to increase its price, the other firms will stay where they are and quickly take a portion of the original firm's market share. Thus, firms tend to keep their prices at a stable level, as evidenced by the fact that average prices of HPDs have been stable from 2001–2004.[22] However, some manufacturers serve niche markets, such as custom-fit or special needs hearing protector devices, i.e. helmets, where they may have flexibility to raise prices and pass along regulatory costs due to limited competition.

5. Distributors and Packagers

Manufacturers of HPDs generally sell their products to distributors of safety equipment or industrial supplies, rather than directly to industrial users. According to the Thomas Register there are at least 220 distributors in the United States,[23] resulting in a less concentrated market than that of manufacturers.

NIOSH estimated there are at least 20 packagers, or ''private labelers,'' of HPDs in the U.S.[24] In many cases the primary manufacturer will package his product with the private label of a distributor or retailer such as supermarkets and home supply chains. In other cases the packagers or private labelers will purchase, in bulk, HPDs that they then package under their private label in smaller quantities or as individual pairs of HPDs for retail sale. Some private labelers go so far as to change the color of their product from that of the original manufacturer in order to establish or preserve their private brand identity.

6. Imports to the U.S.

A number of foreign manufacturers supply HPDs to the U.S. industrial and consumer markets. EPA has identified seven manufacturers in Canada and Europe and 18 manufacturers in Asia.[23] The Agency believes there may be others but is unable to obtain a reliable identification or count.

The International Trade Administration (ITA) publishes statistics on imports and exports for different NAICS codes. Total U.S. imports for NAICS code 339113 in 2004, were estimated at $4.7 billion.[25]

[21] Franks JR, Graydon PS, Jeng C, Murphy WJ, ''NIOSH Hearing Protector Device Compendium,'' *http://www2d.cdc.gov/hp-devices/hp_srchpg01.asp* (2003). as of July 6, 2008.

[22] Frost & Sullivan. 2005. *U.S. Markets for Industrial Hearing Protection Products.*

[23] Thomas Publishing (Thomas Register), *ThomasNet: Hearing Protection Devices,* Accessed July 31, 2007, *http://www.thomasnet.com*

[24] Telephone Contact Report. Deering, A., EC/R Incorporated, with Graydon, P., NIOSH. September 20, 2004.

[25] International Trade Administration. 339113 *Surgical Appliance & Supplies: Customs Value by Customs Value for ALL Countries. http://*

However, this figure is not restricted to HPDs and includes other personal safety equipment, clothing, and surgical supplies. For comparison, the total volume of shipments in 2001 for domestic manufacturers in NAICS code 339113 was approximately $18.9 billion.[26] Thus, imports are about 25 percent of domestic production for the overall NAICS category (including HPDs, other safety equipment, and surgical supplies). The majority of the imports in NAICS code 339113 are from Mexico, China, Taiwan, and Canada.

The impact of these foreign imports on the U.S. market is unclear as the quantity imported to the U.S. cannot be readily determined. Considering that three or four companies hold the larger market share of industrial HPDs, the impact of foreign manufacturers on the industrial market is believed to be small. The Agency believes these latter imports are primarily directed toward the public consumer market through retailers.

7. U.S. Exports

Exports from the U.S. in 2004 for NAICS code 339113 have been estimated at $4.8 billion.[27] This is about 25 percent of estimated total domestic production in that category.[28] However, as noted previously, this category includes a number of products in addition to HPDs.

B. Costs of Production

The U.S. Census Bureau compiles information on production costs and income for manufacturing industries in the U.S. The Census's *Manufacturing* series gives estimates of production costs for various industrial categories and subcategories. Table B–1 presents cost estimates for NAICS code 339113, which covers surgical appliance and supplies manufacturing and personal safety equipment. In addition, the table shows the estimated cost breakdown for the ''Personal Industrial and Nonindustrial Safety Equipment and Clothing'' subcategory (coded as subcategory 3391136). Production costs in this category are estimated as 18 percent of sales for labor, 47 percent for materials, and 3 percent for capital investment.[29] However, these costs may not include certain elements, such as cost of sales.

The Census's *Quarterly Financial Report* series gives income estimates and other financial information for broader industrial categories. In this series, information is available at the level of NAICS code 339, ''Miscellaneous Manufacturing.'' Within this category, estimated income from operations in 2006 was 11.4 percent of net sales. For small companies in this category, estimated income was 5.1 percent of net sales.[30]

TABLE B–1—ESTIMATED COSTS OF PRODUCTION AND NET INCOME AS A FRACTION OF SALES FOR SAFETY EQUIPMENT MANUFACTURE AND MISCELLANEOUS MANUFACTURE [a]

Quantity	Estimated costs and income as a fraction of the total value of shipments (%)					
	NAICS code	Labor cost	Cost of materials	Capital investment	Total costs [b]	Income from operation
Surgical Appliance and Supplies Manufacture (including personal safety equipment)	339113	18	30	3	51	
Personal industrial and nonindustrial safety equipment and clothing subcategory	3391136	18	47	3	68	
All miscellaneous manufacturing, all companies	339	.....	.....	.....	.....	11.4
Small miscellaneous manufacturing [c]	339	.....	.....	.....	.....	5.1

[a] *Source:* Census Bureau
[b] These costs include labor, materials, and capital investment. Certain other costs such as costs of sales may not be included.
[c] For the purposes of this Census survey, small companies have been defined as companies with less than $25 million of assets.

1. Hearing Protector Testing Laboratories

The 1979 regulation requires the devices be tested to determine their effectiveness. As stated previously, under the current rule, product effectiveness testing is required only once in a product's life unless the product is altered in a way that may affect its sound reduction performance. EPA is proposing to require new test methods and recurrent testing throughout a product's life to ensure the continuing accuracy of the labeled NRRs and other performance properties.

Table B–2 provides a list of eight laboratories in the U.S. that perform the ANSI S3.19 tests required by the current regulation. The EPA believes that these laboratories will continue to test HPDs in accordance with the new ANSI S12.6 standard specified in this proposed regulation. Four laboratories currently perform tests on a commercial basis for a fee; two are owned and operated by HPD manufacturers; and two are independent testing laboratories. The remaining four are U.S. government laboratories and, at this time, do not conduct testing for commercial organizations on a fee basis. However, the Agency believes that the new requirement for *recurrent* testing will stimulate the entry of additional testing laboratories to the market.

Three of the laboratories listed below are accredited under the National Voluntary Laboratory Accreditation Program (NVLAP) managed by the National Institute of Standards and Technology (NIST).[31] This accreditation, although not required by the EPA, is used by some companies in their advertisements to give increased credibility to their reported NRR values as compared to their non-accredited competition. The EPA is not requiring NVLAP accreditation of testing laboratories in this proposed regulation

www.ita.doc.gov/td/health/imp339113.htm Accessed October 17, 2007.

[26] International Trade Administration, *Surgical Appliances and Supplies Manufacturing (NAICS 339113), http://www.ita.doc.gov/td/industry/otea/industry_sector/tables_naics/339113.htm*

[27] International Trade Administration. *339113 Surgical Appliance and Supplies: U.S. Domestic Exports. http://www.ita.doc.gov/td/health/exp339113.html* Accessed October 17, 2007.

[28] International Trade Administration. *339113 Surgical Appliance and Supplies: U.S. Domestic Exports. http://www.ita.doc.gov/td/health/exp339113.html* Accessed October 17, 2007.

[29] U.S. Census Bureau, *2002 Economic Census, Manufacturing Industry Series: Surgical Appliance and Supplies Manufacturing, EC02–311–339113 (RV),* 2002, *http://www.census.gov/prod/ec01/ec023li339113.pdf.*

[30] U.S. Census Bureau, *Quarterly Financial Report for Manufacturing, Mining, and Trade Corporations, QFR/06–Q1,* 2006, *http://www.census.gov/prod/2006pubs/qfr06q1.pdf.*

[31] Faison, C. Douglas. *What is the National Institute of Standards and Technology. National Voluntary Laboratory Accreditation Program (NVLAP)?* May 2006. *http://ts.nist.gov/Standards/upload/What-is-the-NVLAP.pdf.*

because it does not believe that such accreditation significantly enhances the technical qualifications of the laboratory to carry out the required tests nor the quality of the test results. More important, the Agency believes that the initial and recurring annual recertification costs of such accreditation may have a chilling effect on the entry of new testing laboratories into the market.

TABLE B–2—HEARING PROTECTION DEVICE TESTING LABORATORIES

Laboratory name	Location	NVLAP accreditation	Currently carries out testing for a fee
Aearo Corporation's E–A–RCAL Acoustical Laboratory	Indianapolis, Indiana	Yes	Yes.
Howard Leight Acoustical Testing Laboratory	San Diego, California	Yes	Yes.
Michael and Associates	College Station, Pennsylvania	Yes	Yes.
Auditory Systems Laboratory at Virginia Polytechnic Institute and State University (Virginia Tech.).	Blacksburg, Virginia	No	*Yes.
U.S. Air Force Research Laboratory	Wright-Patterson Air Force Base, Ohio.	No	No.
National Institute of Occupational Safety and Health (NIOSH) Robert Taft Laboratories.	Cincinnati, Ohio	No	No.
NIOSH Pittsburgh Research Laboratories	Pittsburgh, Pennsylvania	Yes	No.
U.S. Army Aero Medical Research Laboratory	Fort Rucker, Alabama	No	No.

*The testing conducted at Virginia Polytechnic Institute is primarily focused on research.

C. Cost Analysis

To comply with the proposed rule the HPD industry will incur various costs beyond those that are attendant to the current rule. Information obtained from seven HPD manufacturers, selected as a representative cross-section of the industry, and two HPD testing laboratories, formed the initial basis for estimating the potential costs and economic effects of the proposed rule. Once word of EPA's activities to revise the current regulation was heard by interested parties, a number of additional companies volunteered information.

The questionnaire that was used in the formal interviews with the seven manufacturers and the list of companies providing information for this study are contained in the report, *''Cost Analysis for Proposed Labeling Regulation of the Hearing Protection Device Industry''.* Information was also obtained from commercial market databases and advertising materials published by HPD manufacturers. The following sections discuss the estimated costs and potential economic effects of the revised labeling rule and the potential impacts on the HPD industry. A separate analysis of the potential cost impact on small entities is provided in section XI, paragraph C (Statutory and Executive Order Reviews) below.

This proposed regulation would require all hearing protector devices to be tested and rated using new ANSI and EPA test methods. The proposed regulation will also require periodic label verification testing (recurrent testing), that is not required by the 1979 regulation. As stated previously, EPA examined the recurring test intervals of three and five years to determine the effects on all size manufacturers. Based on this analysis the Agency is proposing recurrent testing every five years from the date of the transition test date. As discussed above, if recurrent testing reveals changes in NRR values in excess of the 3 dB criteria the product must be relabeled. In contrast, the current regulation only requires retesting and attendant label changes if the design, composition, or manufacturing process for a product changes its measured performance.

1. Costs of Revised Testing and Labeling Requirements

The cost analysis carried out for this proposed regulation includes the following elements:

- Transition testing required for all existing HPD products using the new ANSI and EPA test methods and rating scheme.
- Labeling all existing products to incorporate the new NRR range information and new label content; applicable to both primary and secondary labels.
- Recurrent testing for all HPDs at either 3 or 5 year intervals.
- Changing the label to reflect a new NRR range of any product for which the recurrent testing yields NRRs that are significantly lower or higher than previously stated on the products label.
- Additional recordkeeping and reporting costs attendant to the periodic retests.

a. Transition Testing and Labeling Costs

Seven HPD manufacturers and two testing laboratories provided a range of estimates of the unit costs to test and label each of their HPD product lines. Some companies provided cost estimates based on their in-house test facilities. Others provided estimates based on historic charges from independent testing laboratories. Most companies provided cost data based on the existing test method; however, some, including one independent test laboratory, provided estimates based on their experience using the new ANSI method.

Table C–1 summarizes the ranges of cost estimates for the existing test method and the new ANSI/EPA test methods. The table also presents the range of unit cost estimates developed from the information collected by this study to analyze the impacts of the proposed rule changes. Testing costs for earmuffs are given for each potential headband position. This means that if a particular earmuff can be worn with the headband in three different positions (behind-the-head, over-the-head, or under-the-chin), then three tests may be required—this analysis provides a conservative evaluation of costs since many manufacturers are expected to identify a preferred headband position. The testing cost estimates reflect the costs of testing using an outside laboratory, although several major manufacturers are expected to use their in-house testing facilities.

The costs of testing using the new ANSI/EPA methods are estimated to be somewhat higher than the costs of testing using the 1979 standard for a number of reasons, the principal one being the requirement for twice as many test subjects. Testing costs are somewhat higher for earplugs and inserts than for earmuffs because of the need to train subjects on how to correctly insert the plugs into their ears.

In addition, the table presents the cost estimates provided by the sampled companies for creating an entirely new product label to reflect the change from

a single number NRR to a range of two NRRs.

The ranges of cost estimates are quite broad, even for the existing test methods. This may be the result of changes in the unit cost of testing depending on the number of products tested at a given time; costs do not reflect potential savings afforded by the use of test subjects for multiple product tests. Further, the relatively large cost range for testing electronic noise cancellation (ANR) systems stems, in part, from uncertainties about the entirely new test method that is proposed here for those devices. The Agency is soliciting comment and cost estimates based on the proposed test protocols.

TABLE C–1—ESTIMATED COSTS OF TESTING AND LABELING FOR EACH PRODUCT LINE

Device type	Range of cost estimates given by industry sources ($)	Range of estimates used in analysis ($)
Testing:		
Existing test methods:		
Earplugs and semi-aural inserts	2,000–3,000	2,000–3,000
Earmuffs and headsets (per headband position, excluding electronic noise cancellation systems).	1,700–4,000	1,700–4,000
Revised test methods:		
Earplugs and semi-aural inserts	2,800–4,000	2,800–4,000
Earmuffs and headsets (per headband position, excluding electronic noise cancellation systems).	2,000–4,000	2,000–3,000
Electronic noise cancellation systems [32]	2,500–10,000	2,500–10,000
Impulse noise reduction [33]	2,000–4,000	2,000–4,000
Labeling:		
Initial label design and printing setup	5,000–10,000 to 25,000–48,000	5,000–10,000
Modification of a label to change the NRR	one manufacturer estimated this cost at 2,700–3,700, while others indicated that it would be the same as a complete label change.	2,700–5,000

The proposed changes in the labeling rule are expected to result in a substantial increase in the volume of product testing. First, all HPDs are to be tested in accordance with the newly proposed ANSI and EPA/NIOSH standards. A transition-testing period of thirty (30) months following the effective date of this proposed regulation is expected to reduce the workload on existing testing facilities. Second, the Agency is proposing that all products must be retested periodically at five (5) year intervals from the completion of the respective transition test; the current regulation does not require such recurrent testing and label verification. As explained above, EPA is proposing a recurrent test period of 5 years was selected to (a) provide a uniform testing period for all parties, (b) allow a longer time between transition test and first recurrent test for the less than three product line manufacturers, (c) provide manufacturers with more than two product lines adequate time to complete transition testing before first recurrent tests become necessary and (d) to amortize near-term testing costs over a reasonable period of time.

The Agency believes the increase in testing volumes may result in lower per product testing costs than the current industry estimates in Table C–1 for two reasons. First, the Agency anticipates additional testing laboratories will enter the marketplace to satisfy the increased and continuing testing demand resulting from the recurrent testing requirement, thereby increasing price competition that may result in lower fees. Second, the increased volume may provide opportunities for improved testing efficiency due to economies of scale. However, for the purpose of this analysis, we have used the average cost estimates from Table C–1 to develop a conservative assessment.

The Agency has also considered the required redesign of the label to display the results of transition testing using the new ANSI/EPA test methods and two-value NRR effectiveness range. Most companies responding to the Agency's questionnaire estimated the cost of developing new product labels to be between $5,000 and $10,000 per HPD model; one company estimated these costs at $25,000–48,000 (Table C–1). These estimates reflect design costs and fabrication of the necessary printing plates and the preparation of required revised secondary labels. The main source of variation in the cost estimates is the estimated time to develop the label design. However, since the EPA is specifying the design, format and content of the new label, the cost estimates for ''creative'' label designs are believed to be on the high side. Discussions with an independent source in the public relations field indicated the cost of label design can be expected to be the lower range of estimates given by industry representatives, i.e., $5,000–10,000.[34]

The Agency was particularly concerned with labeling costs that may be incurred by very small manufacturers and repackagers (one or two product lines). In assessing the marketing methods of this segment of the industry, the Agency believes that their point of sale is principally via the internet. Further, their customer base is primarily individuals or small groups that purchase their products for personal use only. It is primarily for this segment of the industry that the Agency has developed and is proposing the concept of ''electronic labeling.'' We believe that an electronic reproduction of the EPA label will eliminate the costs of art work and printing plates requisite to producing paper labels or printing on packaging for organizations that sell *exclusively* on the internet. The Agency also believes that electronic labeling will greatly simplify and reduce any future costs that would be incurred should recurrent testing dictate new NRR ratings for these small manufacturers.

In light of the proposed recurrent testing requirement, we believe that NRR effectiveness ranges may require change from time to time. In that regard

[32] This cost figure includes the expense for both passive and active testing.

[33] This cost is in addition to the required passive testing.

[34] Personal Communication. Battye, W., EC/R Incorporated, with Erika Schmidt, The Frause Group. August 15, 2007.

we have attempted to quantify the associated cost of relabeling. One company estimated the costs of relabeling to present a revised NRR range would be somewhat lower than the costs of developing the initial new label but was unable to quantify without a definitive cost estimate for the initial new label. However, other manufacturers believed the costs would be roughly the same as those associated with the new transition label.

Table C–2 presents estimates of the nationwide costs of carrying out the transition testing in accordance with ANSI/EPA test methods. The table also presents cost estimates related to changing all existing product labels to reflect the new test results and label information. These estimates are derived using the unit costs given in Table C–1 and the estimated nationwide numbers of HPD currently being sold. The estimates are conservative in that they do not include any estimates of cost savings that may be realized through electronic labeling. The Agency identified approximately 1,029 different HPDs currently for sale in the U.S. The HPD population is believed to consist of 403 earplugs or semi-aural passive devices, 572 passive earmuffs sold either alone or incorporated into communication headsets, 2 active noise reduction (ANR) earplugs and 52 active noise reduction (ANR) earmuffs.

As required in subpart B, § 211.206–1, all HPDs must be tested in their ''passive'' mode which yields 1029 separate tests. In addition, those 54 products identified as ANR will require a second test in their ''active'' mode. Finally, those 156 products identified as ''impulsive'' will require a second test in a high intensity impulse noise environment where human test subjects are replaced by a test fixture. Consequently, 1239 separate tests must be carried out on the 1029 products. The difference between the number of HPDs given above and the actual number of tests given in Table C–2 represents products which are tested by the manufacturer and are labeled for sale by another entity which relies upon the manufacturer's effectiveness data. Foreign manufacturers that export to the U.S. are included in our estimations. Even though the testing and manufacturing costs are incurred outside the U.S., any effects on prices due to the revised regulation may be passed along to the distributors in the U.S. These distributors, as previously mentioned, may pass along the price changes to the buyer.

TABLE C–2—ESTIMATED NATIONWIDE COSTS OF TRANSITION PRODUCT EFFECTIVENESS TESTING AND LABELING

Product type	Number of HPD tests	Unit cost per HPD test ($)	Estimated nationwide cost ($1000)
Testing			
Earplugs and semi-aural inserts	375	2,000–4,000	750–1,500
Earmuffs and headsets	550	[a] 2,540–3,810	1,400–2,100
Active Noise Reduction systems	108	1,250–5,000	140–540
Impulse noise reduction	156	2,000–4,000	310–620
Subtotal	1,189	.....	2,600–4,760
	Number of HPD products	Unit cost per HPD product ($)	Estimated nationwide cost ($1000)
Labeling			
Earplugs and semi-aural inserts	375	5,000–10,000	1,880–3,750
Earmuffs and headsets	550	5,000–10,000	2,750–5,500
Electronic noise cancellation systems	54	5,000–10,000	270–540
Subtotal	979	.....	4,900–9,790
Grand total	.....	.....	7,630–15,090

[a] Based on a testing cost of $2,000–3,000 per headband position, and an average of 1.27 headband positions per product.

The number of HPD products was estimated from reviews of manufacturer's catalogs and advertisements (as published on the Internet). In addition, the NIOSH ''Hearing Protection Device Compendium'' provided significant information on the HPD products sold in the U.S.[35]

Because earmuffs may sometimes be manufactured to be worn in different head band positions, the product must be tested in each position to determine whether their performance/attenuation is changed due to the position. When we account for the positions, and consider that each position requires another test, an average of 1.27 potential headband positions per product-line was used to estimate the number of headband position tests required for earmuffs. This factor is based on the average number of headband positions per product-line for all earmuff models included in the NIOSH Hearing Protector Device Compendium.

b. Costs of Recurrent Testing and Relabeling

Table C–3 presents estimates of costs for recurrent testing and potential relabeling of products due to measured changes in product NRR range. Unit costs of testing each HPD are the average industry estimates shown in Table C–1. Costs have been estimated for a three (3) and five (5) year recurrent testing interval. In each case we have assumed that testing will be spread evenly over the respective time period. Thus, for the 3-year interval we assumed that one third of the HPD models will be tested each year, and for the 5-year interval, we assumed that 20 percent of HPD models would be tested each year.

Based on analysis of inter and intra laboratory variations of product recurrent tests in a recent inter-laboratory test program carried out by EPA and NIOSH,[36] we estimate twelve

[35] Franks JR, Graydon PS, Jeng C, Murphy WJ, ''NIOSH Hearing Protector Device Compendium,'' *http://www2d.cdc.gov/hp-devices/hp_srchpg01.asp (2003).* as of July 6, 2008.

[36] Murphy W.J., Byrne D.C., Gauger D., Ahroon W.A., Berger E., Gerges S.N.Y., McKinley R., Witt

(12) percent of all HPD products will require relabeling based on recurrent tests every five years. The agencies commissioned parallel tests of six different HPD products at six different laboratories. The study provided 180 laboratory-to-laboratory comparisons of the test results; 30 for each of the six products tested. For each of these comparisons, the average test results and the 95 percent confidence intervals for two tests of a single HPD model were determined. If the second test was lower than the first test to the extent that the two 95 percent confidence intervals did not overlap, then it was assumed that the product would need to be relabeled. This occurred in 12 percent of the comparisons. The fraction was the same for earplugs and earmuffs. However, for reasons stated above, the Agency has selected a ± 3dB criteria rather than the 95 percent confidence interval to initiate relabeling. Therefore, for this analysis the 12 percent represents a conservative assessment of the potential cost impact.

TABLE C–3—ESTIMATED NATIONWIDE ANNUAL COSTS OF PRODUCT RECURRENT TESTING AND RELABELING FOR MANUFACTURERS

Product type	Estimated number of HPD tests per year		Unit Cost per HPD test ($)	Estimated nationwide costs ($1000/year)	
	3-Year interval [a]	5-Year interval [b]		3-Year interval	5-Year interval
Periodic Recurrent Testing					
Earplugs and semi-aural inserts	125.0	75.0	2,000–4,000	250–500	150–300
Earmuffs and headsets	183.3	110.0	[c] 2,540–3,810	470–700	280–420
Electronic noise cancellation systems	36.0	21.6	[d] 2,500–10,000	90–360	54–216
Impulse noise reduction	52.0	31.2	2,000–4,000	100–210	60–120
Subtotal	396.3	237.8		910–1,770	544–1,056
Relabel as Necessary	Estimated number of HPD products per year				
[e] Subtotal	39.2	23.5		106–196	63–117
Grand total				1,016–1,966	607–1,173

[a] Under the 3-year recurrent test interval, one third of all HPD models are assumed to be retested each year.
[b] Under the 5-year recurrent test interval, 20% of all HPD models are assumed to be retested in a given year.
[c] Based on a testing cost of $2,000–3,000 per headband position, and an average of 1.27 headband positions per product.
[d] This cost figure includes both the expense for passive and active testing.
[e] Based on NIOSH/EPA inter-laboratory testing, a change in the label NRR may be required for 12% of products tested in periodic effectiveness tests.
[f] Based on the cost of making a simple modification to the label to change the NRR (Table 3–1).

c. Manufacturers' Costs of Reporting and Recordkeeping

Pursuant to Sec. 13 (a)(1) of the Noise Control Act, manufacturers are required to provide the EPA Administrator reports of the laboratory test results for each HPD model. The cost of generating these reports is incorporated in the cost of product testing (as summarized in Table C–1). However, we believe manufacturers may incur limited additional costs to track and retain periodic recurrent testing reports. Table C–4 presents estimates of the nationwide costs of these recordkeeping and reporting requirements. We have estimated that 30 minutes per product may be required for record keeping and reporting.

TABLE C–4—ESTIMATED ANNUAL ONGOING COSTS OF RECORDKEEPING AND REPORTING

Product type	Estimated number of HPD tests per year		Clerical labor per product line (hours)	Labor cost ($/hour) [c]	Estimated nationwide costs ($1000/year)	
	3-Year interval [a]	5-Year interval [b]			3-Year interval	5-Year interval
Earplugs and semi-aural inserts	125	75.0	0.5	31	1.9	1.2
Earmuffs and headsets	183.3	110.0	0.5	31	2.8	1.7
Electronic noise cancellation systems	18.0	10.8	0.5	31	0.3	0.2
Total	326.3	195.8			5.0	3.1

[a] Under the 3-year recurrent testing interval, about one third of all HPD models are assumed to be retested each year.
[b] Under the 5-year recurrent testing interval, about 20% of all HPD models are assumed to be retested in a given year.
[c] Estimate based on Bureau of Labor Statistics information for the medical supplies manufacturing industry, hourly rates include an overhead factor (including benefits) of 100%.

d. Costs for Relabelers

Companies that relabel products manufactured by other companies for sale under their own label or under the labels of brand name retailers may also incur labeling costs. These companies, identified as ''relabelers'' typically use the results of NRR tests carried out by the products manufacturers, and therefore, are not expected to incur costs for product testing. However, they are

B., Krieg E.F. (2009). ''Results of the National Institute for Occupational Safety and Health—U.S. Environmental Protection Agency Interlaboratory Comparison of American National Standards Institute S12.6–1997 Methods A and B.'' J. Acoust. Soc. Am. 125(5):3262–3277.

expected to incur costs for redesigning product labels to incorporate new NRR values and required labeling information. Table C–5 summarizes the estimated costs of compliance for these relabelers. However, no adjustments have been made for those relabelers that sell exclusively via the internet and adopt electronic labeling. In this latter case the costs of relabeling are expected to be significantly less than those of Table C–5 since no changes will be required for artwork or packaging. The Agency has not quantified these costs savings. Consequently, we believe the costs presented in Table C–5 to be very conservative (i.e. likely overestimated).

TABLE C–5—ESTIMATED NATIONWIDE LABELING COSTS FOR COMPANIES WHICH DO NOT MANUFACTURE HPD, BUT ONLY RELABEL PRODUCTS

Product type	Estimated number of products		Unit cost per HPD product test ($)	Estimated nationwide costs ($1,000)	
	3-Year interval [a]	5-Year interval [b]		3-Year interval	5-Year interval
Transition Label Costs					
Earplugs and semi-aural inserts	46		5,000–10,000	230–460	
Earmuffs and headsets	32		5,000–10,000	160–320	
Electronic noise cancellation systems	83		5,000–10,000	420–830	
Total				810–1,610	

Recurrent label costs	Products per year			Cost per year	
Earplugs and semi-aural inserts	1.8	1.1	2,700–5,000	5–9	3–6
Earmuffs and headsets	1.3	0.8	2,700–5,000	4–7	2–4
Electronic noise cancellation systems	3.3	2.0	2,700–5,000	9–17	5–10
Total				18–33	10–20

[a] Under the 3-year recurrent test interval, one third of all HPD models are assumed to be retested each year.
[b] Under the 5-year recurrent test interval, 20% of all HPD models are assumed to be retested in a given year.
[c] Based on NIOSH/EPA inter-laboratory testing, a change in the label NRR may be required for 12% of products tested in periodic effectiveness tests.

D. Summary of Nationwide Costs of Revised HPD Labeling Rule

Table D–1 summarizes the estimated nationwide costs of the proposed revisions to the HPD labeling rule. The initial or capital costs will be primarily transition testing of all HPD products in the U.S. market on the effective date of this proposed rule. In addition, we have incorporated the amortized costs of transition product labeling to reflect the new NRR range presentation and revised user information. In the latter case, the transition labeling costs have been amortized over a 20-year period using an interest rate of 7 percent. The transition testing costs are estimated to be between $2.5 million and $4.6 million and are expected to be spread over a period of 30 months from the effective date of the regulation. New labeling costs are estimated to be between $5.1 and $10.1 million to produce product labels with the new NRR range presentation and mandated statements. The industry provided cost estimates associated with the required secondary labels are incorporated in the total cost of labeling.

Annualized costs of the revised rule depend, in large part, on the recurrent product testing intervals. Two options have been evaluated: A 3-year interval and a 5-year interval. As stated previously, after evaluating the two approaches, the Agency is proposing the 5-year interval for all manufacturers. Recurrent testing of products would commence 5 years from the date of completion of their respective transition test. The annualized costs include the costs of changing product labels to reflect the new NRR range of the 12% of products that fail their recurrent test and costs of reporting and recordkeeping.

TABLE D–1—TOTAL COSTS COMPARED WITH TOTAL SALES

Cost element	Estimated nationwide costs ($1000/year)	
Manufacturers:		
Transition costs		
Product model testing [a]		2,600–4,760
Initial revisions to labels [a]		4,900–9,790
	3-Year recurrent test interval	5-Year recurrent test interval
Annualized costs		
Periodic product effectiveness tests [b]	910–1,770	544–1,056
Changing product labeling, as necessary [c]	106–196	63–117
Recordkeeping and reporting	5.0	3.1
Amortized cost of initial labeling [c, f]	462–924	462–924

	3-Year recurrent test interval	5-Year recurrent test interval
Total annualized costs for manufacturers	1,484–2,896	1,073–2,101
Relabelers: [g]		
Initial revisions to labels	810–1,610	
Annualized costs.		
Amortized cost of initial labeling [c f]	76–152	76–152
Label changes as necessary from recurrent ftesting	18–33	10–20
Total annualized costs for relabelers [g]	94–185	86–172
Total annual cost	1,578–3,081	1,159–2,273
Annual cost as a fraction of total industrial product sales [f]	0.3–0.7%	0.3–0.5%

[a] Table C–2 provides additional details on initial testing and labeling costs for manufacturers.
[b] Product tests are assumed to be carried out at a uniform rate over the recurrent test period. (See Table C–3).
[c] Based on NIOSH/EPA inter-laboratory testing, a change in the label NRR may be required for 12% of products tested in periodic effectiveness tests. (See Table C–3)
[d] Costs of developing product labels to reflect the revised test methods are amortized over a 20 year period using an interest rate of 7%.
[e] Annualized costs do not include the amortized costs of the initial tests, since this would double-count the first round of recurrent testing costs.
[f] Total industrial product sales were obtained from Frost & Sullivan (see Table A–2). Consumer sales are believed to be minor in comparison with industrial sales.
[g] Table C–5 provides additional details on costs for relabelers.

Table D–1 presents the total annualized costs of complying with the proposed labeling rule changes. These are estimated to be 0.3–0.5 percent of total industrial product sales for the 5-year interval. Industrial product sales were obtained from the Frost & Sullivan market research report, totaling $242.9 million. Estimates developed by EPA from limited information obtained from site visits for consumer and military sales are $216.2 million. Therefore, the estimated costs of compliance with the proposed labeling rule changes may range from 0.16 to 0.4 percent of total combined industrial, consumer and military sales.

E. Economic Impacts

Based on the results of analyses in the previous section, compliance costs associated with the proposed labeling rule changes are expected to be on average 0.3 to 0.6 percent of the total wholesale price. As noted earlier, seven HPD manufacturers were interviewed on the potential costs and economic impacts of the new labeling rule. The larger companies indicated they did not plan to pass along the costs of compliance in the prices of their products. However, some of the smaller companies indicated that they would probably pass on a portion or all of the costs of compliance to distributors and consumers.

In the event that prices are increased to cover the cost of compliance, industrial and other occupational sales of HPDs are not expected to change. These uses are generally mandated by occupational safety regulations and are not an optional purchase. Consumer purchases of HPDs are also not expected to be significantly impacted, since the overall impact of compliance costs is a relatively small fraction of the wholesale price.

HPD manufacturers indicated they do not expect to close any operations as a result of increased compliance costs. However, most indicated they would probably discontinue some marginally profitable product lines rather than incur the associated cost of transition testing and labeling. In particular, the companies indicated that product lines which are not selling well on the current market due to their effectiveness rating, comfort, or competition may be discontinued when the new labeling rules are implemented.

F. Impacts on Small Business

Please see paragraph XI—C (Statutory and Executive Order Reviews) below.

XI. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

This action is not a ''significant regulatory action'' under terms of Executive Order (EO) 12866 (58 FR 51735, October 4, 1993) and is therefore not subject to review under that Order

Although a Regulatory Impact Analysis was not required or conducted, EPA did carry out a cost impact analysis, as just set forth in the previous section. The annual effect on the economy resulting from the proposed compliance costs is estimated to be less than $2,800,000. A copy of the ''Cost Analysis for Proposed Labeling Regulation of the Hearing Protection Device Industry'' is available in the docket for this action.

B. Paperwork Reduction Act

The information collection requirements in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the *Paperwork Reduction Act,* 44 U.S.C. 3501 *et seq.* The Information Collection Request (ICR) document prepared by EPA has been assigned EPA ICR number 2341.01.

Section 13 of the Act, *''Records, Reports and Information,''* states that manufacturers of products which emit noise capable of adversely affecting the public health or welfare, or which is sold wholly or in part on the basis of its effectiveness in reducing noise, shall establish and maintain such records, make such reports, provide such information, and make such tests, as the Administrator may reasonably require to enable him to determine whether such manufacturer has acted or is acting in compliance with the Act.

Pursuant to this provision, the Agency proposes to collect information to ensure compliance with the provisions in this rule. EPA is also proposing recurrent testing requirements, as discussed previously. In order to establish reliable baseline performance information for each device, against which future performance can be compared, the EPA is proposing that manufacturers provide the Agency with their product test information following each required product test.

The 1979 regulation required manufacturers to establish and retain adequately organized and indexed records of the testing protocols that provide the basis for the claimed Noise Reduction Ratings (NRR) that is placed on the mandated label. The regulation also required manufacturers to submit

hearing protector test data reports for the attendant NRR to the EPA. In 1982, 40 CFR Part 211 was amended to suspend the submittal of test data reports to the EPA due to the closure of the Agency's Office of Noise Abatement and Control. However, manufacturers were still required to retain all pertinent test data reports for recordkeeping purposes. EPA is proposing to reinstitute the requirement for manufacturers to submit to the Agency test data reports following each required product test. The reports would have to include measurement information, test results and calculated lesser and greater NRRs obtained from the testing laboratory for each product or product category. Manufacturers would continue to retain such records for a period of two (2) testing periods. However, if a manufacturer elects to alter the product design or materials prior to expiration of the 5 year recurrent testing cycle, the manufacturer would be required to test and submit the product's new test data report to the EPA.

The annual reporting burden for this collection of information for the initial test data report for approximately 81 respondents is estimated to be 185 labor hours per year [555 total hours] at a total annual cost of $5,735 [$17,205 total cost]. This burden estimate includes time to complete the cover sheet per Annex A of the proposed regulation, time to convert the results into a PDF document, and time to submit the test data report(s) to the EPA. Burden is defined at 5 CFR 1320.3(b).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR Part 9.

To comment on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, EPA has established a public docket for this rule, which includes this ICR, under Docket ID number EPA–HQ–OAR–2003–0024. Submit any comments related to the ICR to the EPA docket noted above and to OMB. See 'Addresses' section at the beginning of this notice for where to submit comments to EPA. Send comments to OMB at the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW., Washington, DC 20503, Attention: Desk Office for EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after August 5, 2009, a comment to OMB is best assured of having its full effect if OMB receives it by September 4, 2009. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of today's proposed rule on small entities, small entity is defined as: (1) A small business engaged in manufacturing, distributing, relabeling and/or importing of hearing protection devices having NAICS codes presented in Table A–2; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today's proposed rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. The small entities directly regulated by this proposed rule are manufacturers, distributors, repackagers and importers of hearing protector devices. We have determined that fewer than 100 U.S. small businesses are expected to be subject to the planned rule changes and using conservative assumptions only 1 or 2 of those potentially affected face significant adverse impacts.

In its analysis of the impacts of the rule, EPA made a significant effort was made to ensure that we identified as many as possible of the companies that manufacture or distribute HPDs, including any that are small businesses. A number of steps were taken to identify these companies, including reviews of the NIOSH Hearing Protection Device Compendium and the membership directory of the National Hearing Conservation Association (NHCA). Further, the NHCA was contacted to obtain a listing of small companies engaged in the manufacture or relabeling of HPDs. The NHCA assisted by providing information on some companies which obtain HPD from manufacturers for sale under their own labels. We also reviewed a number of directories of HPD and safety equipment vendors, including the Noise Pollution Clearinghouse, the International Safety Equipment Association Buyer's Guide, the Thomas directory, the Business Internet, Hoover's Online, and Mergent Online.

It is possible that some manufacturers or distributors were not identified in these efforts. Because of the classification of HPD manufacturers in the Census, it is particularly difficult to identify all HPD manufacturers. As discussed in paragraph X (A), HPD manufacturers are generally in a miscellaneous manufacturing category (NAICS Code 339113) along with manufacturers of surgical appliances and supplies because many HPD manufacturers also produce other products. In addition, many of these companies classify themselves under other NAICS categories. Therefore, the Census does not provide an explicit count of HPD manufacturers. We believe that most of the small manufacturers and distributors of HPDs have been identified, but we invite reviewers to submit any additional relevant data in this regard.

For most categories applicable to HPD manufacturers, a small business is defined as any company which employs fewer than 500 employees (and which is not owned by another large business). The small business size threshold is 750 employees for firms which also produce electronic or communications equipment, as is the case with most manufacturers of active HPDs. For distributors that merely relabel HPDs, the small business size threshold is 100 employees.

Using the applicable NAICS size thresholds, 54 of the 96 identified HPD manufacturers and relabelers would be classified as small businesses. However, it must be noted that the NAICS thresholds overstate the number of truly small businesses. This is because most passive HPD manufacturers fall into a catch-all miscellaneous manufacturing category which was primarily designed to characterize the manufacturers of surgical equipment. Thus, the 500 employee threshold used for this category probably does not reflect the conditions of the HPD manufacturing industry. Nevertheless, we have analyzed the costs of compliance for all of the companies that would be classified as small under the applicable NAICS threshold. However, we have also paid special attention to a subset of ''very small'' companies, which produce only one or two HPD product lines. Of

the 96 identified HPD manufacturers and relabelers, 34 would fall into this ''very small'' business category.

After identifying the small businesses likely to be subject to the rule, we estimated the potential economic impacts of the proposed rule on small entities. For this proposed rule, we evaluated the compliance costs as a percentage of total sales for any small businesses affected by any proposed regulatory action. Costs of compliance were identified for each of these small and very small companies based on the numbers of HPD models they sell and using the calculation methods and assumptions outlined in paragraph X (C) above. Some of these companies were interviewed as part of the effort to develop background information to estimate the costs and economic impacts of labeling rule changes; these companies gave information on the number of HPD models sold.[37] We estimated the numbers of product models sold by other small businesses from catalogs and other advertising materials published on the Internet.

Table F–1 summarizes the estimated impacts of the proposed labeling rule changes on U.S. small businesses, including the initial costs of compliance and the ongoing annualized costs for the 3-year and 5-year recurrent test options. Therefore, we have analyzed small business impacts for both ends of this range. In addition, we have analyzed impacts for the ranges of testing and labeling costs identified in Table F–1, and the ranges of labor requirements shown in Table C–4 for reporting and recordkeeping. The table gives ranges of costs, depending on which underlying unit cost estimates are used for testing, labeling, and recordkeeping.

We have estimated that the initial testing and labeling costs would average 1.1–2.1 percent of sales during the initial compliance period for all 54 U.S. small businesses affected by the rule. For the 3-year recurrent test interval, we have estimated that the average annual compliance costs for all 54 U.S. small businesses affected by the rule would be 0.5–0.7 percent of annual sales. The estimates of ongoing annual costs include the amortized initial compliance costs. The majority of small businesses (44 to 47) are expected to incur ongoing annual costs of less than 1 percent of the total annual sales. However, between 7 and 10 small businesses are expected to incur annual ongoing compliance costs exceeding 1 percent of their total annual sales. (Of these small businesses, we estimate that one or two are very small businesses (produce less than 3 types of product)). It is possible that one or more small businesses may experience costs exceeding 3 percent of sales. However, our data set is limited for sources in this size range (generally facilities with very low annual sales volume).

TABLE F–1—SUMMARY OF IMPACTS ON SMALL BUSINESSES

Cost element	3-Year recurrent testing	5-Year recurrent testing
Total number of small businesses affected by the rule in the U.S	54	
Initial testing and labeling:		
Estimated initial costs of compliance:		
Lowest cost for a small business	<1,000	
Average cost for a small business	47,000–94,000	
Maximum cost for a small business	298,000–620,000	
Ongoing annual costs of compliance		
Estimated annual costs		
Lowest cost for a small business	500	500
Average cost for a small business	10,000–14,000	8,000–11,000
Maximum cost for a small business	63,000–90,000	49,000–68,000
Estimated annual cost as a fraction of annual sales: [a] [b]		
Lowest cost for a small business	<0.01%	<0.01%
Average cost for a small business	0.5–0.7%	0.4–0.6%
Maximum cost for a small business	11–17%	9–12%
Number of small businesses with estimated annual compliance costs greater than:		
1% of annual sales	7–10	4–8
3% of annual sales [c]	1	1

[a] Sales figures used in these calculations are from market databases, such as Dun and Bradstreet, and include not only HPD, but all products sold by the companies, such as other safety equipment.
[b] Annualized costs of compliance include amortized costs of initial testing and labeling.
[c] One or more companies may experience costs above 3% of sales, but our data set is limited in this size range.

At the 5-year recurrent test interval, the average annual compliance costs for all 54 U.S. small businesses affected by the rule is estimated to be 0.4–0.6 percent of annual sales. The majority of small businesses (46 to 50) are expected to incur ongoing annual costs of less than 1 percent of the total annual sales. However, between 4 and 8 small businesses are expected to incur ongoing annual compliance costs above 1 percent of their annual sales. This means that 7 to 15 percent of the small businesses subject to the rule are expected to face economic impacts greater than 1 percent. (Of these small businesses, we estimate that one or two are very small businesses (produce less than 3 types of product)). It is possible that one or more small businesses may experience costs that exceed 3 percent of sales. Once again, we note that our data set is limited for sources in this size range (generally facilities with very low annual sales volume).

Given that there are some impacts on small businesses, we looked for ways to mitigate these impacts. One step we have taken, as discussed earlier, is to exempt companies that sell exclusively over the Internet from the requirement to provide hard copy labels on their product packaging; an electronic label is being proposed as the exclusive labeling requirement for such entities. Additionally, after considering

[37] The referenced interviews can be found in the Federal Docket at *http://www.regulations.gov*, docket number EPA–HQ–OAR–2003–0024.

regulatory options to require retesting every 3 years versus every 5 years, we have selected the 5-year option. This option will allow manufacturers to time-stream the testing of their product categories. Finally, we think that companies will take steps on their own to reduce compliance costs by reviewing their product slates and reducing the number of HPD models that are low sales products and/or older products that have updated versions. These actions would reduce their costs of compliance with the revised testing and labeling requirements. We continue to be interested in the potential impacts of this proposed rule on small entities and solicit comments on issues related to such impacts.

Small governments are not affected since enforcement of the proposed regulation would continue to be carried out by the federal EPA. Further, not-for-profit enterprises engaged in the distribution of hearing protectors do not assume responsibility or incur the costs of testing and labeling of a product and therefore, are not impacted by the rule.

Although this proposed rule will not have a significant economic impact on a substantial number of small entities, EPA nonetheless has tried to reduce the impact of this rule on small entities through the means described above. When developing the proposed rule, we took special steps to ensure that the burdens imposed on small entities were minimal. We continue to be interested in the potential impacts of this proposed rule on small entities and solicit comments on issues related to such impacts.

D. Unfunded Mandates Reform Act

This action contains no Federal mandates under the provisions of Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1531–1538 for State, local, or tribal governments or the private sector. This action imposes no enforceable duty on any State, local or tribal governments or the private sector.

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires the Agency to identify and consider a reasonable number of regulatory alternatives and to adopt the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective, or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before we establish any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, a small government plan must be developed under section 203 of the UMRA. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

We have determined that this proposed action does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or to the private sector in any one year. Thus, this proposed action is not subject to the requirements of sections 202 and 205 of the UMRA.

E. Executive Order 13132: Federalism

Executive Order 13132, entitled ''Federalism,'' (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

This proposed rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. This proposed rule applies to manufacturers and distributors of hearing protection devices and has no association with State and local governments. Thus, Executive Order 13132 does not apply to this rule.

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

This action does not have tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). Executive Order (EO) 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' This proposed action will have no substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes as specified in EO 13175. Thus, Executive Order 13175 does not apply to this proposed action.

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

EPA interprets EO 13045 (62 FR 19885, April 23, 1997) as applying to those regulatory actions that concern health or safety risks to children, such that the analysis required under section 5–501 of the Order has the potential to influence the regulation. This action is not subject to EO 13045 because it is based solely on technology performance.

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

This action is not subject to Executive Order 13211 (66 FR 28355 (May 22, 2001)), because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (''NTTAA''), Public Law No. 104–113 (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards (VCS) in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. VCS are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by VCS

bodies. NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable VCS.

This proposed rulemaking involves technical standards. Therefore, EPA conducted a search to identify potentially applicable VCS. We identified several that have direct or partial applicability to the technical requirements specified in the rule. To the extent possible the Agency has *incorporated by reference* the principal elements of the American National Standards Institute (ANSI) standard S12.6 (2008). In addition, we have also incorporated by reference various elements of ANSI S12.68 (2007) and S12.42. The Agency also gave careful consideration to all relevant standards of the International Standards Organization (ISO) and the International Electrotechnical Commission (IEC) and determined that the above mentioned ANSI standards and the IEC standard 60711 were the most appropriate for this action.

EPA welcomes comments on this aspect of the proposed rulemaking and, specifically, invites the public to identify potentially-applicable VCS and to explain why such standards should be used in this regulation.

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

Executive Order (EO) 12898 (59 FR 7629 (Feb. 16, 1994)) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this proposed rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because hearing protectors provide protection to the human health of all affected populations without having any disproportionately high and adverse human health or environmental effects on any population, including any minority or low-income population.

List of Subjects in 40 CFR Part 211

Environmental Protection, Incorporation by reference, Noise Abatement Programs, Product Noise Labeling, Hearing Protection Devices.

Dated: July 21, 2009.

Lisa P. Jackson,

Administrator.

For the reasons stated in the preamble, title 40, chapter I of the Code of Federal Regulations is proposed to be amended as follows:

PART 211—PRODUCT NOISE LABELING

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

Authority: Sec. 8, Noise Control Act of 1972, (42 U.S.C. 4907), and other authority as specified.

Subpart B—[Amended]

2. Section 211.201 is revised to read as follows:

§ 211.201 Applicability.

(a) Unless this part states otherwise, the provisions of subpart B, part 211, apply to all devices or materials sold as ''hearing protection devices'' on the basis of their ability to reduce the level of sound entering the user's ears and thus claim to protect the users hearing. The proposed regulation also applies to devices of which hearing protection may not be their primary function, but which are nonetheless sold in-part as providing protection to the user's hearing.

(b) To the extent that a product manufacturer, importer, packager or any other party introduces into U.S. commerce any product that incorporates an explicit or implicit claim that said product can protect the hearing of the user, or stipulates the level of sound reduction offered by such product, then it shall be subject to the requirements of this proposed regulation (*See* 211.203(u) for definition of ''hearing protection device.'')

(c) This rule does not apply to those devices or materials that are designed to fit over or into the user's ears to, for example, preclude the entrance of water during swimming, reduce the level of annoyance from snoring or to enhance listening to music or video dialogue presentations.

(d) This regulation is also applicable to those devices or materials that while not designed for or intended to be used as hearing protection devices can, due to their similarity in appearance or function, be easily mistaken for products that are hearing protection devices. To the extent that a product manufacturer, importer, packager or any other party introduces into U.S. commerce any product that incorporates an explicit or implicit claim that said product can protect the hearing of the user, or stipulates the level of sound reduction offered by such product, then such product shall be subject to the requirements of this proposed regulation.

(e) The provisions of subpart A apply to all products for which regulations are published under part 211 and manufactured after [EFFECTIVE DATE OF FINAL RULE], unless they are made inapplicable by product-specific regulations.

3. Section 211.202 is revised to read as follows:

§ 211.202 Effective Date.

Manufacturers of hearing protection devices must comply with the requirements set forth in this subpart for hearing protective devices manufactured on or after [date TBD]. All hearing protection devices that are manufactured on or after the effective date of this subpart must be tested and labeled in accordance with the applicable procedures set forth herein.

4. Section 211.203 is revised to read as follows:

§ 211.203 Definitions.

As used in subpart B, all terms not defined here have the meaning given them in the Noise Control Act of 1972 (the Act) (42 U.S.C. 4907), or in subpart A of this part.

(a) *A-Duration.* The duration of an impulsive sound from its initial sharp increase in positive sound pressure to the point where the sound pressure becomes negative.

(b) *A-Weighted Sound Level.* A single number representing the overall sound level of a noise that emphasizes sounds containing frequencies between about 500 and 5000 Hz and deemphasizes frequencies outside that range. The resultant sound level is referred to as A-weighted units in dB, generally indicated as dBA and considered to be representative of the human ears frequency response to sounds.

(c) *Acoustic Test Fixture (ATF).* A device that approximates the size and shape of a human head and which includes acoustic elements to simulate the acoustic response of the ear canal. An ATF with ear canals approximates the cross sectional area and length of the human ear canal.

(d) *Active Noise Reduction.* The reduction of sound transmission based on the use of electronic elements (e.g. circuits and transducers) to produce acoustic signals of approximately equal and opposite phase and amplitude to reduce the transmitted sound.

(e) *ANSI/ASA S12.6–2008.* ''American National Standard—Methods for Measuring the Real-Ear Attenuation of Hearing Protectors.'' A procedure for measuring the hearing protector sound attenuation values at various frequencies using one-third octave band noise stimuli presented to subjects in a diffuse sound field.

(f) *ANSI S12.42–1995 (R2002).* ''American National Standard—Microphone-in-Real-Ear and Acoustic Test Fixture Methods for the Measurement of Insertion Loss of Circumaural Hearing Protection Devices.'' A procedure for measuring the acoustical insertion loss of earmuff using a miniature microphone positioned in the ear canal.

(g) *ANSI/ASA S12.68–2007.* ''American National Standard—Methods of Estimating Effective A-weighted Sound Pressure Levels When Hearing Protectors are Worn.'' Procedures for calculating Noise Reduction Ratings.

(h) *Assumed Protection Value (APV_{fx}).* The protection in a given octave band computed as the mean attenuation, minus the standard deviation of that octave band multiplied by a constant.

(i) *Attenuation.* The reduction of sound pressure level provided by a hearing protection device by either structural elements, acoustic pathways, electronic or mechanical means.

(j) *Carrying Case.* The container used to store reusable hearing protectors.

(k) *Category.* A group of hearing protectors which are identical in all aspects to the parameters listed in § 211.210–2(a)(3).

(l) *Claim.* An assertion made by a manufacturer regarding the intended purpose, general performance and the sound attenuating effectiveness of his product.

(m) *Decibel (dB).* Unit of measure of sound level used in this regulation for both sound pressure level and hearing threshold level.

(n) *Dispenser.* The permanent or disposable container designed to hold more than one complete set of hearing protector(s) for the express purpose of display to promote sale or display to promote use or both.

(o) *Disposable Device.* A hearing protection device that is intended to be discarded after one or otherwise specified period of use.

(p) *Effective A-weighted Sound Pressure Level (L'_A).* The sound pressure level, A-weighted and referred to an equivalent diffuse sound field condition, that is estimated to be experienced by users when the hearing protector is worn.

(q) *Effective Peak Sound Pressure Level (L'P).* The estimated peak sound pressure level underneath the hearing protection device.

(r) *Estimated Noise Level Reduction (ENR).* The value in decibels derived from the variability of noise reduction as a function of noise spectra.

(s) *Fitting Instruction.* Guidance on the demonstration and fitting of a hearing protection device that is provided to the testing laboratory and included with the product as entered into commerce.

(t) *Headband.* A component of a hearing protection device that applies force to, and holds in place on a person's head, the sound attenuating component that is intended to acoustically seal the ear canal. The headband can be positioned over-the-head, behind-the-head or under-the-chin of the user.

(u) *Hearing Protection Device (HPD).* Devices or materials intended to reduce the level of sound entering a user's ears. Such devices include those of which hearing protection may not be the primary function, but which are nonetheless sold partially as providing hearing protection to the user. This term is used interchangeably with the terms, ''hearing protective device'', ''hearing protector'', ''device'' and ''HPD'' in subpart B. The following list, although not all inclusive, presently represents products that are subject to this part.

(1) *Passive Hearing Protection Device.* A device that relies solely on its structural elements to block or otherwise control the transmission of sound into the ear canal and that does not use electronic circuits or fluid dynamic means to reduce the entry of external sound.

(2) *Active Hearing Protection Device.* A device that contains electronic components including transducers (i.e. speakers and microphones) to increase or decrease the transmission of sound into the ear canal. Also referred to as an electronic hearing protection device.

(3) *Ear plug.* A hearing protection device that is designed to be inserted into the ear canal and held in place principally by virtue of its fit inside the ear canal.

(4) *Ear cap. See* ''Semi-insert Device''.

(5) *Ear cup.* The combination of the hard shell, soft cushion and sound attenuating material that encloses the external ear or pinna in ear muff applications.

(6) *Ear muff.* A hearing protection device usually comprised of a headband which applies spring-like force/pressure to two ear cups with soft cushions to seal against the external ear or pinna (supra-aural) or the sides of the head around the pinna (circumaural). The ear cups may also be held in position by attachment arms mounted on a hardhat or hardcap.

(7) *Active Noise Reduction Hearing Protection Device.* A device that uses single or in combination, electrical components and structural elements to reduce the sound transmitted to the ear canal through acoustic cancellation of the air-conducted and/or bone-conducted external sound.

(8) *Amplitude-Sensitive Hearing Protection Device.* A device that is designed to produce a change in sound attenuation as a function of the external sound level. Amplitude-sensitive hearing protection devices include passive devices, active devices, and impulsive noise devices.

(9) *Communication Headset.* A voice communication device (ear plug, ear muff, semi-insert device or helmet) that is also designed to reduce the level of sound at the users' ears by either structural elements and/or electronic means.

(10) *Custom-molded Hearing Protection Device.* A device that is made to conform to a specific person's ears (pinnas) and ear canals.

(11) *Electronic Hearing Protection Device. See* ''Active Hearing Protection Device.''

(12) *Helmet.* A hearing protection device that provides impact protection to the head or skull and designed with ear cups to reduce the external sound from entering the ears through either structural elements and/or electronic means.

(13) *Level-Dependent Hearing Protection Device. See* Amplitude-Sensitive Hearing Protection Device.

(14) *Semi-insert Device.* An ear plug-like hearing protection device consisting of soft pods or tips that are held in place by a lightweight band. The pods are positioned in the conchae covering the entrances to the ear canals, or fitted to varying depths within the ear canals. Semi-inserts that cap the ear canal require the force of the band to retain their position and acoustic seal. Semi-inserts that enter the ear canal behave more like ear plugs; they seal the ear to block noise with or without the application of band force. Also referred to as canal cap or banded hearing protector.

(v) *Impulsive Acoustic Test Fixture (IATF).* A device that approximates the size and shape of a human head, simulates the acoustic response of the human ear canal, and includes a microphone(s) and electronic circuitry to detect acoustic signals.

(w) *Impulsive Noise.* A sound or series of sounds that are characterized

by a sharp rise and rapid decay in sound pressure level and have duration of less than one second.

(x) *Impulsive Noise Reduction.* The reduction of peak impulse sound transmission based upon the single or combined use of passive and/or active noise reduction elements.

(y) *Insertion Loss.* The arithmetic difference in decibels between the sound pressure levels measured at a reference point (i.e. the ear canal or microphone of the acoustic test fixture) with and without a hearing protection device in place.

(z) *Label.* A notice, as described in this subpart, which is inscribed on, affixed to or appended to a product, its packaging, or both for the purpose of giving the purchaser or product user information regarding the products designed use, noise reduction effectiveness, operating or fitting instructions and other information appropriate to the product.

(aa) *Manufacturer.* Any person engaged in the manufacturing or assembling of products, or the importing of products for resale, or who purchases products from an original equipment manufacturer (OEM) for the purpose of repackaging or relabeling or who acts for, and is controlled by any such person in connection with the distribution of such products in U.S. commerce.

(bb) *Microphone in Real Ear (MIRE).* A testing method where miniature microphones are positioned at the entrance to the subject's blocked ear canals to measure the sound pressure level underneath a hearing protection device.

(cc) *Noise.* Undesired or unwanted sound. For the purpose of this subpart, noise and sound are used interchangeably.

(dd) *Noise Reduction Rating (NRR).* A single number metric used to describe noise reduction in decibels.

(ee) *Noise Reduction Variability Data Points.* The values of the noise reductions calculated for the spectral balances given by L_C–L_A = (−1, 2, 6 and 13 dB).

(ff) *Occluded Threshold of Hearing.* The minimum level of sound heard at a specific frequency when a hearing protection device is worn.

(gg) *Octave Band Attenuation.* The amount of sound reduction determined according to the measurement procedure of § 211.206 for one-third octave bands of noise.

(hh) *Open Threshold of Hearing.* The minimum level of sound heard at a specific frequency when a hearing protection device is not worn. Also referred to as ''unoccluded'' threshold of hearing.

(ii) *Package.* The container in which a hearing protection device is presented for purchase or use. The package in some cases may be the same as the carrying case.

(jj) *Passive Noise Reduction.* The reduction of sound transmission based solely on the use of materials and/or structural elements.

(kk) *Pink Noise.* Noise for which the spectrum density varies as the inverse of frequency.

(ll) *Primary Panel.* The surface of the product package that is considered to be the front surface or that surface on the package which is intended for initial viewing at the point of ultimate sale or the point of distribution for use.

(mm) *Random Incident Field.* A sound field in which sound waves are incident from all directions with equal probability.

(nn) *Real-Ear Attenuation at Threshold (REAT).* The mean value in decibels of the occluded threshold of hearing minus the open threshold of hearing for all trials of each test subject under otherwise identical test conditions.

(oo) *Real-Ear Attenuation at Threshold (REAT).* The mean value in decibels of the occluded threshold of hearing minus the open threshold of hearing for all trials of each test subject under otherwise identical test conditions.

(pp) *Residual Volume.* The volume of air between the termination of an ear plug and the sensing surface of the microphone when an ear plug is inserted into an acoustic test fixture.

(qq) *Reverberation Time.* The time, in seconds, required for a sound produced in an enclosure to decay to a designated level once the sound source is turned off.

(rr) *Spectral Balance (B).* The difference in decibels between the C-weighted and A-weighted levels of a sound spectrum ($L_C - L_A$), indicating the proportion of energy at low frequencies in the spectrum.

(ss) *Sound pressure level (dB SPL).* Ten times the logarithm to the base 10 of the ratio of the time mean square sound pressure to the square of the reference sound pressure, given by: $L_p = 10 \log_{10} (p^2/p_0^2)$, where p is the root mean square value of sound pressure in pascals, and the reference sound pressure p_0 is 20 micropascal (20×10^{-6} Newtons per meter squared) for measurements in air. Unit: decibel (dB).

(tt) *Spectral uncertainty.* Variation in the attenuation provided by a hearing protector due to the frequency content of the noise in which a device is worn.

(uu) *Subject uncertainty.* Variation in the attenuation provided by a hearing protector due to the effect of different subjects fitting the device when the attenuation is assessed.

(vv) *Tag.* Stiff paper, metal or other hard material that is tied or otherwise affixed to the packaging of a protector.

(ww) *Test Facility.* A laboratory that tests hearing protection devices in accordance with the requirements of this subpart.

(xx) *Test Hearing Protector.* A hearing protector that has been selected for testing to determine the NRR value(s) to be put on the label, or which has been designated for testing to verify the labeled value(s) and determine compliance of the protector with this subpart.

(yy) *Test Request.* A request submitted to the manufacturer by the Administrator of the Environmental Protection Agency (EPA) that will specify the hearing protector category, and test sample size to be tested according to § 211.212, and other information regarding the audit.

(zz) *Test Subject.* Any person of any gender, ethnicity or age who is selected from a group of candidates that exhibit physical and mental characteristics requisite to the conduct of testing in accordance with § 211.206–1(b)(5) and other requirements of this subpart.

(aaa) *Third-octave band microphone free-field rejection.* The variation in sound field (decibels) of the microphone polar response (front to back for cardioid and front to side for cosine) for each measured third-octave band.

(bbb) *Threshold of Hearing.* For a specified signal, the average minimum sound pressure level as indicated by the test subject's responses.

(ccc) *Trial.* A complete series of occluded and unoccluded hearing threshold measurements on a single test subject for a single hearing protector.

(ddd) *White Noise.* Noise for which the spectrum density is independent of frequency over a specified frequency range.

5. Section 211.204–1 is revised to read as follows:

§ 211.204–1 Information content of primary label.

The information to appear on the primary label must be according to § 211.104 of Subpart A except as stated here and prescribed in Figures 1, 2 and 3 of § 211.204–1.

(a) Primary Label for all PASSIVE Hearing Protection Devices (Figure 1):

(1) Area A must state ''Noise Reduction Rating''.

(2) Area B must contain the range(s) of the Noise Reduction Ratings (NRR) in

decibels for the designed mode(s) of use of that model hearing protector.

(i) The range shall be depicted by a bar-graph that shall include a numeric scale from 0 to 50 decibels in equal increments of 10 decibels.

(ii) A solid color bar, as presented in Figure 1 of this section, shall be superimposed on the bar-graph scale indicating the lesser and greater Noise Reduction Ratings from the 80th and 20th percentiles.

(iii) The lesser and greater NRR values shown on the numeric scale shall be determined in accordance with § 211.207–2.

(iv) For devices with headbands that may be used in different positions, the labeled NRR shall represent the 80th and 20th percentiles for the manufacturers recommended position as determined in § 211.207–2.

(v) The word ''PASSIVE'' shall be placed and centered below the bar-graph. For multi-positional head band protectors, the tested position shall be indicated by the words, ''OVER HEAD'', ''BEHIND HEAD'' or ''UNDER CHIN'' placed immediately following ''PASSIVE''.

(3) Area C must state ''PASSIVE NRR values indicate range of noise reduction when used as instructed by the manufacturer. When used in steady and intermittent noise environments, the difference between the noise level and respective NRRs is the user's estimated exposure level. This protector was not tested for impulse noise.''

(4) Area D of the primary label must state the manufacturers' name, city and state of principal office and may include a primary web address.

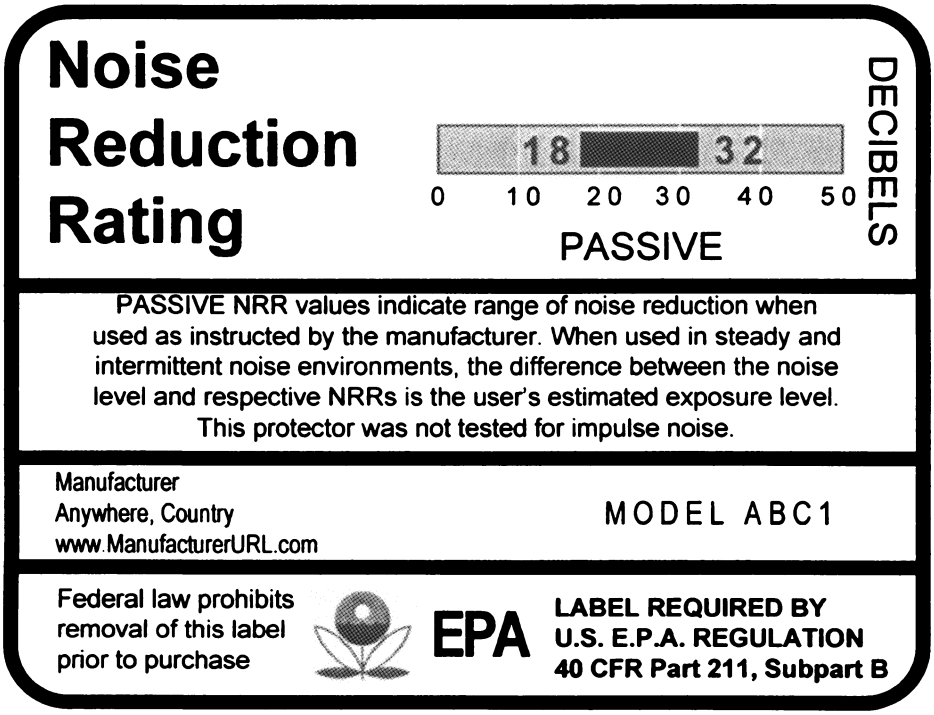

Figure 1. Primary Label for All PASSIVE Hearing Protection Devices

(b) Primary Label for ACTIVE Noise Reduction Hearing Protection Devices (Figure 2):

(1) Area A must state ''Noise Reduction Rating''.

(2) Area B must contain the range(s) of the Noise Reduction Ratings (NRR) in decibels for the designed mode(s) of use of that model hearing protector.

(i) There shall be two bar-graphs with numeric scales from 0 to 50 decibels in equal increments of 10 decibels. The two bar-graphs shall be aligned one above the other as shown in Figure 2 of this section.

(ii) The word ''ACTIVE'' shall be placed and centered above the upper bar-graph.

(iii) The word ''PASSIVE'' shall be placed and centered below the lower bar-graph.

(iv) A solid color bar shall be superimposed on the respective bar-graphs indicating their lesser and greater Noise Reduction Ratings from the 80th and 20th percentiles.

(v) The lesser and greater NRR values shown on the upper bar-graph shall be determined in accordance with § 211.207–3.

(vi) The lesser and greater NRR values shown on the lower numeric scale shall be determined in accordance with § 211.207–3.

(vii) For devices with headbands that may be used in different positions, the labeled NRR shall represent the 80th and 20th percentiles for the manufacturers recommended position(s) as determined in § 211.207–3. The tested position shall be indicated by the words, ''OVER HEAD'', ''BEHIND HEAD'' or ''UNDER CHIN'' placed immediately following ''PASSIVE'' and ''ACTIVE''.

(2) Area C must state ''ACTIVE and PASSIVE NRR values indicate range of noise reduction with and without electronic activation when used as instructed by the manufacturer. In steady and intermittent noise environments, the difference between the noise level and respective NRRs is the user's estimated exposure level. This protector was not tested for impulse noise.''

(3) Area D of the primary label must state the manufacturers' name, city and state of principal office and may include a primary web address.

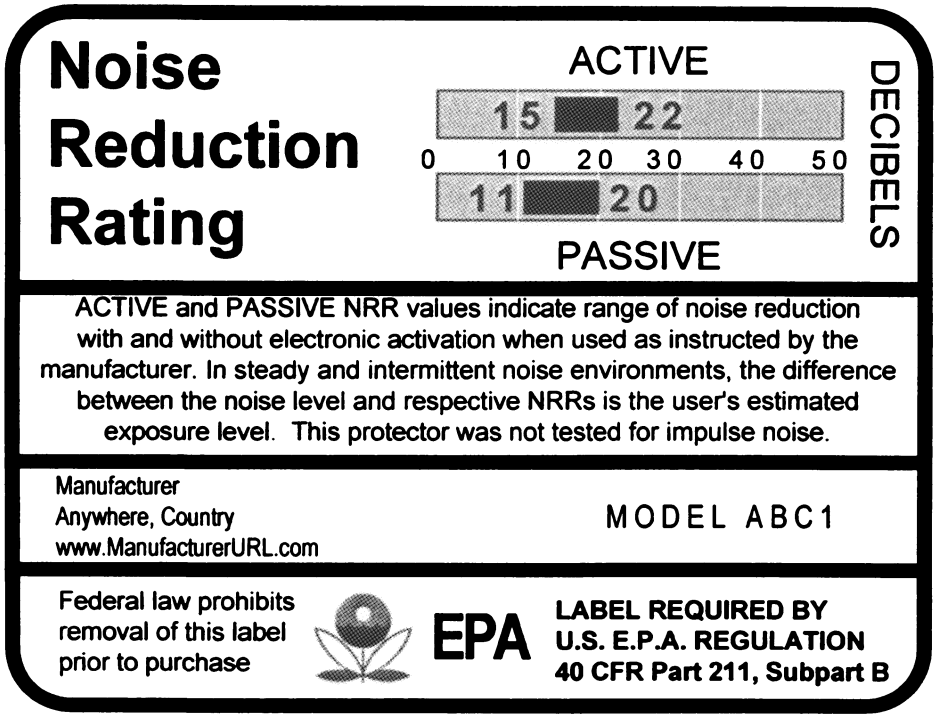

Figure 2. Primary Label for ACTIVE Noise Reduction Hearing Protection Devices

(c) Primary Label for IMPULSIVE Noise Hearing Protection Devices (Figure 3):

(1) Area A must state ''Noise Reduction Rating''.

(2) Area B must contain the range(s) of the Noise Reduction Ratings (NRR) in decibels for the designed mode(s) of use of that model hearing protector.

(i) There shall be two bar-graphs with numeric scales from 0 to 50 decibels in equal increments of 10 decibels. The two bar-graphs shall be aligned one above the other as shown in Figure 3 of this section.

(ii) The word ''IMPULSIVE'' shall be placed and centered above the upper bar-graph.

(iii) The word ''PASSIVE'' shall be placed and centered below the lower bar-graph.

(iv) A solid color bar shall be superimposed on the respective scales indicating their lesser and greater Noise Reduction Ratings from the 80th and 20th percentiles.

(v) The *lesser* impulsive NRR values shown on the upper numeric scale shall be determined in accordance with § 211.207–4(f).

(vi) The *greater* impulsive NRR values shown on the upper numeric scale shall be determined in accordance with § 211.207–4(g).

(vii) The *lesser* and *greater* passive NRR values shown on the lower numeric scale shall be determine in accordance with § 211.207–2.

(viii) For devices with headbands that may be used in different positions, the labeled NRR shall represent the 80th and 20th percentiles for the manufacturers recommended position as determined in § 211.207–2. The tested position shall be indicated by the words, ''OVER HEAD'', ''BEHIND HEAD'' or ''UNDER CHIN'' placed immediately following ''IMPULSIVE'' and ''PASSIVE.''

(3) Area C must state ''IMPULSIVE and PASSIVE NRR values indicate the range of noise reduction in impulsive and continuous noise environments when used as instructed by the manufacturer. The difference between the noise level and respective NRRs is the user's estimated exposure level.''

(4) Area D of the primary label must state the manufacturers' name, city and state of principal office and may include a primary web address.

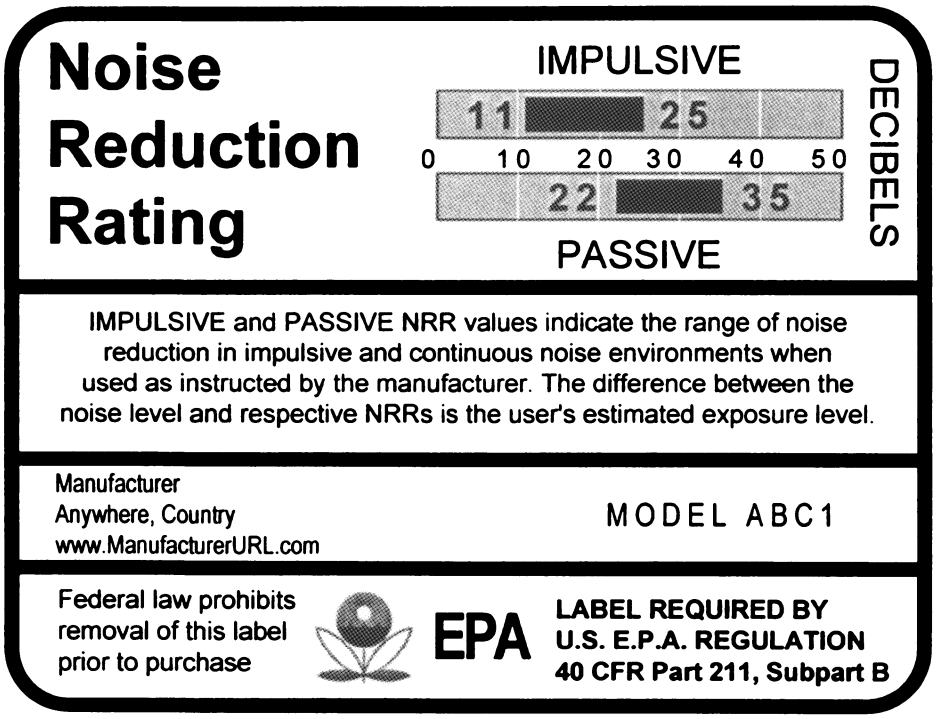

Figure 3. Primary Label for IMPULSIVE Noise Hearing Protection Devices

6. Section 211.204–2 is amended as follows:

a. Revise paragraphs (b)(2) and (b)(3).

b. Revise (c) and (d).

c. Add new paragraphs (e) through (l).

§ 211.204–2 Primary label size, print and color.

* * * * *

(b) * * *

(2) Area B—2.1 mm or 6 point for numerals and

(3) Area A and B—1.7 mm or 5 point for words.

* * * * *

(c) The use of upper and lower case letters and the general appearance of the label must be similar to the example in Figure 1 of § 211.204–1.

(d) The color of the EPA logo shall be a solid color with sufficient contrast with surrounding information or if it is printed in full color, it must be the colors of the official EPA logo.

(e) The minimum dimensions of the scale shall be 2.2 (cm) (0.87 inch) long and 0.3 (cm) (0.12 inch) high.

(f) The minimum font size of the labels for the bar shall be 4 point type.

(g) The values depicted on the bar shall be at least 6 point in bold type face.

(h) The solid range bar shall be a minimum of 0.2 (cm) (0,079 inch) high, vertically centered in the bar-graph scale and of sharply contrasted solid-color with the endpoints positioned at the respective numeric limits.

(i) For all PASSIVE hearing protection devices the layout shall be according to Figure 1 of § 211.204–1.

(j) For ACTIVE hearing protection devices the layout shall be according to Figure 2 of § 211.204–1.

(k) For IMPULSIVE hearing protection devices the layout shall be according to Figure 3 of § 211.204–1.

7. Section 211.204–3 is amended by revising paragraphs (a) introductory text and (a)(2) and by adding paragraph (a)(3) to read as follows:

§ 211.204–3 Label location and type.

(a) The manufacturer or entity that introduces the product into commerce is responsible for labeling the product for ultimate sale or use. Such manufacturer or entity shall select the primary product label in accordance with § 211.204–1 and locate it as follows:

* * * * *

(2) Affixed to the primary panel of the product packaging if the label complying with § 211.204–1 is not visible at the point of ultimate purchase or the point of distribution to users.

(3) Products that are sold exclusively over the Internet and thus constitute the point of sale to ultimate purchasers or users, shall present the requisite primary and secondary labels as readily visible electronic images for each product category offered for sale. Such electronic labels shall contain all information that is required for labels that are required to be affixed to and contained within the package of products with a point of sale outside the Internet. Such labels must be automatically downloaded to the purchaser along with confirmation of acceptance of payment from the purchaser. Electronic labels shall not be used for bulk container sales or for non-Internet resale.

* * * * *

8. Section 211.204–4 is revised to read as follows:

§ 211.204–4 Supporting information.

The following minimum supporting information must accompany all hearing protection devices in a manner that ensures its availability to the perspective user in an easily readable format. In the case of bulk packaging and dispensing, such supporting information must be affixed to the bulk container or dispenser in the same manner as the label, and in a readily visible location. Such information shall be presented in tabular form except where specified otherwise.

(a) The mean sound attenuation for each octave band test frequency as determined from the measurements prescribed in § 211.206–1.

(b) The standard deviation of the mean sound attenuation across subjects for each octave band test frequency as determined from the measurements prescribed in § 211.206–1.

(c) The Assumed Protection Values (APV) for the 80th and 20th percentiles of the sound attenuation for each octave band test frequency as determined from the measurements prescribed in § 211.206–1.

(d) The noise reduction as a function of spectral balance shall be presented as shown in the example given in Table 1 of this section.

TABLE 1—EXAMPLE—NOISE REDUCTION VARIABILITY DATA POINTS

[spectral balance]

	−1 dB	−2 dB	6 dB	13 dB
	Noise Reductions (dB)			
20th Percentile	30.6	24.0	18.7	11.9
80th Percentile	26.8	19.2	13.7	8.1

(e) The variability of attenuation as a function of noise spectrum shall be presented in a graphical format as shown in Figure 1 of this section.

(1) The figure caption shall be ''Variability of Noise Reduction as a function of Noise Spectra.''

(2) The dimensions of the body of the graph shall be no smaller than 5.0 cm wide by 3.8 cm high (1.97 x 1.5 inches).

(3) The dimensions of the body of the graph shall be no smaller than 5.0 cm wide by 3.8 cm high (1.97 x 1.5 inches).

(4) The ordinate scale shall be linear from −2 to 16 decibels with increments of 2 decibels. The axis label shall be ''Spectral Balance B = LC − LA (dB)''.

(5) The abscissa scale shall be linear from 0 to 50 decibels with increments of 5 decibels. The abscissa scale shall be labeled ''Estimated Noise Reduction (dB)''.

(6) The use of a grid is optional to facilitate interpolation of values.

(7) The symbols for the 80th percentile shall be filled and connected by solid lines.

(8) The symbols for the 20th percentile shall be unfilled and connected by solid lines.

(9) A legend shall be placed in the body of the graph as shown in the example of Figure 1 of this section.

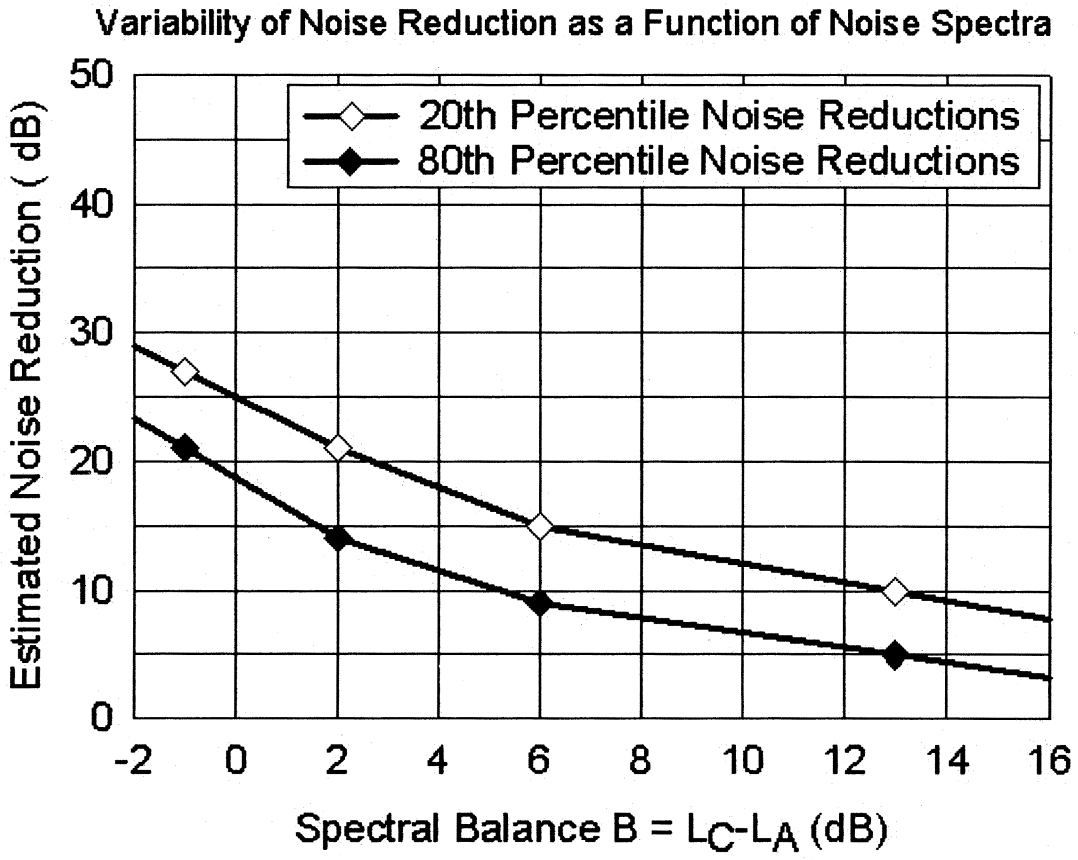

Figure 1. Example – Variability of Noise Reduction as a function of Noise Spectra

(f) For hearing protection devices with a headband that can be worn in multiple positions (over head, behind head and/or under chin) the mean sound attenuation values, standard deviations and APV, as prescribed in paragraphs

(a), (b), (c), (d) and (e) of this section, shall be provided for each tested position.

(g) The following statement, ''When this device is worn as directed, the level of noise entering a person's ear is approximated by the differences between the A-weighted environmental noise level and the lesser and greater NRRs.'' except as stated in § 211.204–5 for ACTIVE devices and as stated in § 211.204–6 for IMPULSIVE devices.

(h) The following example shall be included except as stated in § 211.204–5 for ACTIVE devices and in § 211.204–6 for IMPULSIVE devices:

''Example:

(1) X: the sound pressure level as measured at the user's location in decibels A-weighted (dBA).

(2) Lesser and greater NRRs: the PASSIVE NRR ratings obtained from the primary label or from the graph of noise reduction variability with spectral balance.

(3) The approximate range of sound pressure levels at the user's ears with hearing protection:

(X — lesser NRR) = the greater sound pressure level.

(X — greater NRR) = the lesser sound pressure level.

The sound pressure level at the user's ears will depend upon the fit of the protector.''

(i) The following cautionary note shall be included except as stated in § 211.204–5 for ACTIVE devices and as stated in § 211.204–6 for IMPULSIVE devices.

''Caution: For predominantly low frequency noise environments in which the difference in the measured C-weighted and A-weighted noise levels (dBC—dBA) exceeds 3 dB, the user is directed to the enclosed graph of the variability of noise reduction with noise spectra to determine the level of protection.''

(j) The month and year of production of the device shall be printed on the outside of the package using a minimum font size of 8 point.

(k) Instructions as to the proper use, fitting technique and care of the device.

(l) The following statement: ''Improper fit or improper use of this device will decrease noise reduction effectiveness and increase the risk of hearing damage.

9. Section 211.204–5 is added to read as follows:

§ 211.204–5 Supporting information for Active Noise Reduction Hearing Protection Devices.

In addition to the supporting information required in § 211.204–4, the following minimum supporting information must accompany all ACTIVE devices in an easily readable format.

(a) The mean total sound attenuation for each octave band test frequency as determined from the measurements prescribed in § 211.206–2.

(b) The standard deviation of the mean total sound attenuation across subjects for each octave band test frequency as determined from the measurements prescribed in § 211.206–2.

(c) The Assumed Protection Values (APV) for the 80th and 20th percentiles of the sound attenuation for each octave band test frequency as determined from the measurements prescribed in § 211.206–2.

(d) The passive, active and total noise reduction data points as a function of spectral balance shall be presented as shown in the example in Table 1 of this section.

TABLE 1—EXAMPLE—COMBINED ACTIVE AND PASSIVE NOISE REDUCTION VARIABILITY AS A FUNCTION OF SPECTRAL BALANCE

	−1 dB	2 dB	6 dB	13 dB
	Noise Reductions (dB)			
20th Percentile Passive	21.0	14.0	9.0	5.0
80th Percentile Passive	27.0	21.0	15.0	10.0
20th Percentile Active	−1.0	0.7	6.2	12.5
80th Percentile Active	0.0	0.0	7.5	14.0
20th Percentile Total	20.0	14.7	15.2	17.5
80th Percentile Total	27.0	21.0	22.5	24.0

(e) The variability of attenuation as a function of noise spectrum shall be presented in a graphical format as shown in Figure 1 of this section.

(1) The figure caption shall be ''Variability of Noise Reduction as a Function of Noise Spectra.'' The dimensions of the body of the graph shall be no smaller than 5.0 cm wide by 3.8 cm high (1.97 x 1.5 inches).

(2) The font size for the title, ordinate and abscissa scales, and the legends shall be no smaller than 4 point.

(3) The ordinate scale shall be linear from −2 to +16 decibels with increments of 2 decibels. The axis label shall be ''Spectral Balance B = LC—LA (dB)''.

(4) The abscissa scale shall be linear from 0 to 50 decibels with increments of 5 decibels. The abscissa scale shall be labeled ''Estimated Noise Reduction (dB)''.

(5) The use of a grid is optional to facilitate interpolation of values.

(6) The symbols for the 80th percentile passive noise reductions shall be filled and connected by solid lines.

(7) The symbols for the 20th percentile passive noise reductions shall be unfilled and connected by solid lines.

(8) The symbols for the 80th percentile total noise reductions shall be filled, distinctly different from the passive symbols and connected by dashed lines.

(9) The symbols for the 20th percentile total noise reductions shall be unfilled, distinctly different from the passive symbols and connected by dashed lines.

(10) A legend shall be placed in the body as shown in the example given in Figure 1 of this section.

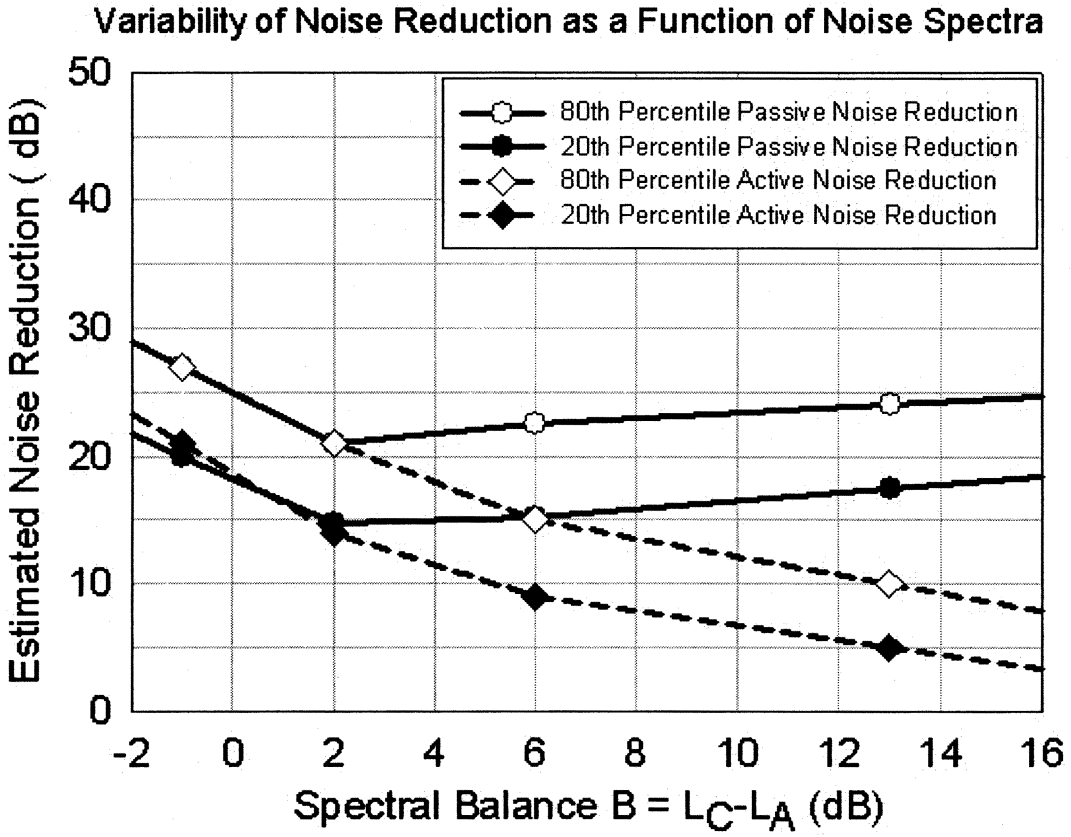

Figure 1 Example – Variability of Noise Reduction as a Function of Noise Spectra

(f) The following statement, ''When this device is worn as instructed and operated in its PASSIVE mode, the level of noise entering a person's ear is approximated by the differences between the A-weighted sound pressure level at the user's location and the lesser and greater PASSIVE NRRs. When this device is operated in its ACTIVE mode, the level of noise entering the person's ear is approximated by the difference between the A-weighted sound pressure level at the user's location and the lesser and greater ACTIVE NRRs.''

(g) The following example shall be included for ACTIVE devices: ''Example:

(1) X: The sound pressure level as measured at the user's location in decibels A-weighted (dBA).

(2) Lesser and greater NRR: The ACTIVE or PASSIVE ratings obtained either from the primary label or from the graph of noise reduction variability with spectral balance.

(3)(I) The approximate range of sound pressure levels at the user's ears with the HPD in either its ACTIVE or PASSIVE mode:

(A) (X − lesser NRR) = the greater sound pressure level.

(B) (X − greater NRR) = the lesser sound pressure level.

(ii) The sound pressure level at the user's ears will depend upon the fit and operating mode of the protector.''

(h) The following cautionary note shall be included in the secondary label for active noise reduction hearing protectors: ''Caution: For the ACTIVE mode in predominantly low frequency environments in which the difference in the measured C-weighted and A-weighted sound pressure levels (dBC-dBA) exceeds 3 dB, the user is directed to the enclosed graph of the variability of noise reduction with noise spectra to determine the level of protection.''

(i) The following statement shall be included: ''This device, in ACTIVE mode, is recommended for use in environmental noise levels from X to Y dBA.'' The manufacturer shall designate the values of X and Y.

(j) If the total combined attenuation of REAT and L_{ACTIVE}, as calculated in § 211.206–2, for any octave band exceeds 50 dB, the following cautionary statement shall be included: ''The combined attenuation of this device has been measured to be in excess of 50 dB at XXX Hz. Sound energy transmitted through the head or oral/nasal cavities to the inner ear may be greater than the level of sound when attenuated by the hearing protection device.'' The manufacturer shall designate the frequency band(s) where the attenuation exceeds 50 dB.

(k) The battery type, number of batteries and expected use time for the product.

10. Section 211.204–6 is added to read as follows:

§ 211.204–6 Supporting information for Amplitude-Sensitive Hearing Protection Devices.

In addition to the supporting information required in § 211.204–4, the following minimum supporting information must accompany all Amplitude-Sensitive hearing protection devices in an easily readable format. In the case of bulk packaging and dispensing, such supporting information must be affixed to the bulk container or dispenser in the same manner as the label, and in a readily visible location. The information

resulting from the measurements prescribed in § 211.206–3 shall be presented in tabular and graphical form as shown in Table 1 and Figure 1 of this section for PASSIVE Amplitude-Sensitive hearing protection devices and as shown in Table 2 and Figure 2 of this section for ACTIVE Amplitude-Sensitive devices.

(a) The mean peak sound pressure levels.

(b) The mean impulsive noise reduction at each mean peak sound pressure level.

(c) The minimum and maximum impulsive noise reduction values at each mean peak sound pressure level.

TABLE 1—EXAMPLE—VARIABILITY OF IMPULSIVE NOISE REDUCTION FOR ABC PROTECTOR

[Passive mode]

Mean peak sound pressure level	131 dB	150 dB	167 dB
Mean Impulse Noise Reduction	23.2	22.9	23.4
Maximum Impulse Noise Reduction	24.0	23.1	24.4
Minimum Impulse Noise Reduction	21.5	22.4	22.7

TABLE 2—EXAMPLE—VARIABILITY OF IMPULSIVE NOISE REDUCTION FOR XYZ PROTECTOR

[Active and passive modes]

Mean peak sound pressure level	133 dB	150 dB	167 dB
Mean Impulse Noise Reduction (Passive)	32.2	32.8	33.9
Maximum Impulse Noise Reduction (Passive)	32.6	33.4	34.2
Minimum Impulse Noise Reduction (Passive)	31.2	31.7	33.7
Mean Impulse Noise Reduction (Active)	32.0	31.6	32.7
Maximum Impulse Noise Reduction (Active)	32.1	32.3	33.8
Minimum Impulse Noise Reduction (Active)	30.5	31.2	30.6

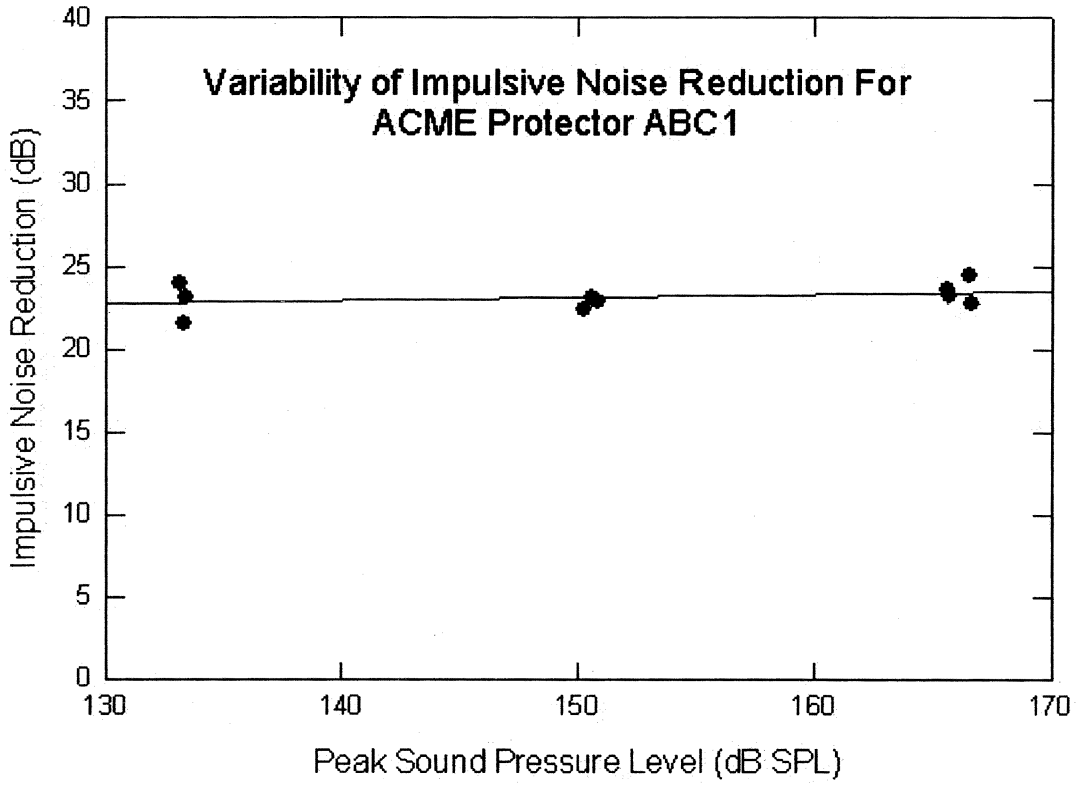

Figure 1. Example - Variability of Impulsive Noise Reduction with Peak Sound Pressure Level

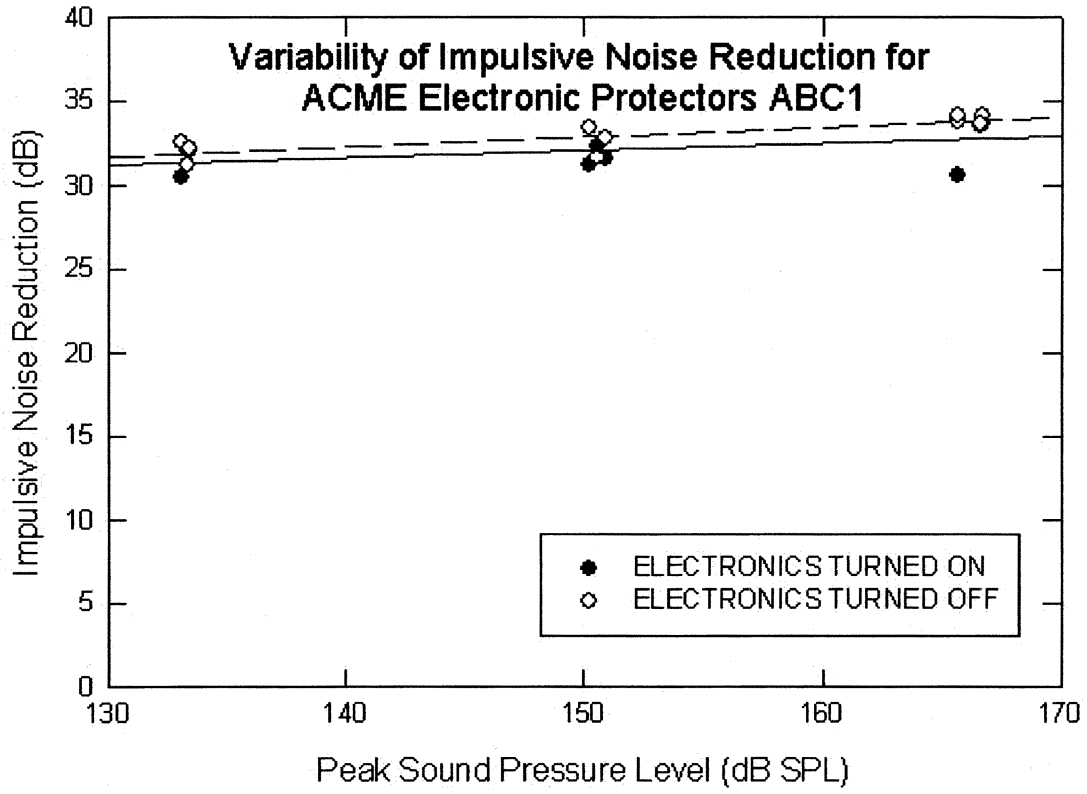

Figure 2. Example – Variability of Impulsive Noise Reduction with Peak Sound Pressure Level

(d) The battery type, number of batteries and expected operating time for the product as appropriate.

(e) The following statement: ''This device is recommended for use in impulsive noise environments having peak levels between 130 to X dB SPL.'' (X dB is equal to 130 dB plus the mean passive impulsive noise reduction)

(f) The following cautionary note shall be included for ACTIVE noise reduction hearing protectors. ''Caution: This device is not intended for use in impulsive noise environments exceeding Y dB peak sound pressure levels. The risk of hearing loss increases with multiple exposures to high level peak impulses.'' (Y dB is equal to 130 dB plus the mean active impulsive noise reduction)

(g) The following statement: ''The PASSIVE Noise Reduction Rating is based on the attenuation of continuous noise and is not an accurate indicator of the protection attainable against impulsive noise. The IMPULSIVE Noise Reduction Rating is based on the attenuation of high-level impulsive noise and is not an accurate indicator of the protection attainable for continuous noise.''

(h) The following example shall be included for amplitude-sensitive devices:

''Example:

(1) X: the peak sound pressure level as measured at the user's location in decibels A-weighted (dBA).

(2) Lesser and greater NRR: the IMPULSIVE ratings obtained from the primary label.

(3)(i) The approximate range of sound pressure levels at the user's ears with hearing protection:

(A) (X − Lesser NRR) = the greater effective peak sound pressure level.

(B) (X − Greater NRR) = the lesser effective peak sound pressure level.

(ii) The peak sound pressure level at the user's ears will depend upon the fit and operating mode of the protector. For a more accurate estimate of the impulsive noise reduction the user is directed to the graph of Figure 2 of this section.''

11. Section 211.204–7 is added to read as follows:

§ 211.204–7 Supporting information for Amplitude-Sensitive Hearing Protection Devices with Active Noise Reduction.

Devices that incorporate both ACTIVE noise reduction and ACTIVE amplitude-sensitive noise reduction shall comply with both sections § 211.204–1(b) and § 211.204–1(c) for primary labeling and with both sections § 211.204–5 and § 211.204–6 for supporting information.

12. Section 211.205 is revised to read as follows:

§ 211.205 Special claims and exceptions.

(a) Any manufacturer wishing to make claims regarding the acoustic effectiveness of a device, other than its Noise Reduction Ratings, must demonstrate the validity of such claims, including the presentation of test data and the specific methods used to validate the claims.

(b) Any request concerning an exception must be supported by scientific test data that establishes the exception without doubt, and must be submitted for consideration and approval to: The Administrator or his designee at U.S. EPA, Office of the Administrator. The Agency will notify the manufacturer within thirty (30) business days of receipt of the request if: the special claim or exception is approved, disapproved, additional information is needed, or the Agency needs additional time to consider the request.

13. Section 211.206–1 is revised to read as follows:

§ 211.206–1 Real ear attenuation at threshold (REAT).

(a) The provisions of this section shall apply to the following devices:

(1) Passive Hearing Protection Devices;

(2) Active Hearing Protection Devices in their ''off'' mode of operation;

(3) Active Noise Reduction Hearing Protection Devices in their ''off'' mode of operation; and

(4) Amplitude-Sensitive Hearing Protection Devices in their ''off'' mode of operation (if they incorporate electronics).

(b) The sound attenuation to be used in the calculation of the Noise Reduction Rating shall be determined in accordance with all clauses of ANSI/ASA S12.6–2008 ''Methods for Measuring the Real-ear Attenuation of Hearing Protectors,'' incorporated by reference at § 211.213 of this subpart, except as stipulated in the identified ANSI clauses below:

(1) For subpart B, the word ''requester'' as used in ANSI/ASA S12.6–2008 shall be replaced with the word ''manufacturer'' as defined in § 211.203.

(2) For subpart B, only those requirements addressing Method A of ANSI/ASA S12.6–2008 shall be applicable.

(3) Clause 3 of ANSI/ASA S12.6–2008. Terms and Definitions. The definitions given in § 211.203 shall be used in this subpart.

(4) Clause 4 of ANSI/ASA S12.6–2008. Physical Requirements of Test Facility. For subpart B, the following new provision shall be in addition to that of Clause 4.3.1: ''The electrical test signals measured at the input terminals of the speaker or speakers shall consist of one-third octave bands of pink or white noise, with a spectrum shape equivalent to that which would be created by a filter meeting the requirements of Class O of ANSI S1.11–2004, incorporated by reference at § 211.213 of this subpart. The mode of operation in changing from one band to another shall be a discrete step function; a gradual continuously adjustable mode of change shall not be used.''

(5) Clause 5 of ANSI/ASA S12.6–2008—Test Subjects.

(i) For subpart B, the following new provision shall be in addition to Clause 5.3. ''Prior to audiometric qualification and participation in attenuation testing, the dimensions of both the right and left ear canals, and the bitragion width and head height of the test subject shall be measured in accordance with the procedure of ANSI 12.6–2008, Annex B.

(6) Clause 6 of ANSI/ASA S12.6–2008. Product Samples.

(i) For subpart B, the following new provisions shall be in addition to Clause 6.1 of ANSI/ASA S12.6–2008:

(A) Formable ear plugs: a minimum of three pairs of ear plugs per test subject shall be provided. A new pair shall be used for training and for each subsequent occluded trial. When a specific product is available in different sizes, three pairs of each product size shall be provided per test subject.

(B) Premolded ear plugs and semi-insert devices: a minimum of one pair of ear plugs per test subject shall be provided. When a specific product is available in different sizes, one pair of each product size shall be provided per test subject.

(C) Custom ear plugs: One pair of custom ear plugs for each test subject shall be provided.

(D) Ear muffs: a minimum of one pair of ear muffs for every two test subjects shall be provided. When a specific product is available in different sizes, one pair of each product size shall be provided for every two test subjects.

(E) Ear muffs attached to a hardhat: The hardhat sample shall be specified by the manufacturer of the hearing protection device. A minimum of one pair of ear muffs for every two test subjects shall be provided. When an ear muff is available in different sizes, one pair of each size shall be provided for every two test subjects. For each size of hardhat, two samples shall be provided in each size.

(F) Helmets: a minimum of one sample shall be provided for each size helmet to be tested. Helmets incorporating other hearing protection devices (e.g. ear plugs, ear muffs) shall be tested as a system. The hearing protection device(s) incorporated in a helmet shall be provided by the manufacturer of the helmet. The minimum number of samples of the hearing protection device(s) to be used in combination with the helmet shall be as specified in paragraph (b)(6)(i)(A) through (E) of this section.

(ii) For subpart B, the following new provisions shall be in addition to Clause 6.2 of ANSI/ASA S12.6–2008: ''Ear muffs and semi-insert devices with bands or attached to hardhats, which include adjustment mechanisms allowing the band force to be varied, shall be initially set to the minimum application force of their adjustment range prior to being provided to each subject. During fitting, the devices may be readjusted per the provisions of Clauses 8.1 of ANSI/ASA S12.6–2008.''

(iii) For subpart B, Clause 6.3 of ANSI/ASA S12.6–2008, shall not be applicable.

(7) Clause 7 of ANSI/ASA S12.6–2008—Psychophysical Procedure.

(i) For subpart B, Clause 7.1.1 of ANSI/ASA S12.6–2008, shall not be applicable.

(ii) For subpart B, Clause 7.5 of ANSI/ASA S12.6–2008, shall read as follows: ''If the range of open threshold measurements at any frequency exceeds 6 dB during a test session, the threshold at that frequency shall be retested until two open thresholds are obtained within 6 dB of each other.''

(8) Clause 8 of ANSI/ASA S12.6–2008—Method A: Trained-subject Fit:

(i) For subpart B, the following new provisions shall be in addition to Clause 8.1 of ANSI/ASA S12.6–2008:

(A) ''The experimenter shall give each subject precise directions and practice in fitting the hearing protector in accordance with the instructions that are provided by the manufacturer with the product to all users. The manufacturer's instructions shall not be modified by the experimenter's own knowledge in fitting the same or similar devices. No indicators, marks, or lubricants shall be utilized unless supplied or recommended by the manufacturer as a part of normal use. No alterations shall be made to the device to facilitate fitting. When applicable the experimenter shall assist the subject in selecting the appropriate size hearing protector, and in adjusting products with variable band force. Subjects can select the size appropriate to fit their right and left ears. The selected size(s) must be used throughout the two product trials.

(B) The experimenter may provide demonstrations of the manufacturer's fitting instructions during the training period. The experimenter may personally fit the device to the test subject as part of the training process. The experimenter shall train the subject in the use of the fitting noise (Clause 4.3.6 of ANSI/ASA S12.6–2008) to assist in fitting the protector. There is no limitation on either the duration of the training or the number of practice fittings that may be performed. Trial sound attenuation measurements during the training period are prohibited. Once the experimenter has determined the subject can properly fit the hearing protector, the test shall begin.''

(ii) For subpart B, the following new provisions shall be in addition to Clause 8.2 of ANSI/ASA S12.6–2008: ''After training, a subject shall be dismissed if the subject cannot obtain an acceptable product fit based on any one of the following criteria:

(A) Subjects assessment of the quality of the hearing protector fit based on

listening to the loudness of the fitting noise,

(B) Visual evaluation by the experimenter,

(C) Tactile evaluation by the experimenter working in conjunction with the subject,

(D) Guidance specific to that product as provided by the manufacturer,

(E) Repeated failure to meet the requirements of Clause 7.5

(F) Illness or physical inability to participate on the day of the test, and

(G) Inability to remain attentive during instruction or testing sessions.

Subjects shall not be retested or dismissed as the result of the attenuation they obtained during the testing process.''

(iii) For subpart B, the following new provisions shall be in addition to Clause 8.3 of ANSI/ASA S12.6–2008:

(A) ''For the occluded tests, the subject shall fit the hearing protector without the experimenter present in the test chamber. The fitting noise shall be introduced into the test chamber and the subject shall be told to manipulate the hearing protector to obtain the lowest level of perceived noise. The experimenter shall observe the subject during the fitting test from outside the chamber. Once the subject is satisfied with the fit, and after observing the quiet period specified in Clause 7.6 and the waiting period specified in Clause 7.7 of ANSI/ASA S12.6–2008, the test shall begin.

(B) Adjustments of the fit of the hearing protector during the occluded threshold tests are not allowed. However, the subject shall be instructed to inform the experimenter if, during the test, a change in fit of the device is noticed, and if so, the test shall be stopped. The subject shall refit the device and the occluded threshold test restarted from the beginning. If this occurs a second time the occluded threshold testing shall be completed without refit and the attenuation data shall be used in the computation of the rating.''

(9) For subpart B, Clause 9 of ANSI/ASA S12.6–2008 is not applicable.

14. Section 211.206–2 is revised to read as follows:

§ 211.206–2 Active noise reduction (ANR).

The provisions of this section shall apply to all Active Noise Reduction hearing protection devices as defined in § 211.203(u)(7).

(a) The measurement of active sound attenuation requisite to the Noise Reduction Rating for Active Noise Reduction hearing protection devices shall be in accordance with the methods defined in this section and only those clauses of ANSI S12.42–1995 (R2004), incorporated by reference at § 211.213 of this subpart, stated below. The octave band attenuation shall be calculated using one-third octave band insertion loss measurements as described in paragraph (m)(2) of this section.

(b) The definitions given in § 211.203 shall be used.

(c) Acoustic Environment of Test Room: The requirements of this subpart shall be applicable to measurements of all Active Noise Reduction devices.

(1) Sound Field Generation Equipment: For subpart B, Clause 6.1 of ANSI/ASA S12.6–2008, shall be applicable.

(2) Sound Field Characteristics: For subpart B, Clauses 6.2.1 and 6.2.2 and Table 1 of ANSI S12.42, shall be applicable.

(3) Sound Field Frequency Characteristics: The sound field shall be a broad band noise incorporating frequencies from 100 to 10000 Hz. The difference between the maximum and minimum one-third octave band levels within the specified frequency range shall not exceed 10 dB. The difference between adjacent one-third octave band levels shall not exceed 3 dB.

(4) Sound Field Integration Time: The integration time shall not be less than 32 seconds using linear spectral averaged third octave band analysis.

(5) Sound Field Reference Levels ($L_{REF}(f)$): The signal generation equipment shall be capable of producing a continuous sound field of 105 dB SPL without a subject in the room. The field shall be measured with an ANSI Type I Pressure Microphone. The attenuation settings shall be recorded to permit replication.

(6) Ambient Noise Floor of Test Room: The noise floor of the test chamber, with all external equipment operating and no sound field present, shall be at least 60 dB less than sound field levels measured at each third octave band.

(7) Fitting Noise: The fitting noise shall be as specified in paragraph (c)(3) of this section and presented at a level of 85 dB SPL.

(d) Measurement Equipment:

(1) For subpart B, Clauses 6.3.1, 6.3.2, and 6.3.4 of ANSI S12.42, shall be applicable.

(2) For subpart B, the following new provision shall be in addition to Clause 6.3.6 of ANSI S12.42: ''A spectrum analyzer using a third-octave band analog or digital filter bank or a Type I sound level meter with a third-octave band filter set shall be used for measuring the sound pressure levels. The measurement system shall have sufficient dynamic range such that all measurements are a minimum of 10 dB above the instrumentation noise floor and test chamber's ambient background noise level. When using a Fast Fourier Transform (FFT) analyzer, it shall have internally generated digital pseudorandom white and pink noise sources with known statistical characteristics, i.e., wide sense stationary, and shall be used for the third-octave band calculation of true random noises. All decibel measurements shall be referenced to 20×10^{-6} N/m^2 (20 μPa).''

(3) Signal to Noise Ratio of the measurement microphone in the test chamber: The difference in microphone output levels with and without the sound field present shall be at least 10 dB in each third-octave band from 80 to 12500 Hz.

(e) Active Attenuation Method for ear muffs using Microphone In Real Ear (MIRE).

(1) MIRE Microphone: For subpart B, a microphone that fulfills the requirements set forth in Clause 8 of ANSI S12.42, is required.

(2) For subpart B, the following new provision shall be in addition to Clause 8.1.2 of ANSI/ASA S12.6–2008: ''The microphone may be wireless or wired. If wired, the wires from the microphone, including insulation, shall not be more than 0.3204 millimeters (0.0126 inches) in diameter to minimize leakage of sound into the protector cavity.''

(3) For subpart B, the following new provision shall be in addition to Clause 8.1.3 of ANSI/ASA S12.6–2008: ''The experimenter shall fit appropriate ear plugs into the subject's ear canals such that their external surfaces are flush with the base of each ears conchae. The subject shall be instructed that removal of any hearing protector is prohibited during the test without permission from the experimenter.''

(4) Position of microphone: The MIRE microphone shall be positioned by the experimenter on the external surface of the ear plug at the entrance of the ear canal, as shown in Figure 1 of this section. The sensing surface shall be perpendicular to the axis of the ear canal, centered in the ear canal and directed away from the center of the subject's head.

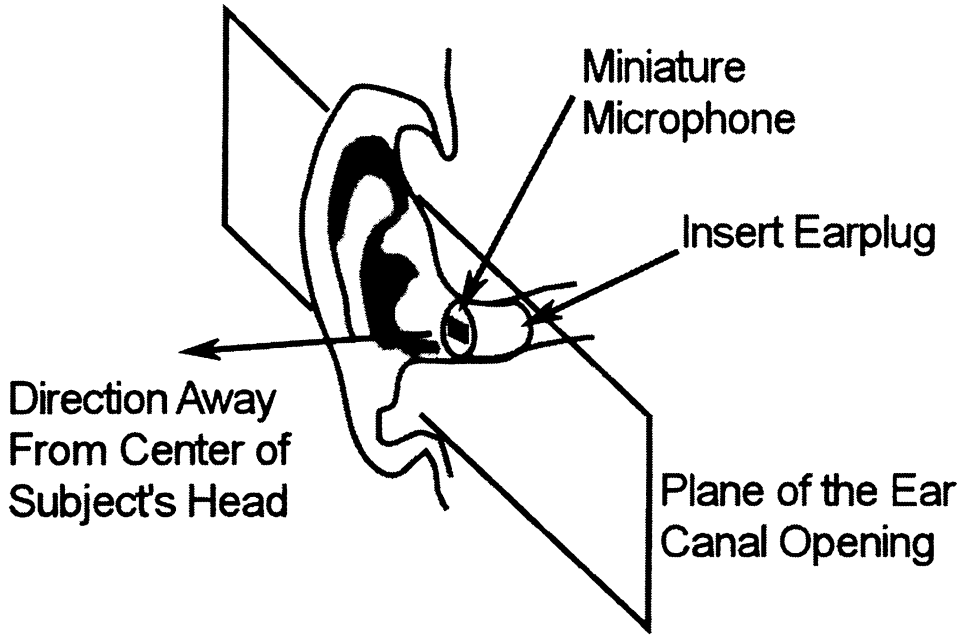

Figure 1. MIRE microphone position for measuring the Active Noise Reduction of ear muffs.

(f) Product selection:

(1) Ear muffs: A minimum of one pair of ear muffs for every two test subjects shall be provided. Subjects shall use the same ear muff as for the REAT testing. When a specific product is available in different sizes, one pair of each product size shall be provided for every two test subjects.

(2) Ear muffs attached to a hardhat: The hardhat sample shall be specified by the manufacturer of the hearing protection device. A minimum of one pair of ear muffs for every two test subjects shall be provided. When an ear muff is available in different sizes, one pair of each size shall be provided for every two test subjects. For each size of hard hat, two samples shall be provided in each size.

(3) Helmets: A minimum of one sample for each size helmet to be tested shall be provided. Helmets incorporating ear muffs shall be tested as a system. The integral ear muffs for a helmet shall be provided by the manufacturer of the helmet. If the ear muffs are removable, the minimum number to be used in combination with the helmet shall be as specified in § 211.206–1(b)(6)(i)(D).

(g) Measurement Procedure:

(1) Subject Selection: Only those subjects who completed the REAT tests with protectors specified in § 211.206–1(a)(3) shall be used for the MIRE tests set forth in this section.

(2) Subject Position: A head-positioning device, such as a plumb-bob to the nose or the forehead of the subject, shall be used to maintain the subject's head at the reference point. The head positioning device shall not transmit to the head vibrations that affect the threshold measurements, and shall not measurably affect the uniformity of the sound field of the room as specified in Clause 6.2.1 of ANSI S12.42. The use of a headrest or bite bar is not permitted.

(h) Fitting the protectors:

(1) The subject shall fit the protector as instructed for the REAT testing. No additional fitting training shall be given. However, the experimenter shall ensure that the integrity of the MIRE microphone and its wires is maintained during the fit process.

(2) The fitting noise shall be introduced into the test chamber and the subject shall be told to adjust the hearing protector to minimize the level of the perceived noise.

(3) To allow hearing protectors to conform to the subject's ears and/or head, MIRE measurements shall begin a minimum of two minutes after the hearing protectors have been fitted unless the manufacturer's standard instructions state otherwise.

(4) Adjustments of hearing protector fit during the test are not permitted. The subject shall be told to inform the experimenter if a change in the fit of the device is noticed. If the experimenter is so informed, the occluded test shall be stopped. The subject shall refit the device and the experimenter shall confirm the integrity of the MIRE system, after which the test shall be restarted from the beginning. If change in the fit occurs a second time but the MIRE system is unaffected, the test shall be completed without refit and the attenuation data shall be used in the computation of the active noise reduction.

(i) MIRE Sound Levels with Protectors Activated ($L_{TOTAL}(f)$):

(1) The experimenter shall verify that the device is activated as specified by the manufacturer's standard instructions.

(2) The sound field shall be presented in the test chamber at the reference level of 105 dB SPL as specified in paragraph (c)(5) of this section.

(3) The MIRE output signal shall be measured in one-third octave bands ($L_{TOTAL}(f)$) using linear spectral averaging and an integration time of no less than 32 seconds.

(j) MIRE Sound Levels with Protectors Deactivated ($L_{PASSIVE}(f)$):

(1) The experimenter shall verify that the device is deactivated as specified by the manufacturer's standard instructions.

(2) The sound field shall be presented in the test chamber at the reference level

of 105 dB SPL as specified in paragraph (c)(5) of this section.

(3) The MIRE output signal shall be measured in one-third octave bands ($L_{PASSIVE}(f)$) using linear spectral averaging and an integration time of no less than 32 seconds.

(4) The measurements in paragraph (i)(j) of this section shall be repeated and the $L_{PASSIVE}(f)$ and $L_{TOTAL}(f)$ levels for each measurement recorded.

(5) Verification of MIRE microphone position: Upon completion of the measurements in paragraph (i)(j) of this section, the experimenter shall confirm the position of the MIRE has not changed. If the position has changed, the measurements shall be repeated.

(k) Active Attenuation Method for ear plugs using Acoustic Test Fixture (ATF).

(1) Acoustic Test Fixture:

(i) The ATF shall incorporate two ear canal couplers and ear simulators.

(ii) The ATF ear simulators shall comply with the International Electrotechnical Commission (IEC) specification 60711—''Occluded-ear simulator for the measurement of earphones coupled to the ear by ear inserts,''

(iii) The length of the ear canal couplers shall provide a residual volume of between 0.5 and 2.0 cubic centimeters after insertion of the ear plug.

(iv) The ATF microphones shall meet or exceed the following minimum specifications.

(A) Frequency range 20 to 12500 Hz.

(B) Dynamic range: 40 to 130 dB SPL.

(v) The insertion loss of the ATF shall not be less than 60 dB for a sound field as specified in § 211.206–2(c)(5).

(2) Product selection:

(i) Custom Ear plugs:

(A) The testing lab shall provide the manufacturer with impressions of the ATF ear canal that provide a residual volume between 0.5 cubic centimeters (cc) and 1.0 cc.

(B) The manufacturer shall provide the testing lab a minimum of five ANR electronic control units and five pairs of ANR ear plugs that are custom fitted to the ATF ear canal coupler.

(ii) Non-custom Ear plugs:

(A) The manufacturer shall provide the testing lab a minimum of five ANR electronic control units and five pairs of ANR ear plugs.

(B) Alternatively, the ear plugs from the REAT test may be reused for this ATF test.

(3) Measurement Procedure for Active Noise Reduction Performance of ear plugs.

(i) Fitting the protectors:

(A) The experimenter shall fit the protectors into the ear couplers of the ATF such that their respective residual volumes are not less than 0.5 cc and no greater than 1.0 cc.

(ii) ATF Sound Levels with Protectors Activated ($L_{TOTAL}(f)$):

(A) The experimenter shall activate the device as specified by the manufacturer's standard instructions.

(B) The sound field in the test room shall be at the reference level of 105 dB SPL as specified in paragraph (c)(5) of this section.

(C) The output signals of the ATF microphone(s) shall be measured in one-third octave bands ($L_{TOTAL}(f)$) using linear spectral averaging and a minimum integration time of 32 seconds.

(iii) ATF Sound Levels with Protectors Deactivated ($L_{PASSIVE}(f)$):

(A) The experimenter shall deactivate the device as specified by the manufacturer's standard instructions.

(B) The sound field in the test room shall be at the reference level of 105 dB SPL as specified in paragraph (c)(5) of this section.

(C) The ATF microphone(s) output signal shall be measured in one-third octave bands ($L_{PASSIVE}(f)$) using linear spectral averaging and a minimum integration time of 32 seconds.

(D) The measurements in paragraphs (k)(3)(ii) and (iii) of this section shall be repeated for a total of forty trials. Each ANR control unit and each pair of ear plugs shall be used an equal number of times. The $L_{PASSIVE}(f)$ and $L_{TOTAL}(f)$ levels for each measurement shall be recorded.

(l) ANR performance for helmets with integral ear plugs or ear muffs or both ear plugs and ear muffs.

(1) The tests set forth in paragraph (k)(3) of this section for ANR muffs and plugs shall be used singularly or in combination as appropriate.

(m) Calculation of Attenuation of ANR devices:

(1) The passive attenuation for each subject shall be the average of the individual REAT attenuation measurements for octave band frequencies from 125 to 8000 Hz.

(2) The octave band active attenuation for each trial shall be calculated using the third octave band insertion loss measurements (from 100 to 10000 Hz), as follows:

(i) L_{ACTIVE} (one-third octave band insertion losses) for each trial for each one-third octave band shall be calculated as:

(A) L_{ACTIVE} (⅓ OB) = $L_{TOTAL} - L_{PASSIVE}$

(B) L_{ACTIVE} (octave band insertion losses) for each trial shall be calculated as the median of the one-third octave band active attenuations, described in § 211.206–2(k)(3)(ii) and (iii), measured for both the right and left ears.

(C) An example calculation is presented in Table 1 of this section. The six (6) insertion losses for the active mode have a median of 11.4 dB. The six values are sorted first (10.4, 10.8, 11.1, 11.7, 12.1 and 12.6). The values 11.1 and 11.7 bracket the 50th percentile and their average is 11.4 dB.

TABLE 1—EXAMPLE OF THE MEDIAN OCTAVE BAND INSERTION LOSS COMBINED WITH REAT FOR ACTIVE MODE

	− ⅓ octave	Center band	+⅓ octave
REAT Attenuation	.....	25.4	.....
Right Ear Active Insertion Loss	10.4	12.1	11.7
Left Ear Active Insertion Loss	10.8	11.1	12.6
Median Insertion Loss	.....	11.4	.....
REAT + Median Insertion Loss	.....	36.8	.....

(3) The total octave band attenuation for each trial in the Active mode (electronics turned on) shall be the sum of the REAT octave band attenuations and the L_{ACTIVE} octave band insertion losses as computed in paragraph (m)(2) of this section. These total octave band attenuation values (REAT + L_{ACTIVE}) shall be used in the computation of the NRR and the NRR_G as specified in ANSI S12.68–2007. If the total octave band attenuation values exceed 50 dB in any band then a cautionary note must be provided regarding the influence of bone conduction according to § 211.204–5(j).

15. Section 211.206–3 is added to read as follows:

§ 211.206–3 Reduction of Peak Impulsive Noise.

Hearing protection devices sold or offered on the basis of providing protection from impulsive noises in excess of 130 dB peak sound pressure level shall be tested in accordance with this section.

(a) Product Selection.

(1) Custom Ear plugs:

(i) The manufacturer shall provide the testing lab a minimum of five pairs of ear plugs that are custom fit to the ear canal couplers of the ATF.

(ii) The testing lab shall provide the manufacturer with impressions of the ATF ear canals such that the residual volume is not less than 0.5 cubic centimeters (cc) or greater than 1.0 cc.

(2) Ear plugs:

(i) The manufacturer shall provide the testing lab a minimum of five pairs of ear plugs selected at random from production lots.

(ii) Alternatively, the ear plugs from the REAT test may be reused for this ATF test.

(iii) The testing lab shall insert the ear plug such that the residual volume is not less than 0.5 cc or greater than 1.0 cc.

(3) Ear muffs:

(i) The manufacturer shall provide the testing lab a minimum of five pairs of ear muffs selected at random from production lots, appropriately sized for the ATF.

(ii) Alternatively, the ear muffs from the REAT test may be reused for this ATF test if they meet the ATF size requirements.

(4) Ear muffs attached to a hardhat:

(i) The manufacturer shall provide the testing lab a minimum of five pairs of ear muffs attached to a hardhat selected at random from production lots, appropriately sized for the ATF.

(ii) Alternatively, the hard hat(s) and ear muffs from the REAT test may be reused for this test if they meet the ATF size requirements.

(5) Helmets incorporating ear cups:

(i) Helmets incorporating ear cups shall be tested as a system for impulse noise reduction. The manufacturer shall provide the testing lab a minimum of one helmet and five pairs of ear cups selected at random from production lots, appropriately sized for the ATF.

(ii) Reserved.

(6) Combination of ear plugs, ear muffs and/or helmets:

(i) The manufacturer shall provide the testing lab five (5) pairs of each protector. The device shall be tested as a system in combination as appropriate.

(ii) Reserved.

(b) Impulsive Noise Characteristics.

(1) Three different peak impulse noise levels shall be used. The peak impulse levels shall be in the following ranges 130–134 dB, 148–152 dB and 166–170 dB. Manufacturers may elect to test at levels in excess of the required 170 dB, in which case notice must be given on both the primary and secondary labels as required in § 211.204–1(c) and § 211.204–6 and the information reported to the EPA on the required test report per § 211.212–5.

(2) The minimum permissible A-duration shall not be less than 0.5 milliseconds and the maximum shall not be greater than 2.0 milliseconds.

(3) The peak level and A-duration of the impulse noise shall not be affected by acoustic reflections.

(c) Measurement Equipment.

(1) Impulsive Acoustic Test Fixture or Dummy Head (IATF).

(i) The hearing protection device shall be tested on an IATF which meets the requirements of ANSI S12.42–1995, Section 9.1—*Acoustic Test Fixture Method.*

(ii) The insertion loss of the IATF shall not be less than 65 dB for impulses in the ranges described in paragraph (b)(1) of this section.

(iii) The IATF shall include two identical simulated ears, including representative pinnas, conchas, and ear canal coupler, and identical instrumentation. The ear canal coupler shall be in accordance with IEC 60711 (1984) but incorporate a 6.35 mm (0.25 inch) pressure microphone to satisfy the required dynamic range of 130 db to 170 dB.

(2) Free-Field Pressure Probe/ Microphone.

(i) A free-field pressure probe/ microphone capable of accurately measuring impulse levels of 180 dB peak SPL shall be used as the external microphone.

(ii) The free-field pressure probe shall be a cylindrical body as depicted in Figure 1 of this section, having a minimum length, d3, of 40.64 cm (16 inches), a maximum diameter of 5.08 cm (2 inches) and a taper from the tip, d1, of 5.08 to 10.16 cm (2 to 4 inches). The pressure transducer shall be flush with the side of the cylindrical body and located a distance d2, from the tip, of between 15.24 and 20.32 cm (6 and 8 inches).

(iii) The free-field pressure probe/ microphone shall be positioned as shown in Figure 2 of this section, equidistant and at the same elevation as the microphone(s) of the IATF from the impulse noise source.

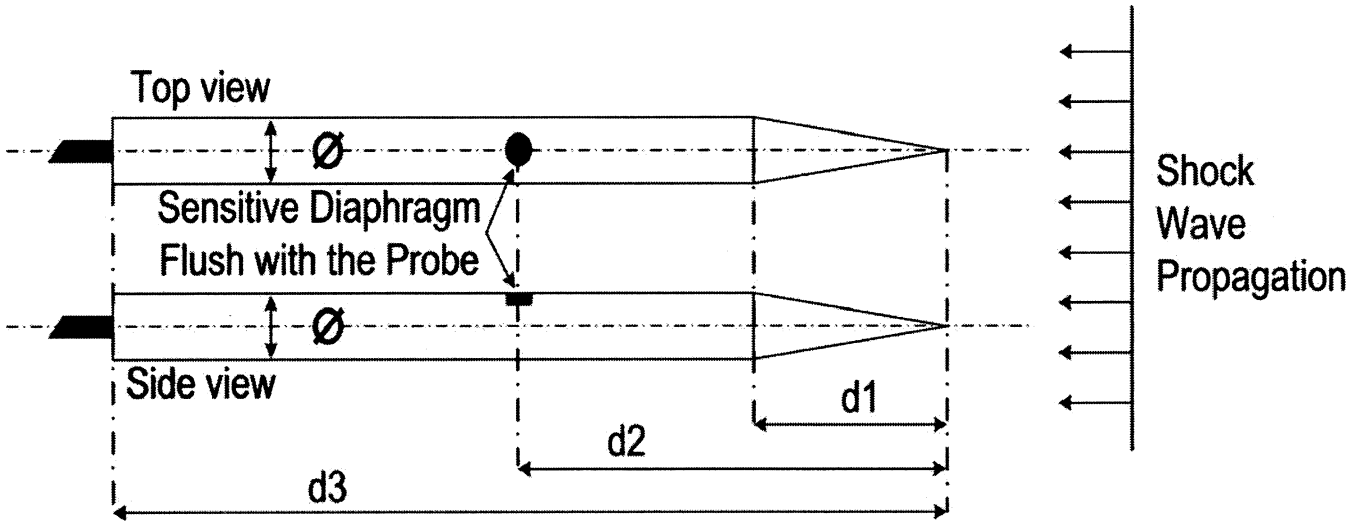

Figure 1. Free Field Pressure Probe

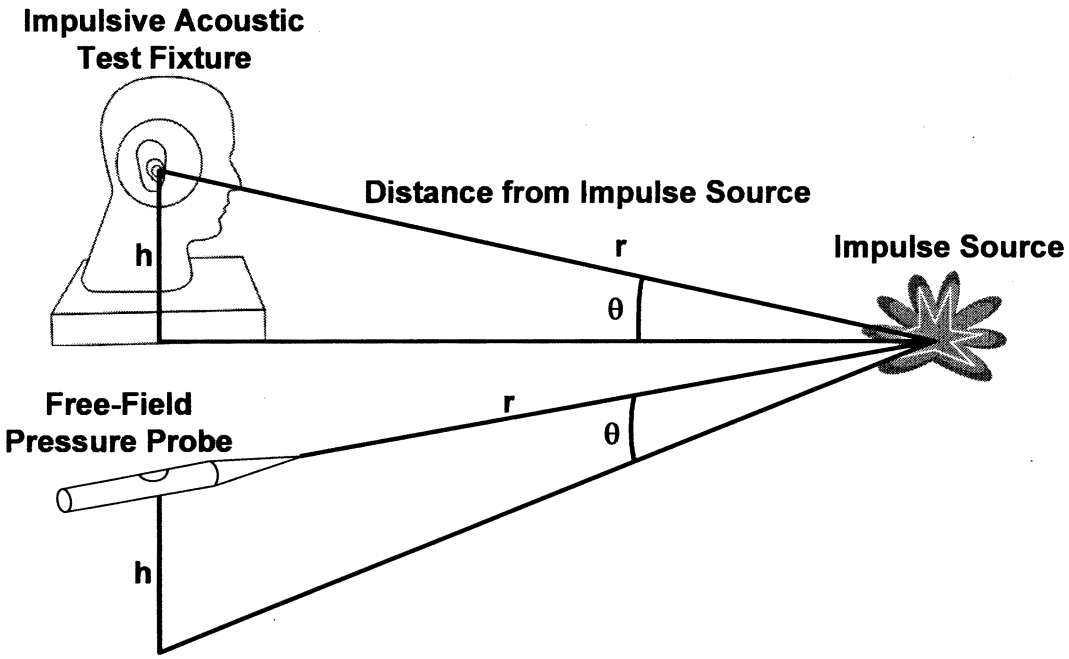

Figure 2. Configuration of Impulsive Acoustic Test Fixture,

Free-field pressure probe and the impulse noise source.

(3) Impulsive Noise Measurement Instrumentation

(i) Sampling rate: The data acquisition system shall be capable of simultaneously sampling the acoustic response of the two ears of the IATF and the free-field pressure probe/microphone with a minimum sampling rate of 96,000 samples per second (96 kHz) for each channel.

(ii) Signal to Noise Ratio: The Signal to Noise Ratio of any captured signal must be greater than 10 dB from 100 to 10000 Hz.

(iii) Sampling Resolution: The resolution of the data acquisition system shall be a minimum of 16-bits.

(4) Instrumentation layout for Measurement of Reduction of Peak Impulsive Noise.

(i) The instrumentation shall be arranged such that each ear of the IATF and the free-field pressure probe/microphone are located equidistant from the impulse noise source as shown in Figure 2 of this section.

(5) Measurement Procedure for the Impulsive Noise Reduction Rating.

(i) Calibration of the Free-field to ear canal transfer function.

(ii) Five impulses shall be produced in the range of 148 to 152 dB peak impulse sound pressure level. The measurement of the free field to ear canal transfer function is not required if impulse peaks are within ± 0.5 dB.

(iii) The complex free-field to ear canal transfer functions ($H_{FF–Right-i}$ and $H_{FF–Left-i}$) shall be calculated for each impulse and each ear.

(iv) The free-field to ear canal transfer functions ($H_{FF–Right}$ and $H_{FF–Left}$) shall be the average of the five respective individual calculated transfer functions.

(A) $H_{FF–Right,\ i}(f) = F(P_{EAR–Right,i}(t))/F(P_{FF,\ i}(t))$

(B) $H_{FF–Left,\ i}(f) = F(P_{EAR–Left,i}(t))/F(P_{FF,\ i}(t))$

(6) Measurement of the Peak Impulsive Noise Reduction for a hearing protection device.

(i) For each sample of the hearing protection device, a minimum of one impulse at each of the three pressure ranges shall be produced as specified in paragraph (b)(1) of this section. The peak pressure can be adjusted by varying the acoustic impulse source and/or altering the distance from the source to the test fixture.

(ii) Each impulse shall be recorded from the free-field, IATF left and right ear canal microphones by the data acquisition system. The total duration of the captured signal shall not be less than 50 milliseconds. The time duration from the beginning of the captured signal to its peak amplitude shall be a minimum of 1.0 millisecond. The time waveforms from the IATF and the free-field pressure probe/microphone shall be sampled simultaneously.

(iii) The measured time waveforms shall be labeled as $P_{FF,\ j,\ k}$ for the free-field pressure probe/microphone and as $P_{ATF–RIGHT,\ j,\ k}$ and $P_{ATF–LEFT,\ j,\ k}$ for the acoustic test fixture/dummy head ear microphones, where j = 1 to 5 for the protector samples, and k=1 to 3 are the respective impulse noise peak ranges, respectively.

(iv) The hearing protector shall be removed and refitted to the IATF for each impulse noise trial.

(v) If an acoustic impulse or HPD fitting is unacceptable, the HPD shall be refitted and the impulse trial shall be repeated. The data from an unacceptable trial shall be discarded.

16. Section 211.206–4 is added to read as follows:

§ 211.206–4 Consideration of alternative test procedures.

The Administrator may approve applications from manufacturers of hearing protectors for the approval of test procedures which differ from those contained in this subpart so long as the alternative procedures have been demonstrated to correlate with the prescribed procedures. To be acceptable, alternative test procedures must be such that the hearing protector test results obtained will fulfill all test and data requirements prescribed in § 211.206 when the product is tested in accordance with the specified methodology. After approval by the Administrator, testing conducted by manufacturers using alternative procedures may be accepted by the Administrator for all purposes including, but not limited to, production verification testing and selective enforcement audit testing.

§ 211.207 [Amended]

17. Section 211.207 is amended by removing the introductory text and Figure 2.

18. Section 211.207–1 is added to read as follows:

§ 211.207–1 Computation of NRR based on statistical and graphical methods.

(a) The Noise Reduction Rating (NRR) in this subpart shall be determined in accordance with the procedures set forth in Clauses 5, 6 and 7 of ANSI/ASA S12.68–2007, incorporated by reference at § 211.213 of this subpart, except as stipulated in paragraphs (b)(1) through (4), (c)(1) and (2), (d), and (e) of this section.

(b) ANSI Clause 5: The computation of the NRR, as set forth in this clause, shall be used to determine the ''PASSIVE mode'' noise reduction performance of all hearing protector devices subject to this regulation.

(1) The ''Noise Level Reduction Statistic for use with A-weighting (NRS_A)'' shall be replaced by the ''Noise Reduction Rating (NRR)'' as used in this subpart.

(2) For subpart B, ANSI Clause 5.1 shall be replaced by the paragraph (b)(3) of this section.

(3) ''The NRR for a hearing protector, as used in this subpart, is comprised of a pair of values representing the lower and upper A-weighted noise level reductions that can be expected when the device is used as directed by the manufacturers' instructions.''

(4) ANSI Clause 5.2: The value of α as used in this subpart shall be for the 80% and 20% protection performance and equal to 0.8416 and -0.8416 respectively.

(c) ANSI Clause 6: The computation of the NRR, as set forth in this clause, shall be used to determine the ''ACTIVE mode'' noise reduction performance of all hearing protector devices that rely in whole or in part on either mechanical, electronic and/or acoustically variable (with respect to sound pressure level) methods of increasing their noise reduction performance.

(1) For subpart B, ANSI Clause 6.0: the ''Noise Level Reduction Statistic, Graphical (NRS_G) shall be replaced by the ''Noise Reduction Rating, Graphical (NRR_G).

(2) This method shall not be used to compute either the ''PASSIVE mode'' or the ''ACTIVE mode'' performance of hearing protectors intended for protection from high level impulsive noise. The appropriate computation is given in paragraph § 211.207–4.

(d) ANSI Clause 7—Octave-Band Method: The computation of the mean attenuation, the standard deviation of attenuations and the Assumed Protection Values (APVs) as a function of frequency, as set forth in this clause, shall be used for all hearing protectors for the ''PASSIVE mode'' and for active noise reduction hearing protectors in the ''ACTIVE mode.''

(e) For subpart B, ANSI Annex A of ANSI/ASA 12.68–2007—''Noise Spectra Used in Calculating the NRR_A and NRR_G,'' shall be applicable.

19. Section 211.207–2 is added to read as follows:

§ 211.207–2 Computation of the Passive Noise Reduction Rating.

The PASSIVE Noise Reduction Rating shall be calculated using the REAT data obtained in § 211.206–1.

(a) Noise Reduction Rating: For each subject, the attenuations from both trials at each octave band frequency (125, 250, 500, 1000, 2000, 4000, and 8000 Hz) shall be averaged, yielding seven attenuations. The averaged attenuation data shall be used for the $R_{p\ f(k)}$ in Equation 1 of ANSI S12.68–2007. The Noise Reduction Rating shall be determined according to Equations 1, 2, 3, 4, 5 and 6 as specified in Clause 5.2 of ANSI/ASA S12.68–2007, incorporated by reference at § 211.213 of this subpart, using the alpha (α) values of 0.8416 and –0.8416, corresponding to the 20th and 80th percentiles.

(b) Variability of Noise Reduction Rating with Spectral Levels: The variability of the Noise Reduction Rating with the spectral level of the

noise environment in which the hearing protector is worn shall be determined according to Equation 8 in Clause 6 of ANSI S12.68–2007 and shall use the noise spectra as specified in Annex B of ANSI S12.68 for determining the variability. For the variability of passive devices, the Estimated Noise Level Reduction shall be determined at the spectral balance values of $L_C - L_A$ = [–1, 2, 6 and 13 dB]. The variability shall be determined for the 20th and 80th percentile assumed protection values. The variability results shall be reported in the supporting information specified in § 211.204–4.

(c) Mean attenuations and standard deviations: The mean attenuations and standard deviations across subjects as a function of octave band frequency (*f*) from 125 to 8000 Hz are determined as follows:

(1) The mean attenuations are:

$$m_f = \frac{1}{P}\sum_{p=1}^{P} R_{pf}$$

Where R_{pf} is the averaged attenuations for each subject and octave band frequency, P is the total number of subjects tested, p is the subject index.

(2) The standard deviations of the mean attenuation are:

$$s_f = \sqrt{\frac{1}{P-1}\sum_{p=1}^{P}\left(R_{pf} - m_f\right)^2}$$

Where R_{pf} is the averaged attenuations for each subject and octave band frequency, P is the total number of subjects tested, p is the subject index.

(d) Assumed Protection Values: The assumed protection values (APV_f) for the ''passive mode'' of a hearing protector as a function of octave band frequency (*f*) from 125 to 8000 Hz are determined as follows:

(1) The assumed protection values are

$APV_f = m_f \pm \alpha s_f$

Where the 20th percentile APV is determined when α = +0.8416 and the 80th percentile APV is determined when α = –0.8416 is used.

(2) [Reserved]

20. Section 211.207–3 is added to read as follows:

§ 211.207–3 Computation of the Active Noise Reduction Rating.

The Active Noise Reduction Rating shall be calculated using total octave band attenuation determined in § 211–206–2(m).

(a) Noise Reduction Rating: The total octave band attenuation (the sum of the REAT octave band attenuations and the L_{ACTIVE} octave band insertion losses) shall be used for the $R_{p\ f(k)}$ in Equation 1 of ANSI S12.68–2007. The Noise Reduction Rating shall be determined according to Equations 1, 2, 3, 4, 5 and 6 as specified in Clause 5.2 of ANSI S12.68–2007, using the alpha (α) value of 0.8416 and –0.8416, corresponding to the 20th and 80th percentiles.

(b) Variability of Noise Reduction Rating with Spectral Levels: The variability of the Noise Reduction Rating with the spectral level of the noise environment in which the hearing protector is worn, shall be determined according to Equation 8 in Clause 6 of ANSI S12.68–2007 and shall use the noise spectra as specified in Annex B of ANSI S12.68 for determining the variability.

(1) For the variability of passive devices, the Estimated Noise Level Reduction shall be determined at the spectral balance values of $L_C - L_A$ = [–1, 2, 6 and 13 dB]. The variability shall be determined for the 20th and 80th percentile assumed protection values. The variability results shall be reported in the supporting information specified in § 211.204–4.

(2) The Estimated Noise Level Reduction (20th and 80th percentiles) determined for the spectral balance value of $L_C - L_A$ = 13 dB shall be used to identify the performance of an active noise reduction hearing protection device in a low frequency noise environment.

(c) Mean attenuations and standard deviations: The mean total attenuations (REAT + L_{ACTIVE}) and standard deviations across subjects as a function of octave band frequency (*f*) from 125 to 8000 Hz are determined as follows:

(1) The mean attenuations are

$$m_f = \frac{1}{P}\sum_{p=1}^{P} R_{pf}$$

Where R_{pf} is the averaged total attenuation for each subject and octave band frequency, P is the total number of subjects tested, p is the subject index.

(2) The standard deviations of the mean attenuation are

$$s_f = \sqrt{\frac{1}{P-1}\sum_{p=1}^{P}\left(R_{pf} - m_f\right)^2}$$

Where R_{pf} is the averaged total attenuation for each subject and octave band frequency, P is the total number of subjects tested, p is the subject index.

(d) The standard deviations of the mean attenuation are

$$s_f = \sqrt{\frac{1}{P-1}\sum_{p=1}^{P}\left(R_{pf} - m_f\right)^2}$$

Where R_{pf} is the averaged total attenuation for each subject and octave band frequency, P is the total number of subjects tested, p is the subject index.

(1) The assumed protection values are

$APV_f = m_f \pm \alpha s_f$

Where the 20th percentile APV is determined when α = +0.8416 and the 80th percentile APV is determined when α = –0.8416 is used.

(2) [Reserved]

21. Section 211.207–4 is added to read as follows:

§ 211.207–4 Computation of the Impulsive Noise Reduction Rating.

(a) The equivalent ear canal time waveform shall be calculated from the measured free-field waveform, $P_{FF,j,k,}$ and the free field to the ear canal transfer function H_{FF} for each ear.

(b) These waveforms shall be referred to as $P_{FF–EAR–Left,j,k}$ and $P_{FF–EAR–Right,j,k}$ and shall be computed by applying the average free-field to ear canal transfer functions ($H_{FF–Right}$ and $H_{FF–Left}$) to the free-field waveforms (P_{FF}). The corrected waveforms shall be computed as:

$P_{FF–EAR–Right,\ j,\ k}(f) = P_{FF,\ j,\ k}(f) * H_{FF–Right}(f)$,

$P_{FF–EAR–Left,\ j,\ k}(f) = P_{FF,\ j,\ k}(f) * H_{FF–Left}(f)$,

$P_{FF–Right,\ j,\ k}(t) = F^{-1}(P_{EAR–Right,\ j,\ k}(f))$,

$P_{FF–Left,\ j,\ k}(t) = F^{-1}(P_{EAR–Left,\ j,\ k}(f))$,

Where:

$F^{-1}(\ )$ is the inverse Fourier transform function. The respective waveforms and transfer functions are represented as linear quantities in the frequency domain.

(c) The reduction of the peak impulse, as affected by the hearing protection device, shall be:

(1) $\Delta P_{Impulse\text{-}Right,\ k} = \Sigma_{j\ =\ 1\ to\ 5}$ [max($P_{FF\_EAR–Right,\ j,\ k}$)— max($P_{ATF–Right,\ j,\ k}$)]/5

(2) $\Delta P_{Impulse\text{-}Left,\ k} = \Sigma_{j\ =\ 1\ to\ 5}$ [max($P_{FF\_EAR–Left,\ j,\ k}$)— max($P_{ATF–Left,\ j,\ k}$)]/5,

Where:

Max( ) is the maximum positive peak pressure of the impulse.

(d) The average impulse noise reduction for each pressure range (k) shall be the average impulse noise reduction for each pressure range (k) shall be:

$\Delta P_{Impulse,\ k}$ = [avg($\Delta P_{Impulse\text{-}Right,\ k}$) + avg($\Delta P_{Impulse\text{-}Left,\ k}$)]/2

(e) The three average impulse noise reductions shall be used to provide the data points for § 211.204–6, Table 2. The three average impulse noise reduction values shall be graphed with a range for the abscissa of 130 to 180 dB (re 20 μPa) and a range for the ordinate of 0 to 50

dB with the symbols connected by a solid line.

(f) The minimum of the three impulse noise reduction values calculated in paragraph (d) of this section shall be the lower endpoint in the impulse noise reduction rating as required in § 211.204–1(c) Figure 3.

(g) The maximum of the three impulse noise reduction values calculated in paragraph (d) of this section, shall be the upper endpoint in the impulse noise reduction rating as required in § 211.204–1(c) Figure 3.

22. Section 211.209 is added to read as follows:

§ 211.209 Maintenance of records.

(a) The manufacturer, as defined in § 211.203(aa), of any hearing protective device subject to this regulation must establish, maintain and retain the following adequately organized and indexed records.

(1) General records.

(i) Identification and description by category parameters of protectors comprising the manufacturer's product line;

(ii) A description of any procedures, other than those contained in this regulation used to perform noise attenuation tests on any test protector, and the results of those tests;

(iii) A record, signed by an authorized representative of the laboratory, of any calibration that was performed during testing by the test laboratory; and

(iv) A record of the date of manufacture of each protector subject to this regulation, keyed to the serial number or other coded identification contained in the supporting information required by § 211.204–4.

(2) Individual records for the test protectors. A complete record, or exact copies of the complete record of all noise attenuation tests performed (except tests performed by EPA directly) which includes all individual worksheets, and other documentation relating to each test required by subpart B.

(3) The manufacturer may fulfill this record retention requirement by keeping a copy of the labeling verification report that he has submitted to the EPA in the format recommended by the Administrator (see Appendix A of this part) and by establishing a record of the information required by § 211.212–5.

(4) The manufacturer must retain all required records for the life of each specific product line. Records may be retained as electronic or hard copy or reduced to microfilm, or other forms of data storage depending on the record retention procedures of the manufacturer.

22a. Section 211.209–1 is added to read as follows:

§ 211.209–1 Reporting requirements.

(a) The manufacturer must submit to the EPA, in hardcopy or electronic format, a completed coversheet according to Annex A, a copy of all authorized measurement information, including test results and calculated NRR values, obtained from the testing laboratory for each product or product category, within ten (10) business days of completion of the required test. The test results are to be in the format recommended in Appendix A and sent to: U.S. Environmental Protection Agency, Attn: Docket Center, Docket Number EPA–HQ–OAR–2003–0024, Mail Code—2822T, 1200 Pennsylvania Avenue, NW., Washington, DC 20460.

(b) On request by the Administrator, the manufacturer must submit to the Administrator information regarding the number of protectors, by category, produced or scheduled for production during the time period designated in the request.

23. Section 211.210–1 is revised to read as follows:

§ 211.210–1 General requirements.

(a) Each manufacturer of hearing protectors for distribution in commerce in the United States, which are subject to the requirements of this regulation as specified in § 211.201.

(1) Must affix a label to each product, as specified in § 211.204, that is readily visible at the point of sale to the ultimate purchaser or distribution to the prospective user.

(2) Must assure that each product meets or exceeds the sound attenuation values determined by the procedures in § 211.206 and explained in § 211.207.

(b) Product manufacturers who introduce protectors into commerce for sale to another manufacturer, as defined herein, for packaging and sale to ultimate purchaser or user, must provide to that manufacturer the attenuation values and standard deviations of each of the one-third octave band center frequencies as determined by the test procedures in § 211.206. The product manufacturer must also provide the Noise Reduction Ratings calculated according to the appropriate product as specified in § 211.207.

24. Section 211.210–2 is amended as follows:

a. Revise paragraphs (a)(1) and (a)(2).

b. Revise paragraph (b)(1).

c. Add and reserve paragraph (b)(2).

d. Revising paragraph (c).

e. Designate the undesignated paragraph at the end of the section as paragraph (d).

§ 211.210–2 Labeling requirements.

(a)(1) A manufacturer responsible for labeling must satisfy the requirements of this subpart for a category of hearing protectors, as defined in § 211.203, before distributing that category of hearing protectors in commerce.

(2) A manufacturer may apply to the Administrator for an extension of time to comply with the labeling requirements of this subpart for a category of protectors that are currently being distributed in commerce. The Administrator may grant the manufacturer an extension of up to 60 days from the date of distribution. The manufacturer must provide reasonable assurance that the protectors will equal or exceed their currently labeled NRR range, and that testing and labeling requirements of this subpart will be satisfied before the extension expires. Requests for extension shall go to the Administrator, U.S. Environmental Protection Agency, Washington, DC 20460. The Administrator will respond to a request within ten (10) business days from receipt of request. Responses may be either written or electronic.

* * * * *

(b) * * *

(1) Testing hearing protectors according to §§ 211–204 through 211–206. The hearing protectors must have been assembled by the manufacturer's normal production process and must have been intended for distribution in commerce.

(2) [Reserved]

(c) Each category of hearing protectors is determined by one or a combination of the following parameters. Manufacturers may use additional parameters as needed to create and identify additional categories of protectors.

(1) *Ear muffs.*

(i) Head band tension (spring constant);

(ii) Ear cup volume or shape;

(iii) Mounting of ear cup on head band;

(iv) Ear cushion;

(v) Material composition.

(2) *Ear plugs.*

(i) Shape;

(ii) Size;

(iii) Material composition.

(3) *Custom ear plugs.*

(i) Manufacturing Method;

(ii) Acoustic Filter(s);

(iii) Material composition.

(4) *Semi-insert Devices.*

(i) Hand band tension (spring constant);

(ii) Mounding on pod or tip on head band;

(iii) Shape;

(iv) Size;
(v) Material composition.
(5) *Active Noise Reduction Devices.*
(i) Protector Style;
(A) Ear plug;
(B) Ear muff.
(ii) Circuitry;
(A) Feed-forward control circuit;
(B) Feed-back control circuit;
(6) *Amplitude-Sensitive Devices.*
(i) Active design;
(A) Level-limiting;
(B) Compression circuit;
(C) Peak-clipping.
(ii) Passive design.
(A) Nonlinear resistive orifice.
(B) Physical control valve.
(iii) Protector Style.
(A) Ear plug.
(B) Ear muff.

* * * * *

§ 211.211 [Removed and Reserved]

25. Section 211.211 is removed and reserved.

26. Section 211.211–1 is added to read as follows:

§ 211.211–1 Compliance with labeling requirements.

(a) All hearing protection devices manufactured after the effective date of this regulation, and meeting the applicability requirements of § 211.201, must be labeled according to this subpart, and must comply with the range of Noise Reduction Ratings as determined by the appropriate test procedure as specified in § 211.204 through 211.206 of this subpart.

(b) A manufacturer must take into account both product variability and test-to-test variability when labeling his devices in order to meet the requirements of paragraph (a) of this section. A specific category is considered when the attenuation value at the tested one-third octave band is equal to or greater than the Labeled Value, or mean attenuation value, stated in the supporting information required by § 211.204–4, for that tested frequency. The attenuation value must be determined according to the test procedures of § 211.206. The range of Noise Reduction Ratings for the label must be calculated using the mean attenuation that will be included in the supporting information required by § 211.204–4.

27. Section 211.211–2 is added to read as follows:

§ 211.211–2 Transition testing and labeling requirements.

All hearing protection devices manufactured on or after the effective date of this subpart, and meeting the applicability requirements of § 211.201, must be tested with the appropriate procedure specified in § 211.206 and labeled as specified in § 211.204. Manufacturers shall complete testing and labeling of all categories within thirty (30) months from the effective date of subpart B.

28. Section 211.211–3 is added to read as follows:

§ 211.211–3 Recurrent testing requirements.

All hearing protection devices manufactured after the effective date of this subpart, and meeting the applicability requirements of § 211.201, must be retested periodically, following their initial transition testing and labeling pursuant to § 211.210–2. Manufacturers shall retest their products every five (5) years commencing from the date of a categories transition test.

29. Section 211.211–4 is added to read as follows:

§ 211.211–4 Product change retesting requirement.

(a) Any product that meets the applicability requirements of § 211.201, must be retested prior to entry into commerce if the manufacturer alters the product design, product materials, manufacturing process or takes any action that may alter the noise reduction performance of the product from its previous test state. In the event the NRR values (lesser and/or greater) are a minimum of 3 dB less than the current labeled NRR values, the manufacturer must relabel as specified in § 211.211–3.

(b) The recurrent testing of such product shall commence in accordance with the appropriate schedule in § 211.211–3.

30. Section 211.212–1 is amended as follows:

a. Revise paragraph (a).
b. Revise paragraph (b).
c. Revise paragraphs (e)(2) and (e)(3).
d. Revise paragraph (f).

§ 211.212–1 Test request.

(a) The Administrator will request all compliance audit testing under this section by means of a written request addressed to the manufacturer listed on the product label. The test request will be signed by the Assistant Administrator for Enforcement or his designee.

(b) The test request will be delivered by an EPA Enforcement Officer or sent by certified mail to the plant manager or other responsible official as designated by the listed manufacturer.

* * * * *

(e) * * *

(2) The manufacturer must complete the required testing within ten (10) business days following commencement of the testing.

(3) The manufacturer will be allowed five (5) business days to send test hearing protectors from the assembly plant to the testing facility. The Administrator may approve more time based upon a request by the manufacturer. The request must be accompanied by a satisfactory justification.

(f) Failure to comply with any of the requirements of this section will not be considered a violation of these regulations if conditions and circumstances outside the control of the manufacturer render it impossible for him to comply.

* * * * *

31. Section 211.212–5 is amended by revising paragraph (a)(1) and removing paragraph (c).

The revision reads as follows:

§ 211.212–5 Reporting test results.

(a)(1) The manufacturer must submit in electronic format within five (5) business days of completion of testing, to the Administrator or his designated enforcement representative, a copy of the Compliance Audit Test report for all testing conducted under § 211.212. A suggested compliance audit test report form is included as Appendix B of this part.

* * * * *

32. Section 211.212–6 is amended by revising paragraph (a)(2) to read as follows:

§ 211.212–6 Determination of compliance.

(a) * * *

(2) The Noise Reduction Rating values (lesser and/or greater), as determined by Compliance Audit Test, are equal to or greater than the Noise Reduction Rating values as stated on the label required by § 211.204.

* * * * *

33. Section 211.213 is revised to read as follows:

§ 211.213 Incorporation by Reference.

The American National Standards Institute/Acoustical Society of America standards are incorporated by reference into subpart B with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. The materials are incorporated as they exist on the date of approval, and notice of any change in these materials will be published in the Federal Register. They are available for inspection at the HQ Air Docket Center, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC, and at the

National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.go/federal_register/code_of_federal_regulations/ibr_locations.html.*

(a) The following materials are available for purchase from: Acoustical Society of America, Standards Secretariat, 35 Pinelawn Road, Suite 114E, Melville, New York 11747. Phone: (631) 390–0215; e-mail: *asastds@aip.org;* and Web: *http://asastore.aip.org.*

(1) ANSI/ASA S12.6–2008, ''Methods for Measuring the Real-Ear Attenuation of Hearing Protectors,'' incorporated by reference (IBR) approved for § 211.206–1(b)(1), (b)(2), (b)(3), (b)(4), (b)(5), (b)(6)(i)(A)(B)(C)(D)(E)(F), (6)(ii), (6)(iii), (7)(i), (7)(ii), (8)(i)(A)(B), (8)(ii)(A)(B)(C)(D)(E)(F)(G)(H), (8)(iii)(A)(B), and (9).

(2) ANSI S12.42–1995 (R2002), ''Microphone-in-Real-Ear and Acoustic Test Fixture Methods for the Measurement of Insertion Loss of Circumaural Hearing Protection Devices,'' IBR approved for §§ 211.206–2(a), (c)(1), (c)(2), (d)(1), (d)(2), (e)(1), (e)(2), (e)(3), (g)(2), and 211.206–3(c)(1)(i).

(3) ANSI/ASA S12.68–2007, ''Methods of Estimating Effective A-weighted Sound Pressure Levels When Hearing Protectors are Worn,'' IBR approved for § 211.206–2(l)(3) and §§ 211.207–1(a), and 211.207–2(a), (b), and 211.207–3(a)(b).

(4) ANSI S1.11–2004, ''Specification for Octave-Band and Fractional-Octave-Band Analog and Digital Filters'' incorporated by reference (IBR) approved for § 211.206–1(b)(4).

(b) The following material is available for purchase from: American National Standards Institute, Customer Service Department, 25 W. 43rd Street, 4th Floor, New York, New York 10036. Phone: (212) 642–4980; *e-mail: info@ansi.org*; and web: *http://webstore.ansi.org.*

(1) International Electrotechnical Commission (IEC) standard 60711, Occluded-ear simulator for the measurement of earphones coupled to the ear by ear inserts,'' incorporated by reference (IBR) approved for §§ 211.206–1(k)(1)(ii) and 211.206–1(c)(1)(iii).

(2) [Reserved]

Appendix A to Part 211 [Redesignated as Appendix B to Part 211]

34. Appendix A is redesignated as Appendix B to Part 211 and a new Appendix A is added to read as follows:

Appendix A to Part 211—Reporting Requirements—Attenuation Test Results and Label Verification

1. Date of Report.
2. Manufacturer's Name.
3. Manufacturer's Address.
4. Name of original equipment manufacturer (OEM), if different from above.
5. OEM address if different from above.
6. Name and position of responsible individual for manufacturer.
7. Product country of origin if other than U.S.
8. Product Name.
9. Product Model.
10. Date of Manufacture.
11. Date of last test.
12. Name of Testing Laboratory.

This coversheet must be accompanied by the authorized attenuation test measurements and calculated NRR values obtained from the testing laboratory for each product of product category.

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