

**Comments Regarding Environmental Protection Agency
40 CFR Part 211
Product Noise Labeling Hearing Protection Devices:
Proposed Rule, Wednesday, August 5, 2009**

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**E. H. Berger, M.S.
M. Johansson, Ph.D.
T. K. Madison, M.A.
B. C. Myers, B.S.**

**3M Occupational Health & Environmental Safety Division
E•A•RCALSM Laboratory
7911 Zionsville Road
Indianapolis, IN 46268-1657
direct: 317-692-3031
Elliott.Berger@mmm.com**

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INTRODUCTION

The EPA's proposed revision to 40CFR Part 211 is a complex and important document that provides a valuable perspective in its preamble, and interesting new concepts for labeling HPDs. However, as we read through the document we uncovered numerous issues that we feel must be addressed before the proposed rule becomes law. In the following pages we have separated our comments into four categories: principal technical and regulatory concerns, substantive terminology concerns, secondary technical and regulatory concerns, and suggested edits and other items. As the category names imply, we wish to draw EPA's attention primarily to the first two groups of items, but the secondary technical and regulatory concerns are also substantial. The final section on suggested edits is provided to assist EPA, as they choose, in making a more readable document.

Thank you for the opportunity to comment.

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Principal Technical and Regulatory Concerns

Preamble II.C. Introduction, Test methodology; VI Test methodologies; Method A 80/20

The issue of whether or how to estimate real-world performance and of Method-A vs. Method-B procedures has been well debated and the key points are well recounted in the preamble to the proposed rule. However, it is important to realize the outcome of the choices that were made in the proposed rule. The EPA has selected Method A as the test procedure, and the NRS (to be designated NRR) from ANSI S12.68, at the 80th and 20th percentiles as the rating values. The EPA also has discussed at length in the preamble both their comments and the public's concerns that the current ANSI S3.19-based methodology results in "unrealistically high sound reductions that are generally not attainable in real world use." Thus, an obvious question is how the proposal will affect the situation.

At this time we have available Method-A test data for 8 commercially available earplugs and 4 earmuffs. The results are all from NVLAP accredited facilities – E•A•RCALSM laboratory at 3M, Michael & Associates Inc., and the lab at Sperian (from a NIOSH-commissioned study). Two of the earplugs and one of the earmuffs were tested by both E•A•RCAL and Michael & Associates. On average, the new NRR_{A80} values (the lower of the two values that is proposed by the EPA) are 2-dB *higher* than the current labeled NRRs. This is moving in the wrong direction to achieve EPA's goal of a more realistic rating and is misleading to those who purchase hearing protectors. All but one of the NRR_{A80} values from the Method-A testing were higher than the published NRRs for the same products, with one difference amounting to +4 dB. Even more compelling is the comparison of the NRR_{A80} to the existing NRR-7 dB since the NRR_A values are to be subtracted directly from the dBA noise exposure value, whereas it is necessary to subtract 7 dB from the existing NRR to use it with dBA values. When this comparison is made, the differences are even greater, with the new values predicting an average of 6.5-dB more noise reduction.

As long as Method A is the test procedure of choice, there is no way to fully achieve the EPA goal of a representative real-world rating. At the very least, the Agency should avoid placing values on the label that are generally higher than what is on the label today. 3M proposes using an NRR_{A90} for the low end of the range, but keeping NRS_{A20} for the high end. This amounts to an average reduction in the low rating (NRR_{A90} vs. NRR_{A80}) of about 3 dB for plugs and 2 dB for muffs, based on the data for the 12 devices for which results are available.

Though the proposed range is asymmetric, it is justifiable since using a symmetric 90/10 range vs. the 3M-proposed 90/20 set of values would broaden the range even further and perhaps unreasonably. Also, the NIOSH/EPA interlaboratory study that EPA referenced in the preamble showed that the 20th percentile value is relatively insensitive to fitting method, suggesting that those who fit the device very well can do so with little experimenter intervention, whereas those who fit the device poorly benefit substantially from training, thus the choice of Method-A vs. Method-B data has little affect upon that value.

In summary, 3M proposes that the NRR be computed according to ANSI S12.68, but that Section 211.207-1(b)(4) of the proposed rule specify that values for α of 1.2816 and -0.8416 (from Table 1 of ANSI S12.68) be utilized in order to compute an NRR_{A90} and NRR_{A20} , respectively.

Preamble X B.1. Cost impact analysis, hearing protector testing laboratories, accreditation

The proposed rule does not include mandatory laboratory accreditation because the EPA has concluded it does not significantly enhance the technical qualifications of laboratories and because it would present

a barrier to entry of new laboratories. 3M disagrees. In the European Union as well as Australia, New Zealand, and Brazil, it is required that hearing protector attenuation tests be conducted at an accredited laboratory, and we believe the same should hold true in the U. S. Laboratory accreditation has helped E-A-RCAL assure that our testing is more rigorous and controlled. It is true that some of the accreditation requirements are tedious paperwork, but overall it has enhanced the quality of our work. And in a newer laboratory or perhaps one that is not as experienced or conscientious, it could have an even larger impact.

As for the costs, accreditation would seem to be a small burden compared to the cost of the facility and equipment, and the time to conduct tests. If a lab decides that they will be in the HPD testing/labeling business, this should be viewed as simply a small additional cost of doing business.

While we truly value the NVLAP accreditation that our laboratory maintains, we propose broader and more inclusive accreditation requirements for the purposes of the EPA rule. 3M recommends that test laboratories be required to be accredited for the S12.6 and S12.42 tests that they will conduct in conformance with policies of ISO/IEC 17025:2005. The accrediting body may be the U.S. Department of Commerce's National Voluntary Laboratory Program (NVLAP), a laboratory participating in the American Association for Laboratory Accreditation (A2LA), or an equivalent foreign agency or organization. This approach should make it easier for manufacturers to locate satisfactory test facilities while balancing the need for assuring that quality results are being provided to HPD users.

211.201 Applicability

The regulation does not provide a clear description of devices that must be labeled. In 211.201 (a) it says the rule applies to devices for which hearing protection may not be their primary function as long as in part they are intended to provide protection, and in 211.201 (b) it states that any product must be labeled if it makes explicit or implicit claims regarding hearing protection or if the level of sound reduction provided by the device is stipulated. However, in 211.201 (c) it says the rule does not apply to devices for water protection, annoyance reduction, or to enhance listening to music or dialog.

As an example, if a company sells a device that uses ANR to reduce sound at the ear for enhancing listening to music and dialog, and says it reduces annoying background noise by 15 dB, it would seem that 211.201 (b) would require it be labeled, but 211.201 (c) would suggest it need not be labeled. However, if no claim were made about the amount of sound reduction, but just a statement saying that annoying background noise would be reduced, that would seem to not require labeling. The same confusion arises for an insert earphone that provides music or audio listening capability, as would any standard earphone, but also provides passive noise reduction via sound blockage. Similar confusion arises for a hearing aid in a sealed earmold that could provide noise reduction when turned off, or could reduce noise if it contained suitable electronic compression circuits.

The confusion is that 211.201 (b) relates the determination of labeling to the claims that are made, but 211.201 (c) relates the determination to the function that the device serves. The wording of 211.201 (c) would seem to take precedence over the requirements of 211.201 (b). Clarification on this point is requested.

3M proposes that 211.201 (c) should state that it does not apply to the products enumerated in (c) (and hearing aids should be included in that category), unless a specific claim regarding sound reduction or hearing protection is made. Furthermore, the requirements of 211.201 (d) would also seem to suggest

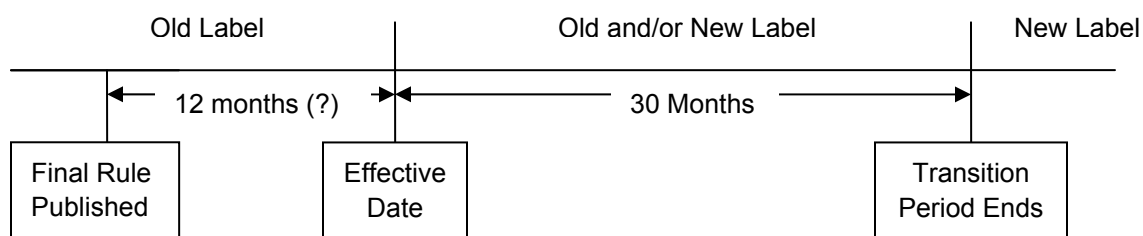
that the alternate wording and interpretation of 211.201 (c) that we suggest is that which is intended by this rule. This issue is important since many people in both occupational and non-occupational noise exposure settings wear devices such as those in category 211.201 (c) for hearing protection in combination with entertainment and communication functions.

211.202 Effective Date

All testing and labeling of products manufactured on or after the effective date is required to comply with the revised testing and labeling requirements, but Section 211.211-2 suggests a 30-month transition period, subsequent to a not-yet-defined effective date. We believe that 30 months may be too short, depending upon the time between publication and the rule's effective date. There is further discussion of this point under 211-211.2 of these comments. In addition to the time frame for compliance, we are concerned that the EPA may be considering the promulgation of regulations that incorporate test methods that are not yet validated and may require special test equipment not yet commercially available. So, the final rule should not be promulgated until the methods for testing impulsive hearing protectors are validated and any required specialized equipment for such testing (such as modified acoustical test fixtures) becomes available.

Another key issue relative to timing is how to handle the transition labeling. Once the new rule is in effect, manufacturers will have a period of 30 months in which to comply with the new labeling rules. It is not clear from the document, but we believe this means that both the old and new labels may be used from the time beginning with the effective date and ending 30 months later. The timing as we understand it is illustrated in Figure 1.

Figure 1 – Illustration of the time frames in the proposed rule



If our understanding of the timing is correct, then both old and new labels would co-exist in the market for 30 months resulting in significant confusion among users. We believe that this confusion would be greatly reduced if the period during which both labels may be in the market was reduced to 18 months. Therefore, we propose that the time between the effective date and the end of the transition period be reduced to 18 months, and that the effective date be at least a year or more after promulgation, depending upon the final timing determined for implementation of the new rule from its publication date. This would not only minimize user confusion over differing labels in the market but also allow manufacturers time to properly perform the testing required prior to the effective date. This suggestion also presumes that manufacturers may begin testing as soon as the final rule is published without waiting for the effective date as is implied in 211-211.2.

211.204-1(a)(3) Information content of primary label, confusion and inappropriate impulsive disclaimer

As written, the requirements in this section are confusing and redundant between paragraphs (a), (b), and (c). The confusion is that manufacturers must choose to designate their product as one of three categories: passive, active noise reduction [sometimes in the proposed rule referred to as “active,” see discussion following re Section 211.204-2(j)], or impulsive, in spite of the fact that a product may serve multiple functions. For example, a passive earplug can also be excellent at blocking impulse noise. Furthermore, all products except those specifically tested in impulsive noise must include the wording in Area C of the label that says “This protector was not tested for impulsive noise.” That designation implies that the device is not suitable for use in impulsive noise.

The fact that customers believe that the “not tested” wording suggests the HPD is not suitable for use in impulsive noise has been repeatedly demonstrated to us over the years when we receive calls about a similar phrase that already appears in the supporting information on labels and says “...the NRR is based on attenuation of continuous noise and may not be an accurate indicator of the protection attainable against impulsive noise such as gunfire.” The customers’ concern in reading that milder wording still exists - “is it ok for me to use this device in impulse noise?” The misperception was also demonstrated at an E•A•R Clinic in Denver, CO, on October 27, 2009, where over 100 professionals and advanced students in audiology were in attendance. When shown a slide of the proposed EPA label including the “not tested” impulsive statement, more than 1/3 of those in the audience indicated they would presume that a device labeled in that way would not be suitable for use in impulsive/gunfire type noise.

We begin here by discussing the impulsive disclaimer, and then the confusion regarding primary labels in the proposed rule.

Impulsive Disclaimer: As we explained during the EPA hearings in the late 1970s, the principal issue is that for level-dependent (also called amplitude-sensitive) HPDs, the conventional NRR is near 0, but in impulsive noise environments such as when gunfire is present many such HPDs provide much higher noise reduction. Thus, the conventional NRR (obtained at low sound levels) inaccurately describes the full effectiveness of such devices for the impulsive noises against which they were *intended* to be used. The value of the impulsive test is to be able to show for such devices that they provide very little attenuation of low sound levels and more attenuation of high level impulsive sounds.

However, the disclaimer as written in the EPA proposal seems to imply that conventional devices do not provide adequate noise reduction for impulsive noises, and that level-dependent protectors specifically tested in impulsive noise, perform better than their conventional counterparts. *This is completely false.* Conventional passive protectors like a foam earplug or earmuff will nearly always block *more* impulsive noise than will a level-dependent device designed specifically for use in impulsive noise. This is because the level-dependent device is NOT designed for more attenuation at high levels, but rather for less attenuation at low levels in order to improve the ability of the wearer to hear when the impulses are not present. At high levels, a level-dependent protector must work to offset its poor low-level attenuation. This can often be successfully accomplished, but rarely, if ever, can a level-dependent device block impulse noise as well a passive device that is simply designed for high levels of attenuation under all circumstances. Thus, it is important that the labeling of passive HPDs not drive users, based on attenuation concerns alone, towards the purchase of potentially less protective, level-dependent designs.

The EPA's proposed disclaimer discriminates against passive devices that would not otherwise be tested in impulsive noise. In response to this, manufacturers of conventional passive device are likely to choose to conduct impulsive tests on all their devices so they can be labeled competitively under the current proposal. This will create multiple problems:

- No labs exist today to conduct impulse tests and it will take time to gear up.
- This large added cost, effectively doubling the cost and time to complete testing, if many existing passive products are tested, was not factored into the EPA's computations.
- This is misleading to the person purchasing the device since there is no reason to believe that the impulsive test provides a better indication of the performance of a passive device in impulse noise than does a real-ear attenuation threshold (REAT) evaluation, as is discussed below.

The impulsive noise test as defined in the proposed rule and in Draft ANSI S12.42 uses blast noises measured with an acoustic test fixture (ATF). The existing fixtures are inadequate as is discussed in S12.42 and the new device that S12.42 contemplates (and predicts, but is not certain, will be a better test fixture) will not be commercially available until after the ANSI standard is approved, hopefully later in 2009. Measurements with the existing fixtures are suspect and do not fully correlate with performance on real heads. For example, if one compares the attenuation for earplugs measured at sound levels below 100 dBA on ATFs to REAT values on human subjects, the values do not correspond. The REAT values are accepted as correct and the ATF values are only an approximation. This means that impulsive tests on the ATF are at best an approximation of what happens on real heads. The tests are needed so that level-dependent HPDs can be evaluated when exposed to high-level impulsive sounds, but the answer is only an approximation because of limitations in the fixture and the methodology.

For a passive device that does not have any built-in level-dependent features such as orifices, valves, or electronic circuitry, there is an alternative for estimation of attenuation in impulsive environments – simply use the REAT data in continuous noise to estimate performance in impulsive noise. There is good precedent to do this and a high likelihood that for impulses up to about 160 dB, and probably somewhat higher, that the REAT value will properly estimate and likely even underestimate the actual attenuation for impulses (Berger and Hamery, 2008; Zera and Mlynski, 2007). It is only in the highest level blasts above 170 dB that have been used by the military in testing that large earmuff cup motions, earplug motions, and seal breakages have been observed. Below those levels there is every reason to believe the REAT values will be at least as good an estimation of the impulsive attenuation as will be the values derived using purposely designed ATF/impulsive tests that have not been fully evaluated by the scientific community. Neither the EPA procedure nor the Draft ANSI procedure has ever been fully implemented and vetted as described. There may be unknown problems or discrepancies that arise when these methods are actually implemented.

To eliminate the unintended incentive for manufacturers of conventional hearing protectors to conduct impulsive tests to be able to sell their products for impulsive noise, 3M strongly encourages the EPA to remove the impulse disclaimer and the associated bias in favor of level-dependent HPDs.

Specific label recommendations, especially regarding Areas B and C: The proposed rule describes three separate labels that are in large part the same except for a few key features. It would be much clearer to describe a generic label with the content that is the same for all devices, and then to focus attention on only the key sections that differ. In fact there is good precedent for this in 40CFR Part 211A which does exactly that; it describes in 211.104, 211.106, 211.107 and 211.108 general requirements that are then specifically delineated in Part 211B.

The proposed rule should call for a label in which Areas A, D, E, F, G and H are the same, and then focus attention on Areas B and C in which different variants would appear depending upon the device being labeled. This is particularly important since as discussed below, the three labels that EPA proposes are confusing and insufficient to cover the ranges of devices available. In fact, we believe that five separate labels would be more appropriate. We begin our discussion with some of the challenges we see with the proposed labels.

PASSIVE LABEL (AS PROPOSED) – “Passive” is a confusing word that does not translate into something meaningful for the general public. One non-expert user, when asked what passive meant to her, replied “wearing the HPD in passive or ambient noise as opposed to active or harmful noise.” Even within our own company the 3M Global Manager for Passive Hearing Protection often has to explain what the word “passive” means to other 3M personnel who are not directly involved in the hearing protection business. Other misinterpretations from the non-expert are also likely. And professionals also find “passive” to be a confusing term. In the same E•A•R Clinic previously referenced, the audience was asked if they knew, or thought they knew what passive meant in reference to an HPD. Only about 1/3 answered in the affirmative. Furthermore, Area C should point out, as argued above regarding impulsive noise, that this rating for conventional passive HPDs is suitable for all types of noise. Exceptions would be high-level military noise above 165 dB or so, but the military can handle those situations directly. Moreover, the EPA’s proposed impulsive procedures only test to 170 dB.

ACTIVE LABEL (AS PROPOSED) – The term “active” is misleading. As defined by EPA in the proposed rule and as understood by experts in the field, “active” refers to any electronic device. It would appear that what was intended was for this label to refer only to the sub-category of active noise reduction (ANR) devices. Furthermore, this label does not contemplate the possibility of an ANR device that might be used in its ON mode in impulsive noise. And finally, active is a confusing term since it is not clear what is active, the device or the noise.

IMPULSIVE LABEL (AS PROPOSED) – This label is also confusing. One non-expert friend thought impulsive meant staccato; it did not bring gunshots to mind. Since in fact the impulse rating is primarily intended for explosive discharges such as gun shots (few other than in the military will be wearing such devices around explosions or heavy weapons such as artillery or rockets), it is important to state in Area C the application for which the impulse rating is primarily intended, namely, gunfire-type noises. One might also wish to apply it to impact noise such as a punch press, but in those environments there is so much contaminating intermittent and steady noise that the impulse rating would be misleading. For example, one would not use the 3M™ Combat Arms™ passive level-dependent earplug in a factory setting with a TWA of 100 dBA that also contained impulsive noise, but this earplug works well for isolated gunshots at higher peak sound pressure levels (SPLs).

Another problem with the impulsive label is that the words in Area C should provide guidance to the user that differs depending upon whether this is an electronic (active) or passive level-dependent HPD.

For all of the labels, the guidance on how to mathematically use the NRR is insufficient and the more important aspect of what the range in NRRs is meant to convey is left out. We suggest instead that the words in Area C discuss that the range of values is related to quality of fit for the Basic and ANR labels, and to the use of different level impulses for the Impulse labels. The math on use of the NRR should be

provided in the secondary information where it can be more appropriately discussed together with related information.

Our proposals are as follows: Area B should specify that one or more bars be presented, to be designated as “Basic” instead of “Passive” (i.e. basic suggests the fundamental, unadorned, unenhanced performance), “Active Noise Reduction,” and “Impulsive.” The manufacturer would in all cases be required to have a Basic NRR and then one or two other bars for the Active Noise Reduction or Impulsive performance. For purposes of uniformity it is suggested that the Basic NRR always be on top followed by one or both of the other bars as appropriate.

The Basic NRR, as argued above under “Impulsive Disclaimer,” is a suitable number to use in all noises when dealing with a conventional passive HPD or an electronic device that is turned OFF. We considered suggesting using no designation for the Basic rating, i.e. no adjective at all, for the Basic NRR, but the problem that creates is when you have two or more NRRs on the label and one is designated with a word like “Impulsive,” and the other has no word, it tends to appear as though the label “Impulsive” applies to both NRRs.

The words in Area C are important to indicate the applicability of the particular bar/rating and whether in the case of an electronic device it is ON or OFF. Also, the guidance differs for passive and active HPDs, since the Basic rating for passive level-dependent devices only applies in steady noise, whereas the Basic rating for an electronic device in the OFF mode applies to all types of noise.

An ANR device would report a Basic and Active Noise Reduction NRR, with the clear indication that the ANR NRR is not suitable for impulsive noise. However, if in the future ANR HPDs are designed that also work in impulse noise, they might have all three NRRs as shown in our third example.

The wording in Area C is unique to whichever bar or set of bars is selected. For the reasons discussed above, the phrase “not tested for impulse noise” should be removed from all labels. Likewise, the phrase about steady and intermittent noise is not needed and is misleading. Since words and space are at a premium, we recommend changing “NRR values,” to “NRR,” which is sufficiently clear, and eliminates the redundancy of “Noise Reduction Rating value.” And finally, the potentially confusing phrase indicating how to compute effective exposure by taking the difference between the noise level and the NRR should also be removed in favor of its placement on the secondary label.

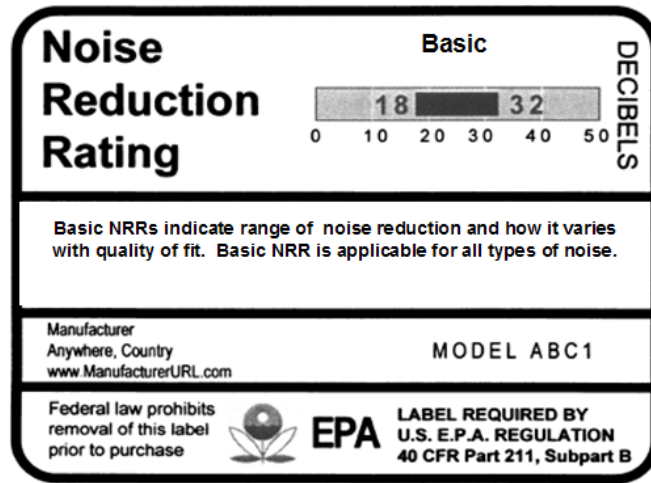
It is important that some guidance be provided about the meaning of the two different numbers on the label. Words explaining the high/low ratings, based on careful deliberations in the ANSI working group, are found in ANSI S12.68. An abbreviated version (in order to fit the allotted space) is included in the proposed labels that appear in Figure 1. It is more important that this guidance be provided than is the general guidance on how to mathematically apply the NRR; that is already provided on the secondary information. Additionally, a further explanation of the meaning of the range should be included in the secondary information as is discussed in our comments on that section.

Our specific suggested wording for Area C follows below. The proposed EPA wording for their lengthiest label option is 46 words (as compared to 19 words in the existing EPA rule). The proposals below range from 37 words for Basic NRR label to 55 words for an ANR device with all three bars.

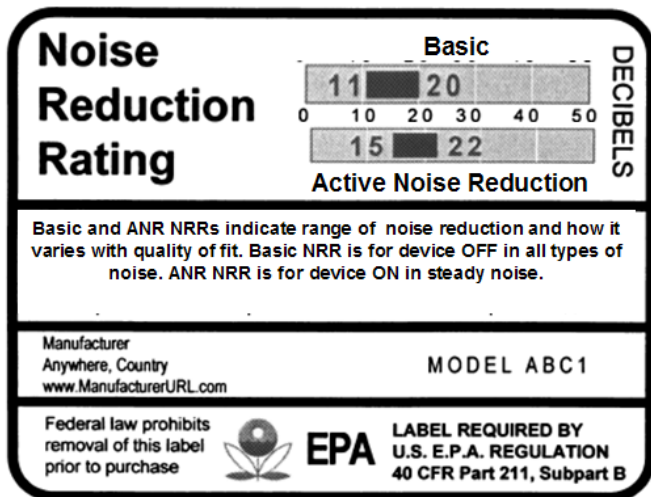
See Figure 2 next page for examples.

Figure 2 – Proposed NRR labels for different types of HPDs.

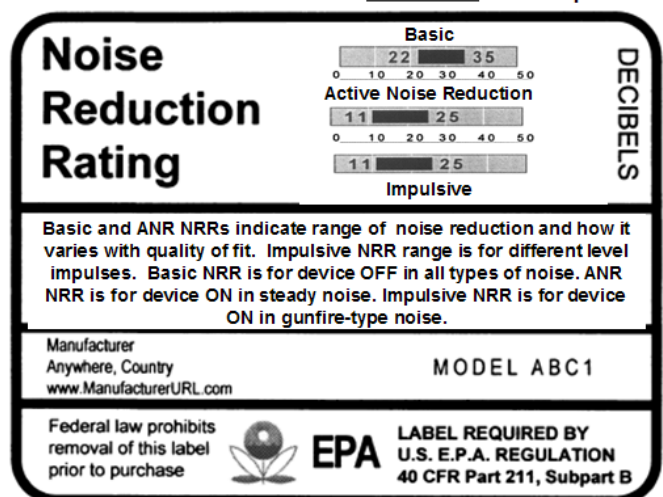
Conventional Passive HPD



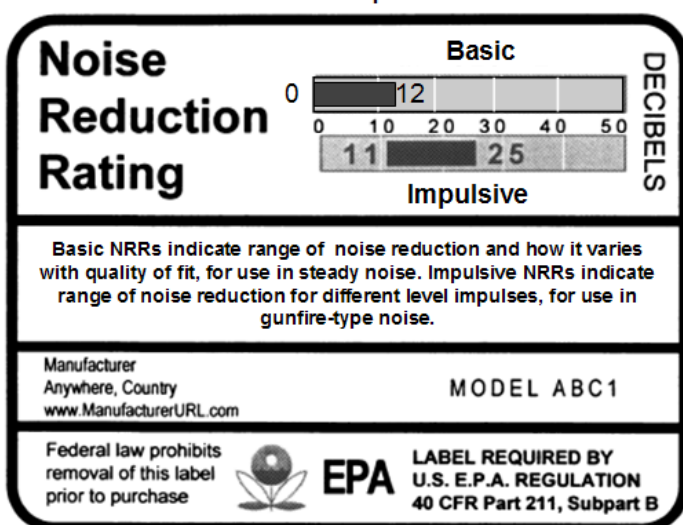
Active Noise Reduction HPD



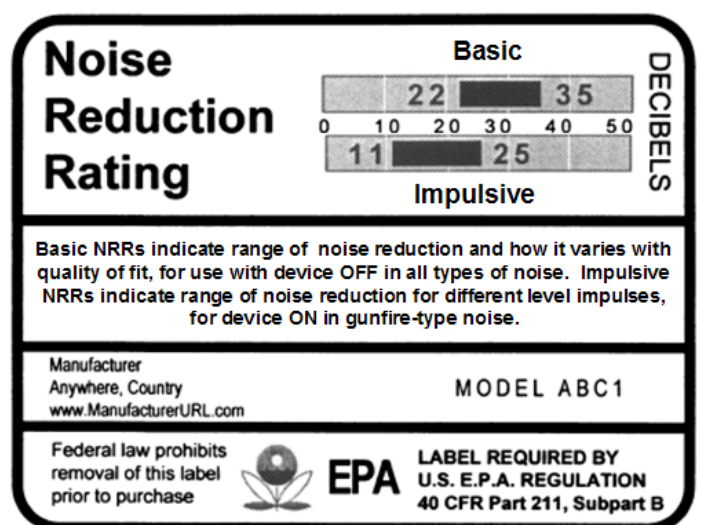
Active Noise Reduction HPD suitable for Impulsive



Passive Level-Dependent HPD



Electronic Sound Transmission HPD



As a final note in this section, one class of HPD in one application is not dealt with on the labels above. It was also not covered in the EPA proposal. That category is an electronic sound transmission HPD worn in high levels of steady noise > 85 dBA. We have not proposed adding such a label since it would be difficult to specify such performance with a single-number NRR-like value. Although it is regrettable that such information will not be available to the purchaser, that choice seems the best in order to accomplish the overall goal of providing the clearest information for most users for most devices.

211.204-3(a)(1) Label location and type, with respect to dispenser boxes

In the existing 1979-regulation this statement is unclear (though to some extent clarified in its supplementary information) and the requirements continue to be unclear in the proposed rule. The proposed rule specifies that the label must be affixed to the device or its carrying case. As was discussed when this rule issued in 1979, products that are inexpensive and sold in bulk, such as foam earplugs, are normally sold in “dispenser” (a term defined in the rule). The packaging for each individual foam earplug is smaller than the required label and is not conducive in size or cost to support a hang tag with the required label information. The interpretation provided by EPA at the time was that it would be sufficient to label only the dispenser box as long as the HPDs are not separated from it prior to purchase. Presumably that is the requirement of the proposed rule, but it would be preferable if this were explicitly acknowledged in this section.

211.204-3(a)(2) Label location and type, for small individual consumer packages

This section requires that the label be affixed to the primary panel of the packaging if the label re (a)(1) is not visible at time of purchase. Among earplug products that are offered in the consumer market today, the labels typically appear on the back panel of the packaging and are easily accessible for review prior to purchase or wearing. Because this current label location is satisfactory to consumers, and avoids the situation in which the front panel of a small package could be largely taken up by the NRR label, the proposed rule should be revised to allow the label to be affixed to any outside surface of the packaging that is readily visible (other than the bottom panel of boxes that stand on their own). For typical consumer products, that would be the back of a 2-sided card and for typical dispenser boxes that would be the front or top panel. Again, even for dispensers, the required EPA label can interfere with the graphic look depending upon where it is situated and is certainly adequately noticeable on the either the front or top of the box.

211.204-4 Supporting information, location

The quantity and complexity of the supporting information that is required has now become extensive enough that it would take essentially an entire panel on a dispenser box. This is infeasible, especially as more companies go to multilingual and multinational packaging. See the attached mockup of a dispenser box for one of our earplugs. Note that we have not even gone to the extent of making all the EPA wording trilingual, and still we are running out of space and having to use the back panel. Furthermore, some of the supporting information has become complex enough that few will ever choose to use it, and those that might would undoubtedly have ready access to the internet. Thus, we suggest that supporting information be separated into secondary information that must appear on the dispenser box or on an insert, and tertiary information that the manufacturer may make available to the customer using other means such as an insert or a web site.

We suggest that (d) Table 1, (e) Figure 1, be removed from the secondary information and that the newly proposed tertiary information include this table and figure, as well as all the other information that is also

included on the secondary label. This also makes better sense since it would allow manufacturers to provide a more in-depth explanation of how to use the spectral information, which if simply presented on the box as is proposed, would be confusing and of little use to most purchasers.

An important point to capture in the secondary information section is the idea that hearing protector ratings, regardless of how they are derived, are only able to describe the average noise reduction obtained by groups of users in the laboratory and cannot predict the noise reduction obtained by individuals in practice. The only way to describe noise reduction for individuals with reasonable accuracy is to conduct individual fit testing. The good news is that today there are many new fit test systems that have come to market. Hence, 3M suggests the required additional information be provided on the secondary label.

“The NRR is based on the average noise reduction obtained by groups of wearers in a laboratory. NRRs near the low end of the range on the label can be obtained by most individually trained users, whereas NRRs near the high end of the range on the label can be obtained by a few users who fit the device very carefully. Your actual noise reduction may vary. For improved accuracy in predicting your noise reduction an individual fit test is recommended.”

These suggestions for 2.11-204-4 apply equally to 204-5 and 204-6.

211.204-5(i) Supporting information for ANR HPDs, recommended use levels

As 3M argues in the next section regarding amplitude-sensitive HPDs, recommending safe use levels is a substantial change in labeling requirements, shifting the responsibility for evaluating those levels from the user to the manufacturer. We find this problematic. A further problem appears in this particular requirement, however, since in addition its wording is unclear. Is safe usage based on the point at which, for certain spectra, the levels under the cup will become “unsafe” based on a particular damage-risk criterion, or is it based on when the cancellation driver exceeds its operating range and can no longer reproduce the needed signal? If this requirement is retained, the EPA should clarify the intent and specify a procedure so that all manufacturers are producing numbers that can be appropriately compared.

211.204-6(e) Supporting information for amplitude-sensitive HPDs, recommended level of 130 dB

Both Sections 2 and 8 of the Noise Control Act empowered the EPA to label noise-reducing devices such as HPDs, and 40 CFR Part 211A mandates specifying a device’s effectiveness in reducing noise and the establishment of a noise reduction rating. But these laws couch their mandate in terms of “noise reduction characteristics” and “effectiveness in reducing noise” rather than speaking to the establishment of a level in which it is safe to utilize such devices. Requiring manufacturers to label a device with such a statement indicating the level to which it can protect or is intended for use, would seem to be inconsistent with the spirit of the Noise Control Act. It is also unsupported by a scientific consensus, and forces manufacturers to assume additional and unwanted potential liability.

The issue of the hazardousness of impulse noise and methods of determining the protection provided by HPDs is a hotly debated topic in the scientific community as evidenced by the workshop devoted to this in Utah in 2008 (AFRL, 2008). Many approaches in use today were debated in the workshop, including the MIL 1474D, equal energy using the integrated L_{Aeq} , the theoretical AHAH model, and others. Critical levels of 140 dB have been hypothesized below which no damage will occur for isolated single impulses, but, as Ward et al. have pointed out (Ward et al., 2000), the establishment of such levels is fraught with variability and controversy.

It seems questionable for EPA to determine, without public discussion or substantial supporting data, that 130 dB is the magic number below which impulsive sounds are safe. This action is compounded by putting great reliance on new and not-fully-tested methods of establishing an impulse NRR (see discussion elsewhere in this document re the impulse disclaimer), in order to require manufacturers to state a range for recommended use.

In terms of liability, there is a large difference between a hearing protector manufacturer claiming a specific noise reduction value for a product, and the claim that a device will protect the wearer up to a specified exposure level. The former claim has to do with attributes of the product (i.e. real-ear or objectively measured attenuation in the laboratory) that the manufacturer can measure using accepted methods according to published standards. However, the latter claim requires the HPD manufacturer to make assumptions about the factors that contribute to the protection provided by a device without the information necessary to do so, such as characteristics of the noise exposure (like spectral information and duration), the ability and motivation of the user to fit and wear the device correctly, and the wear time relative to the total exposure time.

By requiring manufacturers to place language regarding safe use on the package, the EPA forces the manufacturer to assume the risk/liability associated with establishing "safe" or permissible noise exposure levels. This assessment and liability is and should remain the exclusive province of regulatory bodies and should not be borne by manufacturers.

Therefore, 3M recommends that the requirement to state a range of SPLs in which the HPD is recommended for use should be removed from the proposed rule.

211.206-1 REAT test procedure and reference to ANSI S12.6-2008

One of EPA's goals was to update the ANSI reference in the existing 1979 rule that currently specifies testing to an outdated 1974 ANSI standard (S3.19-1974). We wholeheartedly support the proposal to test HPDs according to the current REAT standard, ANSI S12.6-2008. However, in so doing, EPA is proposing to adopt S12.6 with modifications, thereby eliminating the opportunity to expeditiously update the labeling regulation in the future when an updated S12.6 becomes available. Furthermore, the manner of reference in the proposed rule to the ANSI standard, with many minor edits, makes the proposed rule more difficult to follow.

ANSI standards are examined every 5 years and either reaffirmed or updated and then balloted as a new standard. This process allows standards to keep abreast of new technologies and thinking, and provide the best consensus procedures possible. In order to assure that updates to the proposed rule can happen as efficiently as possible, EPA should simply adopt the consensus standard with as little change as absolutely required instead of writing technical specifics into the law. Then the EPA rule could easily be updated by modification, as appropriate at the time, to reference the new ANSI standard.

Furthermore, by including elements of the ANSI standard with edits, into the EPA law, it makes it more difficult for laboratories or others who are familiar with the standard to determine the differences between the ANSI standard and the EPA rule. EPA should simply adopt the standard with as few edits as possible, and if substantive changes are required, simply point out the differences.

The following are a few examples of confusion in the proposed rule and of potential problems presented by incorporating portions of the ANSI standard (instead of adopting the entire ANSI standard with exceptions noted).

In 211.206-1(b)(5)(i), the proposed rule states “the following new provision shall be *in addition* to Clause 5.3,” when it would appear that what is meant is “the following provision shall *replace* Clause 5.3.”

The number of subjects and samples of HPDs to be tested per the ANSI standard was based upon existing datasets and was a collaborative decision within the working group. It was found that earmuffs could be reliably tested in 10 subjects except in the case of hard-hat attached muffs that require 20 subjects, due to increased variability in fitting those devices. Thus, the standard requires 1 pair of earmuffs/2 subjects (a total of 5 samples) and 1 pair of earmuffs-on-hardhats/4 subjects (also a total of 5 samples). No more samples are required for earmuffs-on-hard hats since the product itself is not any more variable; just the ability to fit it. In the extensive rewrite of Clause 6.1 on number of samples, the proposed rule changes little of substance, primarily the phraseology. An exception occurs in the case of muffs on hardhats where it specifies 1 pair/2 subjects, thus doubling the number of required samples, since as far as we can tell EPA still does require 20 subjects as does ANSI. What is the rationale for doubling the required samples in the case of hardhat-attached muffs?

EPA has also proposed changes to Clause 8.1 of the ANSI document. This is important since this Clause is perhaps one of the most critical in the ANSI document. It underwent in excess of a dozen revisions with input from many members of the working group. EPA changes consist of light editing which, in large part, has little effect on the procedure as defined except in one instance where a key phrase was left out: “unless they are included with the product or the product delivery process.” This phrase refers to the use of trial sound attenuation measurements during the fitting process and was specifically included to accommodate at least one product that was on the market at the time that included as part of its molding and custom-fitting process, an objective microphone-in-real-ear sound measurement. If that HPD as fitted to the user failed to meet a criterion value of attenuation, it would either be remade or the user told that the device was not suitable for their use. Thus, to properly test that particular product using Method-A, a trial sound attenuation measurement for the test subject must be included.

We suggest that EPA adopt S12.6 as is, with the only additional specification regarding that standard being the provision of the specific Method that will be utilized, namely Method A.

211.206-2 ANR testing and reference to ANSI S12.42-1995(R2004)

In the absence of an ANSI standard describing how to measure the performance of ANR HPDs, it is understandable that EPA crafted their own. In fact, EPA’s work formed the basis for the initial draft update of ANSI S12.42 by ANSI S12/WG11. However, since that time WG11 has produced over 17 different drafts of the document during a series of 8 meetings by over a dozen experts in the area of hearing protection measurement methodology, including the two scientists who helped develop the EPA proposed rule. The document that was agreed upon and finalized for ballot on August 6, 2009, represents a substantial refinement of the procedures now present in the proposed rule.

The ballot for draft S12.42-200x closed on September 21, 2009 with a vote of 23 affirmative (one with comments), 1 negative with comments, 11 abstentions, and 7 not returned. A final document addressing the comments will be resubmitted for approval which is anticipated by late 2009. Thus, at the least, the

EPA's proposed rule should be revised to reflect the latest draft of the ANSI procedures and, presuming that the timing works out, it would be best if the proposed rule simply adopted the 200x ANSI standard verbatim, for all the same reasons argued with respect to ANSI S12.6 and Section 211.206-1 of the proposed rule.

A few examples of the problems in the proposed rule vis-à-vis the draft ANSI document follow.

In 211.206-2(b)(1), the proposed rule cites Clause 6.1 of S12.6. It meant instead to refer to Clause 6.1 of S12.42-1995 and should simply adopt S12.42-200x without the need for clause-by-clause editing. Note that inappropriate reference to S12.6 instead of S12.42 also appears in 211-206-2(e)(2) and 211.206-2(e)(3).

In 211.206-2(c)(6), the proposed rule adds a requirement for the ambient noise floor. This was adopted from S12.42-1995. In the WG discussions it was realized that such a requirement was not needed and was redundant with other specifications that already assure an uncontaminated signal be measured. Therefore, the requirement was stricken from the current ANSI draft and should be removed from the proposed rule as well.

Section 211.206-2(e) appears to be incorrectly designated since it refers to an active attenuation method, but the HPD type described in that Section is actually an ANR HPD and not an active HPD.

In Section 211.206-2(e)(2) a wire size is specified that is too small to be feasible for use. This problem was discovered in the drafting process for the new S12.42, and the size was adjusted to 0.5 mm including insulation.

Examples of other issues include the specification of an ATF that does not conform to the current ANSI draft, and reference to an occluded ear simulator standard (60711) that is an IEC standard which will soon be supplanted. Also, Figure 1 is a duplication of the same figure in the draft S12.42 and can be deleted once the standard is appropriately cited.

211.206-3 Reduction of peak impulsive noise

As argued with respect to 211.206-2 and -3, this section should be completely revised to reference the draft S12.42-200x or the (hopefully) soon-to-be-approved version thereof. However, there is a larger problem. As discussed elsewhere in these comments, neither the EPA proposed procedure nor the draft S12.42 procedure has ever been fully implemented in practice. Though one European laboratory (ISL) has tested with a procedure similar to that in draft S12.42 and NIOSH Cincinnati has worked with shock tubes, the specific procedures of the EPA or S12.42 have not been vetted. Neither does an appropriate ATF yet exist to do the tests. Thus, it is inappropriate for EPA to mandate testing to procedures that have not been evaluated and shown to work.

There are certainly data to indicate that the procedures are reasonable and *should* yield useful results, but for something that will become law and may be a law for many years to come, the EPA should have the certainty of having actual data in hand to substantiate a new rule. For example, though draft S12.42 mostly describes what is done at ISL with respect to the use of explosives to test HPDs, the math in S12.42 differs from the ISL approach as does the ATF. With experiments as complex as these, problems can arise between the concept, writing, and implementation. This must be evaluated before the procedure is formalized in a regulation.

Other potential issues have also been identified with this section. They include the lack of specification of: a pre-trigger capture of the signal for correction of DC offset, the lack of discussion of anti-aliasing filters, the lack of a maximum noise floor re the peak signals levels on the measurement system, the lack of specifications on the peak handling capabilities of the microphones and preamps, the lack of a requirement for two measurements of each occluded peak level, the lack of a plan view of the test site, and the specification of too short of a minimum length of impulse recorded (50 ms in EPA vs. 300 ms in ANSI).

Figure 1 and 2 are a duplication of the same figures in the draft S12.42 and should be deleted.

211.207-1(c) Computation of NRR based on statistical and graphical methods, re Clause 6

The paragraph appears to be erroneous in terms of its designation, the sequence in which it appears in the proposed rule, and its content.

First, the section title includes the words “based on statistical and graphical methods.” This is confusing since both the NRR and NRR_G are statistical, yet the word “statistical” is left out of the title of the following section that refers to the NRR. The feature that is unique to NRR_G is that it is graphical. This section appears to refer to both NRR and NRR_G , whereas logically it would seem it should refer only to NRR_G and thus the section title should refer to only a graphical method. The NRR is already covered for all device types in the following three sections of the proposed rule.

Second, with respect to the primary label, the proposed rule addresses the NRR before it discusses the NRR_G . It would then seem to follow that in Section 211.207 the same sequence should apply, namely that NRR precedes NRR_G . The next three sections that discuss the NRR for passive, ANR, and impulsive cases should precede Section 211.207-7(c).

Third, this section specifies that only the NRR_G shall be used to determine the “active mode” noise reduction. This is problematic in two ways. First, it would appear from reading other sections of the proposed rule that the EPA in this section meant to refer to ANR, and not “active” since there is no specific labeling specified in the proposed rule for active devices. Second, and of larger concern, is that an active NRR is required to be reported on the primary label and the only procedure in S12.68 to compute the NRR is that found in Clause 5 of the standard, and not the NRR_G procedure in Clause 6 of the ANSI standard.

211.207-2 Computation of the passive NRR

As argued previously, it would ease implementation, aid in compliance, and improve the interpretation of the law, if instead of repeating entire sections from the ANSI standard, a simple reference to it with specific mention of the key changes required by EPA was provided.

211.207-3 Computation of the ANR rating

This section repeats many of the words and requirements of the ANSI S12.68 standard, but in so doing incurs an error, and also a substantial point of confusion. It would be more clear, and easier to implement if the proposed rule simply referenced the ANSI standard.

The error appears in subsection (b)(1) which discusses the variability of passive devices, even though this subsection falls within the part of the proposed rule that is entitled “computation of the ANR rating.” Since passive devices are not considered ANR HPDs their mention does not belong in this part.

The larger point of confusion is that this section repeats the entirety of Section 211.207-2. The *only* point of actual difference between the 211.207-2 and 211.207-3 is that the octave band attenuation values used for computation of the NRR and NRS_G of an ANR HPD must be computed by adding REAT passive (ANR off) to the active attenuation (MIRE ON – MIRE OFF) as described in Section 211.206-2(m). If this section simply instructed one to repeat the computations from 211.207-2 by replacing the REAT values with the REAT + MIRE values for the ANR device, it would be easier to understand and implement.

211.207-4 Computation of the impulsive NRR

Once again, please simply reference ANSI S12.42-200x. The material on computation of impulsive NRRs is out of synchrony with the draft S12.42, and contains at least one error, namely the reference to the maximum positive peak pressure in the equations. The value used should be the absolute value, since the maximum value may be a positive or negative going peak value.

211.209-1 Reporting requirements

The proposed rule requires reporting within 10 days of “completion of the required test.” Does completion refer to the date when the test house completes the test, when the test house provides the test report to the manufacturer, or when the manufacturer completes review of the test report and approves it? Please clarify this reporting requirement.

There is also another substantial issue with the requirement as written. It would appear that it covers devices that are “manufactured” per Section 211.202 regarding effective dates. What happens if a device is manufactured and tested, but then not immediately introduced to the market, or is not introduced at all? Even more problematic is that the 10-day reporting requirement would likely result in data being provided to the EPA, and potentially also to competitors via the Freedom-of-Information Act, prior to devices actually being introduced to the market.

The word “manufactured” in 211.202 should instead say “that are introduced into commerce” on or after the to-be-effective date. Then in this section (211.209-1) the clock should run from date of introduction. The specified start time should be “after test report is issued and accepted by the manufacturer, or after date of introduction to the marketplace, whichever is later.” This revision would then also cover devices that are already in the market at the time this new rule issues.

Another concern is the 10-day time frame. A 30-day time frame would seem adequate for the purposes of this proposed rule. It is unclear why there should be such urgency in this regard. Even with a 30-day reporting obligation for products that are in commerce at the time of testing it would be highly unlikely that a product would ever get packaged, labeled, and re-introduced into commerce before the data were provided to the EPA.

211.211-1(b) Compliance with labeling requirements (also see 211.211-3 and 211.212-6)

The requirements for relabeling appear inconsistent between paragraphs in the proposed rule. In the compliance paragraphs (211.211-1 and 211.212-6), the proposed rule, as in the existing labeling regulation, instructs the manufacturer to take into account both product and test-to-test variability when

labeling devices. However, in 211-211.3 regarding recurrent testing there appears to be no guidance on when relabeling will be required (even though the preamble speaks of a 3-dB requirement on p. 39169), and then in paragraph 211.211-4 on product change retesting, the 3-dB requirement is stipulated. It would be clearer and provide for more uniform labeling and compliance if the requirements for compliance with the rule and for relabeling for recurrent testing and product-change testing were the same in all cases.

With respect to manufacturers taking into account variability, this implies that manufacturers may choose to derate their products below the NRRs established through their testing so that in the event of a compliance audit test, the manufacturer would reduce the likelihood that test variability alone would cause a product to be found out of compliance. Although this does give the manufacturer leeway in making its own choice, in our experience this is misunderstood by manufacturers and may not generally be applied. It also leads to differing choices across companies and greater inconsistency in labeled values between products from different manufacturers, and a reduced ability of consumers to make valid comparisons between products.

It would be preferable for EPA to specify that compliance with the law would be determined by comparing a current compliance test to a labeled value, taking into account test uncertainty as discussed regarding Section 211.211-4 below. This would encourage manufacturers to simply report the values found in their testing, thus creating a more level playing field.

211.211-2 Transition testing and labeling requirements

Based upon our understanding of the proposed rule, all testing and labeling in accordance with the new requirements is to occur within 30 months of the effective date of the regulation. In our preceding comments regarding Section 211.202 we discussed the likelihood of marketplace confusion over the coexistence of old-style and new labeling during the transition period, and hence the need to reduce to the extent possible the 30-month transition period.

The EPA's estimate of the required time for testing/relabeling is based on their survey which found that 1029 passive products, 54 ANR products, and 156 level-dependent products will require testing. EPA further estimated a test rate for four available labs of 150-200 products per year. One of the test labs used in the EPA analysis was the 3M E•A•RCALSM facility. We estimate that with our current one-shift operation, accounting for vacation and subjects who fail to show on schedule, that we could test about 130 products/year, presuming we eliminated all product development work and other tests in our lab and had no down time for contingencies. We could add a partial second shift depending upon subject availability so we might be able to achieve at least the 150 test/yr that EPA estimates, perhaps higher, but again only on the presumption that we eliminate product development testing. That is not feasible since we cannot devote 100% of laboratory time to the conduct of label testing.

EPA bases their time estimate on current REAT testing. However, for ANR products for which MIRE tests in addition to REAT evaluations are required, no US-based facility (including our own), has any substantial experience with the MIRE tests that are required. With time and proficiency MIRE test times may be quicker than for REAT, but there is still the overhead of scheduling subjects and analyzing the data. The test rate most likely will turn out to be about the same, and the MIRE tests must be conducted in the same lab that does the REAT evaluation since the two sets of data must be measured using the same subjects and then combined.

Finally, we come to the impulse tests. There is no laboratory currently in existence, anywhere in the world that has experience with the specific procedure defined by the EPA for impulse-noise testing, or even with the procedure defined by the draft ANSI document. A couple of laboratories have implemented similar procedures, but not these exact procedures. Furthermore, the ATF that is required for optimum results, as defined in the draft ANSI standard does not exist today. The Institute of St. Louis (ISL) test fixture that has been used by the Air Force and NIOSH does not comply with the draft ANSI standard. Its earcanal is too short and it is not heated to body temperature as will be required in the new standard. These are important distinctions. At least one company has indicated that they will build a compliant head for testing purposes, but it will not be available until at least 9 months (and probably one year) after the ANSI standard issues, thus delaying the onset of impulse-noise testing.

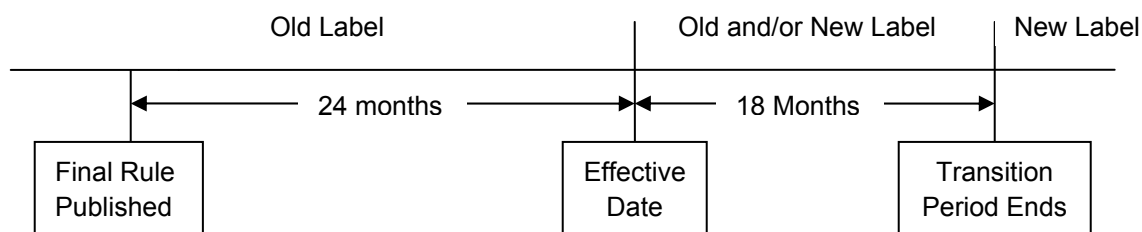
Furthermore, any lab that sets up to do these new tests will have a substantial learning curve prior to becoming proficient at performing these tests. Again, this will cause more delays.

Finally, EPA contemplates new facilities coming on line that should help to address the limited testing resources available at present. This may well happen, but based on prior experience, manufacturers are extremely reluctant to trust their labeling tests to new and inexperienced facilities when differences of as little as 1 dB in labeled NRRs can dramatically affect product sales. Thus, when one accounts for their set-up time, learning curves, and market acceptance, it will likely be some time before those new labs can shoulder the burden. When the 1979 EPA rule was promulgated, three new laboratories appeared, but they never garnered any substantial business and within a couple of years were gone from the marketplace.

Another aspect of labeling that would appear to be unaccounted for by EPA is the time to create new artwork and print new packaging. That could easily add 6 months to the process for large manufacturers such as 3M.

Thus, a more plausible estimate of time to market would use a rate of testing averaged across all the available facilities of 130/yr across all test types (REAT, MIRE, and impulse). Additionally, at least a 6-month delay from the approval of S12.42 later this year would be reasonable. If we presume a 5th facility appears with a test rate of 100/yr to account for its learning curve and other noted challenges and delays, we compute an overall average test rate of 124/yr. That would mean that the 1239 tests would take 24 months to complete. If we added in a 6-month delay to account for start-up problems for labs to implement the new ANR and impulsive tests, and 6 months for packaging revisions and printing, we come to 36 months and not 30 months. If S12.42 appears in December 2009, and the final rule were to incorporate that standard, manufacturers would need 36 months to comply. Thus, as long as the effective date of the rule were delayed until after the acceptance of S12.42 this would be potentially feasible, but nevertheless rushed. This also does not account for issues in drawing down and planning replacement of inventories. A more appropriate time frame would be 42 months subsequent to the effective date of the proposed rule.

For that reason, we recommend an effective date of 24 months from the publication of the final rule and allowance for manufacturers to begin testing their products upon publication of the final rule which should allow ample time for manufacturers to retest their products. This would be followed by an 18-month transition period to make and get the newly labeled products into the marketplace. This change requires amending the timing and clarifying in this section that manufacturers may test products on or after the date of final rule publication. A graphic illustrating our suggestion follows in Figure 3.

Figure 3 – Illustration of 3M’s proposed time frame for transition labeling**211.211-3 Recurrent testing requirements**

Though it may be a useful addition to the proposed rule that there be a requirement on retesting existing HPDs, 3M’s opinion is that retesting should only be required when there is evidence or concern on the part of the manufacturer that the form, fit, or function of the device has varied. It is true that there are products on the market today with NRRs established over 20 years ago, and it can be difficult to assure that raw materials and manufacturing processes have been consistent over those periods. However, the EPA’s analysis for a retesting interval was based only on the costs of retesting and what was presumed feasible for manufacturers and test facilities to accomplish on an ongoing basis, not on what was required to assure accurate labeling. No data were presented to suggest over what range of years problems might arise, or what inaccuracies in hearing protector labeling due to uncontrolled changes have been observed to occur.

Another consideration is that, despite the agency’s contention that its transition proposal will allow staggering of the retests in future years, this will not likely be the case. Since the HPD market is mature, turnover of products is relatively small. With almost a constant pool of products, and the need to rush to market with new tests and labels to meet the transition requirements, most of a manufacturer’s products will be transition tested within a two-to-three year time frame, and thus 5 years later (under the current proposal), a rush to retest would start all over again. Increasing the retest interval to 10 years would facilitate a controlled and suitable retesting and relabeling plan, since more products would come and go during that longer time frame. This time period should still accomplish the EPA’s goal.

A 10-year retesting interval also provides a better balance between the goals of a retesting program (assuring that products have not changed), avoidance of market disruption if relabeling occurs due to random variability and not actual product drift, and the difficulties of redoing so many tests over and over within short time frames. Our experience with vendors and our own success in maintaining product consistency, combined with our appreciation of the realities of the marketplace, is the rationale for the 10-year recommendation.

Another issue with the requirement in this Section is that it is unclear when relabeling must occur. The preamble to the rule discusses on p. 39169 the need for relabeling when changes in NRRs exceed 3 dB. However this requirement seems to be lacking from this section of the proposed rule. 3M requests

clarification on when relabeling would be required for routine retesting, as opposed to the relabeling required for product changes as discussed in 211.211-4. If recurrent testing is to be required, the relabeling requirements should be based on statistical criteria as discussed in our comments on 211.211-4 below.

211.211-4 Product change retesting requirement

The 3-dB value that was selected by EPA for requiring relabeling does not seem well justified, and indeed creates a potential problem. EPA states that this requirement is based on the EPA/NIOSH/WG11 interlaboratory study and the fact that a 3-dB change in the rating doubles or halves the effective protection. That latter statement is true, but is irrelevant if the reliability of the rating is such that the precision in estimating the value is worse than 3 dB.

On p. 39169 it is estimated that this 3-dB criterion would conservatively occur 12 percent of the time, based on the interlaboratory study carried out by the EPA and NIOSH. 3M is concerned that the likelihood of relabeling has been underestimated based on the results of that study. Figure 2 of the cited paper (footnote 36) shows between-laboratory standard deviations of 3 and 5 dB for the two earplugs tested; with this amount of variation, differences on re-testing are likely to be much more common than 12 percent of the time since, for a normal random process, 32% of the cases fall outside the range of ± 1 standard deviation. Customers come to rely on products and frequently specify them based on their attenuation values. If the NRR changes arbitrarily for reasons that have nothing to do with the product, but simply random test variability, this will be a disservice to HPD consumers who will then need to reevaluate her/his hearing conservation program and product choices.

3M requests that the threshold for re-labeling consider the preceding argument. The best way to avoid a significant chance of re-labeling due to random variation (rather than actual product change) is to include a statistical factor in the decision. ANSI/ASA S12.68-2007 Annex D defines such a test that the regulation could incorporate by reference, defining a method for calculating the half-width of the 95% confidence interval reflecting the variation in the test data. Specifically, we suggest that the regulation require relabeling if and only if the lesser NRR from the original label's bar-graph minus the lesser NRR calculated for the re-test is greater than either 3 dB or the sum of the U95 values for the original labeling test and the re-test (i.e., the confidence intervals for the two tests' lesser NRR values do not overlap). This would also require that, when a test is conducted, the U95 uncertainty value defined in the standard be calculated and reported.

Substantive Terminology Concerns

211.204-1(c) Primary label for impulsive noise hearing protection devices

The title to this section is confusing. Though impulsive noise HPDs are discussed in the preamble text, an impulsive noise HPD is never defined within the proposed rule. Rather, the term amplitude sensitive HPD is defined as a passive, active, or impulsive noise device. Furthermore, the terms impulsive noise, impulsive noise reduction, and impulsive noise measurement are used, but again no definition is provided for an impulsive noise HPD. It would appear what is meant is an amplitude-sensitive HPD that is being used in impulsive-noise environments. In fact, impulsive noise HPD is not a term normally found in the literature; usually what is referred to is an amplitude-sensitive or level-dependent HPD. Finally, in Section 211.204-6 regarding supporting information, the label that is used is "amplitude-sensitive HPD."

The proposed rule can be clarified by referring to amplitude-sensitive HPDs throughout and eliminating the term, “impulsive noise HPD.” Then, in line with the suggestion below on active/active noise reduction, the definition of amplitude-sensitive should read,

A device that is designed to ... Amplitude-sensitive HPDs may include passive, electronic, and active noise reduction HPDs.

211.204-2(j) Primary label for active (noise reduction) hearing protectors

The words in this section refer to an “active” HPD. In the definitions [211.203], “active” is defined as an electronic HPD, which is distinct from an “active noise reduction” HPD that acoustically cancels sound. By these definitions, ANR is a subset of active, therefore, it substantially changes the intent of this proposed rule when the terms active and ANR are interchanged.

Although it would appear from reading other parts of the proposed rule, that this section intends to refer to ANR HPDs, the wording says “active HPDs,” thus including all electronic devices. This section requires clarification. Additionally, the EPA should search the document as there are numerous other instances where the term “active” is used when it appears that ANR is intended. For example, in Section 211.204-4, which is labeled “Supporting information for ANR hearing protection devices,” the first paragraph says “...supporting information must accompany all ACTIVE devices in ...” This confusion occurs repeatedly within this section.

The use of the terms active HPD and active noise reduction HPD appear to have been confused in the proposed rule; no doubt these terms will create confusion in the mind of the readers too. The situation is compounded since “active” appears on the label to describe testing when the device is “on,” and indeed potentially both an ANR HPD and an active HPD could be tested for impulse attenuation in their ON modes, further confusing the situation. It would be more clear use “electronic HPD” instead of “active HPD” throughout.

Secondary Technical and Regulatory Concerns

Preamble VI.B.1. Test methodologies, proposed testing protocols, panel pre-screening

EPA rightfully believes that subject selection criteria can be used to identify a *population* to produce high attenuations and lower standard deviations. EPA goes on to say that 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.” This section requires clarification.

The EPA proposed rule allows rejecting subjects during the pretest process. Presumably this means before the label testing has begun. That can be taken to mean that subjects can be evaluated in the screening process to determine if they are to be allowed on the test panel. However, EPA follows up the phrase in quotation marks above with the statement that subjects can not be removed from the pool of tested subjects. Does “tested subjects” refer to subjects used in the labeling test *per se*, which would mean that during the 10- or 20-subject test the lab may not remove a subject because of poor attenuation? Or does “tested subjects” refer to any subjects who are tested in establishing the laboratory’s resident panel, in which case the prohibition also applies to the pretest/prescreening process by which laboratories determine who will be on their resident test panels from which subjects are chosen for particular label tests?

Unfortunately, S12.6-2008 does not address this issue for Method A, though it does for Method B in Clause 9.1, by stating “It is not permitted to optimize a test panel based upon experience gained from subject participation in prior tests.”

We suggest that the intent stipulated by S12.6 in Clause 9.1 is the appropriate one. However, whichever meaning is intended by EPA should be clearly specified.

211.204-1(a)(iv) and (a)(v) Information content of the primary label for HPDs with bands usable in different positions

The current requirement for devices with headbands that are usable in multiple positions is that the NRR for the worst-case position be specified on the label. It would appear that the proposed rule requires that NRRs for all recommended positions be specified on the label. That may create problems with packaging copy space and would be confusing to the user, especially since the NRRs for the various positions are usually within a few dB of one another. We suggest the EPA give the manufacturer the option of either specifying the worst case NRR or all NRRs for the primary label, and then require that data for all recommended positions be included in the secondary label information.

211.204-3(a)(3) Label location and type, internet sales

The law allows products sold exclusively over the internet to only present their primary and secondary labels on the internet; none is required on the packaging. This seems inappropriate. Consider for example companies selling industrially that distribute their products exclusively via a safety distributor’s catalog. Would it not make sense that they too would only have to present information at the point of principal customer contact, namely their catalogs, and not have to place information on their packaging as well? Regardless of initial contact, at some point a customer gets an actual product and it seems, regardless of how it arrived in their hands that it should be properly labeled. If the EPA wants to allow manufacturers to put more of the secondary label information on the internet as we propose [re 211.204-4 Supporting information, location] then that would decrease this burden for all manufacturers.

211.211-1 Compliance with labeling requirements

This is a key section since it deals with compliance with the overall law. Subsection (a) is not clearly worded. It says manufacturers must comply with the “range of NRRs as determined by the appropriate test procedure.” What appears to be intended and what should be stated is that manufacturers “must comply by labeling the device with a bar graph that includes the lesser and greater NRRs as determined by ...”

Subsection (b) is also confusing. It appears to be missing the important words “in compliance” in line 7 after the word “considered.”

211.204-4(h)(3) Supporting information, computational example

At the end of the computational example, the words “The sound pressure level at the user’s ears will depend upon the fit of the protector,” are appropriate and make sense in the context of a dual-number value. However, Section (l) following, requires similar words that are in part redundant, “Improper fit or improper use of this device will decrease noise reduction effectiveness and increase the risk of hearing damage.” Space is at a premium on packaging, especially as many manufacturers move to multilingual

packages. Additionally, clarity can be gained if concepts are grouped instead of distributed throughout. We suggest combining the two similar warnings into a single one following the example, to read as follows,

Actual noise reduction will vary depending on how you fit and wear the device. Better fitting and consistent use increases effectiveness and reduces the risk of hearing damage.

The proposal groups the two messages together for better impact and in total reduces the words by 25% (36 words to 28).

211.204-4(i) Supporting information, caution regarding low-frequency noise

The caution that is proposed is necessary, but it should correspond with the one found in the ANSI S12.68 standard upon which it is based. In the standard it points out on p. 7 that the NRR_A overestimates protection by 3 dB on average when C-A exceeds 5 dB. According to ANSI S12.68, that will occur for 18% of the NIOSH 100 noises. By changing the recommendation to use NRR_C from a C-A of 5 dB to a C-A of 3 dB, the warning will apply to 31% of noises. With that high an “error rate” one questions the utility of the NRR_A . However, a 3-dB error is in fact relatively small when one appreciates the other much larger errors in the system such as the measurement of the attenuation, the percentage wearing time of the HPD, the measurement of the noise levels, and the ability of the user to apply the results. We suggest that the ANSI recommendation for using 5-dB as the criterion for applying NRR_C is more appropriate.

Additionally, the typical consumer applying these data will be unable in most cases to measure A- and C-weighted levels, so a listening indicator may also be helpful. For example,

Caution: For noises with a rumbling, thunderous, or heavy sound in which the difference between the C- and A-weighted noise levels (dBC-dBA) exceeds 5 dB, the user is directed ...”

Additionally, there is no guidance on how to use the graph (Figure 1 in this section) to compute the effective noise exposure. The following wording is suggested, adapted from the first paragraph of Clause 6.3 of ANSI S12.68.

To use the graph, determine the typical spectral balance (the difference between dBC and dBA) from noise measurements made with a sound level meter that can simultaneously measure the A- and C-weighted levels. Locate the spectral balance value on the horizontal axis of the graph, find corresponding points on the two lines, and then read the Estimated Noise Reduction from the y-axis. This value should be used in place of the lesser and greater NRR for a more accurate estimate of the noise reduction.

211.204-6 Supporting information for amplitude sensitive HPDs, Tables 1 and 2

The impulse reduction factors in these tables should be rounded to integer values. The precision of these measurements and even their accuracy and validity is not of the calibre that warrants reporting to a precision of 0.1 dB.

Suggested Edits and Other Items

Figure numbering

It would be clearer if figures were numbered sequentially throughout the document instead of the figure numbering restarting within each section thus resulting in multiple Figure 1s, Figure 2s, etc.

Preamble VI.B.2.a. Test methodologies, test procedure – incorrect use of dBA

Beginning in the second paragraph, throughout the preamble, and in many (but not all) places in the proposed rule, peak SPLs are referred to as measured in dBA. This is incorrect. Peak SPLs are normally measured unweighted, or sometimes C-weighted, but not with A weighting. See for example the corresponding items in ANSI S12.42.

Preamble VI.B.2.d. Test methodologies, test procedure - confusing

This section is labeled “computation of the NRR,” but discusses measurement procedures. Furthermore, it would appear that this section covers the testing of ANR devices (devices that are actually tested in their on and off modes), but mistakenly designates them as amplitude-sensitive devices, which do not actually appear to be covered in this proposed rule. This needs clarification.

211.203(b) A-weighted sound level

Since A weighting is a negative value from 20 Hz up until the frequency of 1000 Hz (for example -3.2 dB at 500 Hz), it is inappropriate to suggest that it emphasizes sound from 500 to 5000 Hz. It would be correct to state “emphasizes sound between 1000 and 6300 Hz.”

211.203(d) ATF and (v)IATF

The definitions do not differentiate the ATF and IATF. Both definitions speak to approximating the head and simulating the acoustic response of the human ear canal. The ATF definition speaks to dimensions of the ear canals and the IATF definition to microphones and electronic circuitry. The key difference between them, however, is lacking, namely that the IATF has microphones and preamps that will properly handle, without overload, the high-level impulsive test signals. Also, these definitions will not be needed if reference is made to S12.42-200x.

211.203(ee) Noise reduction variability data points

The use of the word “variability” is confusing in the phrase “noise reduction variability.” Variability is usually interpreted to mean “able or apt to vary or subject to variation.” The implication, therefore, is that these points are subject to random variation and not fully determinate. That is not the case. These data points are computed from a determinate set of noise spectra and will be the same each time they are computed presuming the attenuation data for each subject is unchanged in the calculation. A more appropriate term would be “noise reduction spectral balance data points.” It may be even clearer to simply not define this term at all, and instead to relabel Figure 1 in Section 211.204-4 (and related figures) as “Variation of noise reduction as a function of noise spectra.”

211.203(oo), definition of REAT

Section (oo) is a duplicate of the preceding Section (nn).

211.204-4 Table 1 column headings

The heading to the second column of the table should be “2 dB” and not “-2 dB.”

211.204-4 Figure 1 variability of noise reduction as a function of noise spectra

As in the comment to 211.203(ee), the title to the Figure is misleading. It implies that the estimated noise reduction is more variable at certain values of the spectral balance. That is not true. What is true, however, is that estimated noise reduction varies as a function of the spectral balance. A clearer title would be "Variation of noise reduction as a function of noise spectrum."

211.204-4(e)(3), (4), and (5) Supporting information, dimensions of graph

Section (3) is a duplicate of the preceding Section (2). In Sections (4) and (5), ordinate and abscissa are incorrectly cited. Section (4) refers to the x-axis and this should be designated the abscissa, and Section (5) refers to the y-axis which should be designated the ordinate. These mistakes regarding the abscissa and ordinate occur throughout all of Section 211.204.

211.204-6(f) Supporting information for amplitude-sensitive HPDs, Cautionary note terminology

This Section refers to a cautionary note for ANR hearing protectors with the word "ACTIVE" in all capital letters, but 204-6 is a Section dealing with amplitude-sensitive HPDs and impulse noise. This requires correction.

Also, this note must be reworded with respect to the 130-dB recommended level as was previously discussed with respect to 211.204-6(e).

211.207-4(d) Computation of the impulsive NRR, the average noise reduction

The words "the average impulse noise reduction for each pressure range (k)" following the words "shall be" in line 3 are duplicated and should be deleted.

211.207-3(d) Computation of the ANR rating, standard deviations

The text and equation in this section are a repeat of what is found in 211.207-3(c)(2) that precedes it.

References

ANSI S3.19-1974. "Method for the measurement of real-ear protection of hearing protectors and physical attenuation of earmuffs," ANSI, New York, NY.

ANSI S12-42-1997(R2004). "Microphone-in-real-ear and acoustic test fixture methods for the measurement of insertion loss of circumaural hearing protection devices," ANSI, New York, NY.

ANSI S12.68-2007. "Methods of estimating effective A-weighted sound pressure levels when hearing protectors are worn," ANSI, New York, NY.

ANSI S12.6-2008. "Methods for measuring the real-ear attenuation of hearing protectors," ANSI, New York, NY.

ANSI S12.42-200x (DRAFT). "Methods for the measurement of insertion loss of hearing protection devices in continuous or impulsive noise using microphone-in-real-ear or acoustic test fixture procedures," ANSI, New York, NY.

AFRL (2008). "High intensity continuous and impulse/blast noise workshop, sponsored by Air Force Res. Lab, Human Effectiveness Directorate, Moab Utah, Feb. 20-22."

Berger, EH, (2005). "Preferred methods for measuring hearing protector attenuation," Proc. Inter-Noise 05, Noise Control Foundation, Poughkeepsie, NY

Berger, EH and Hamery, P (2008). Empirical evaluation using impulse noise of the level-dependency of various passive earplug designs," J. Acoust. Soc. Am. 123(5), Pt. 2, p. 3528.

ISO/IEC 17025:2005. "General requirements for the competence of testing and calibration laboratories," Switzerland.

Ward, DW, Royster, JD, and Royster, LH (2000). "Auditory and nonauditory effects of noise," in *The Noise Manual* 5th Edition, edited by EH Berger, LH Royster, JD Royster, DP Driscoll, and M Layne, Am. Ind. Hyg. Assoc., Fairfax, VA, 123-147.

Zera, J and Mlynski, R (2007). "Attenuation of high-level impulses by earmuffs," J. Acoust. Soc. Am. 122(4), 2082-2096.