United States Environmental Protection Agency

Workshop on Hearing Protector Devices
Washington, DC
March 27-28, 2003

Papers and Proceedings

Proceedings prepared by Alice H. Suter, Ph.D. under NIOSH contract order number 0000336337.

Disclaimer

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U.S. Environmental Protection Agency
Workshop on Hearing Protector Devices

Introduction

On March 27-28, 2003, the U.S. Environmental Protection Agency (EPA) held a workshop to collect information relevant to its anticipated action to revise the federal regulation at 40 CFR Part 211 regarding the effectiveness rating and labeling of hearing protector devices. The workshop took place at EPA headquarters, East building, 1201 Constitution Ave., NW., Washington, DC, beginning at 8:00 am on March 27 and ending at 5:30 pm on March 28. The public was given notice of the workshop in the Federal Register and on the Internet.

EPA sought information from all interested parties regarding all aspects of the current labeling requirements, particularly in the following areas:

I. Product label:

- Primary label information
- Supporting information
- Label placement

II. Noise reduction effectiveness rating strategies:

- Test methodologies
- Passive and active devices
- Effectiveness metric
- Recertification

III. New hearing protector technologies:

- Sound restoration systems
- Active and passive non-linear devices
- Active noise reduction
- Communication systems/radios

The workshop began with a day-long plenary session split into two parts. The morning session was comprised of invited papers providing: the historic basis for the current hearing protector regulation; a review of advances in effectiveness test methods since the 1979 promulgation of the regulation; an analysis of the relationship of the current Noise Reduction Rating (NRR) to new ANSI test protocols; and an overview of new hearing protector technologies.

The second part of the plenary session took place in the afternoon and was devoted to presentations of relevant information, comments, and recommendations from those interested parties who submitted requests for formal presentations to EPA in advance and who provided the EPA full text of presentation in "PowerPoint" format. All formal presentations have been placed in the EPA docket #OAR-2003-0024 for public review.

The second day of the workshop consisted of three "breakout" sessions which ran concurrently. Each session addressed one of the three major topic areas noted above. The sessions were facilitated by NIOSH personnel, but were conducted informally to stimulate the free flow of ideas and exchange of information. Summaries of each of these sessions by the NIOSH recorders appear toward the end of this document, along with a single summary that combines the outcomes of the three sessions.

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EPA Workshop on Hearing Protector Devices

Invited Presentations

March 27, 2003 – Morning Session

1. Alice H. Suter, Ph.D., Suter and Associates, Ashland, Oregon
   History and Use of EPA's Hearing Protector Labeling Regulation

2. John R. Franks, Ph.D., Chief, Hearing Loss Prevention Section, NIOSH
   Comparison of the Regulatory Noise Reduction Rating (NRR) and the Required ANSI S3.19 Test Method With Real-World Outcomes and Results From Testing With the New ANSI S12.6B Method

3. William J. Murphy, Ph.D., Hearing Loss Prevention Section, NIOSH
   Deriving a New NRR from the ANSI S12.6B Method, Interlaboratory Reproducibility of Data, and Precision of the Data

4. John G. Casali, Ph.D., CPE and Gary S. Robinson, Ph.D., Auditory Systems Laboratory, Virginia Tech
   "Augmented" HPDs: Active Noise Reduction, Level-Dependent, Sound Transmission, Uniform Attenuation, and Adjustable Devices – Technology Overview and Performance Testing Issues

5. Elliott H. Berger, M.S., Chair ANSI S12/WG11 "Hearing Protector Attenuation and Performance"
   Rating Metrics for Hearing Protectors

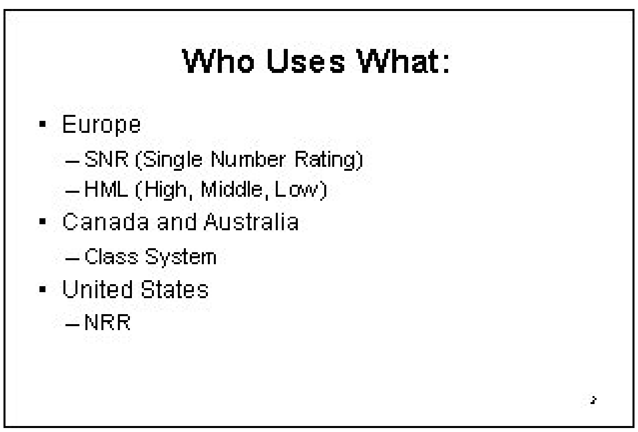
History and Use of EPA's Hearing Protector Labeling Regulation

Alice H. Suter, Ph.D.

Ashland, Oregon

INTRODUCTION

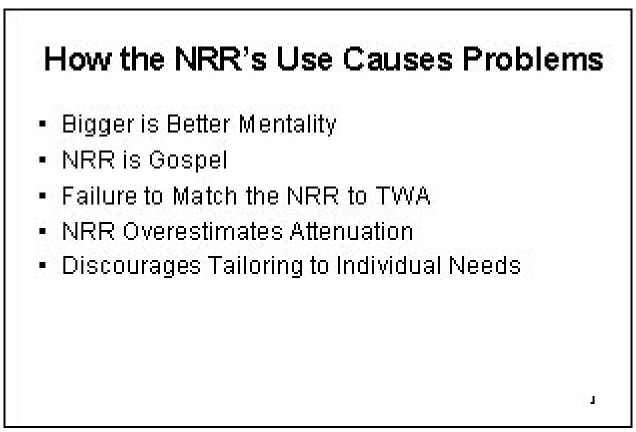
As a former employee of EPA's Office of Noise Abatement, then OSHA's Office of Health Standards, then NIOSH's Physical Agents Effects Branch (now the Engineering and Physical Hazards Branch), you can see that I am well traveled in the federal bureaucracy. I have a sense of history about these matters, and I know about the long and arduous nature of the rulemaking process. But I have also worked in the private sector for many years, and I believe that I can approach this subject with some degree of objectivity.



EPA's labeling rule for hearing protectors was published in 1975, and since that time, most manufacturers in the U.S. have used the NRR to label their hearing protection products. The NRR received added emphasis when OSHA promulgated the hearing conservation amendment to its noise regulation in 1981 (OSHA, 1981). Hearing protector manufacturers as well as employers and hearing conservation professionals in the U.S. have become quite accustomed to the NRR, for better or worse, over the two and one-half decades since that time. Despite our somewhat insular mentality, interested individuals in the U.S. are aware that the NRR is not the only method for rating hearing protectors. There are other methods used elsewhere in the world.

HOW THE NRR'S USE CAUSES PROBLEMS

In the preparing for this talk I called several of my colleagues in hearing conservation to find out about their experience with employers and their representatives, including those who actually order hearing protectors. It became clear that most of the people in the field who use and order these devices have little understanding of the NRR. For those who order them, the "bigger is better" mentality prevails, causing people to make selection decisions on the basis of differences as small as 1 dB, whereas issues of comfort, compatibility with safety equipment, and ease of use are so much more important. Most people treat the NRR as gospel, believing that it tells the truth about what will happen to anyone who wears it, and if it isn't high, it isn't good. As one colleague said, it's a "very tight mindset." In addition, people don't really match the NRR with the worker's attenuation needs, they don't follow OSHA's mandatory requirements in Appendix B of the revised version of the hearing conservation amendment (OSHA, 1983a), and some of them are under the impression that the hearing protector is supposed to block out all sound, so they are surprised when the wearer can hear anything!

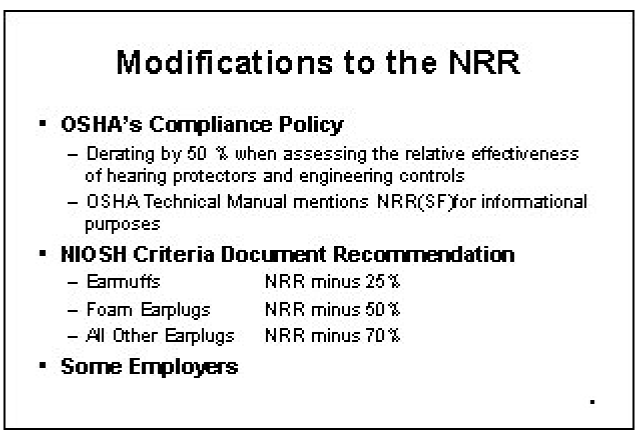


One of the most common problems is that workers move around so much during the day that it is difficult to assess the amount of attenuation that is needed. In fact, my colleagues report that most employers don't even know what the worker's time-weighted average exposure level (TWA) is. Moreover, the TWA doesn't always give a good estimate of the worker's attenuation needs, especially in intermittent and varying noise environments, because workers can be seriously over-protected at times if employers and supervisors make hearing protection mandatory throughout the exposure period.

There are several reasons why a more realistic descriptor of attenuation is needed. First, if people are going to treat the labeled value as gospel, it ought to bear some resemblance to reality, and I don't think many would dispute the fact that the present NRR bears little resemblance to what most workers achieve in real-world use. It gives both management and workers a false sense of security. "Here, wear this and you'll be OK." If the loudest noise you're exposed to is 110 dBA and the NRR is 29, you're fine. And if the level during the majority of the day is around 95 dBA, you're in quietland. Even if the employer were to take the instructions seriously and subtract the NRR from the C-weighted noise level in the worker's environment, it still would yield a gross overestimate of the worker's protected level in most cases.

In addition, the NRR discourages those who fit and select hearing protectors from tailoring the protector to the individual's attenuation needs because the spread of attenuation values, especially among muffs, appears to be relatively small. Of course the "bigger is better" attitude discourages it even more.

MODIFICATIONS TO THE NRR



In 1983, OSHA issued a compliance policy that is still in effect today (OSHA, 1983b). OSHA inspectors are not to cite a company for failing to use feasible engineering or administrative controls between TWAs of 90 and 100 dBA unless the company does not have "an effective hearing conservation program." Although OSHA has never given an explanation of exactly what constitutes an effective hearing conservation program, the Agency has instructed inspectors to derate the hearing protector's expected attenuation by 50 % when assessing the relative effectiveness of hearing protectors and engineering controls.

Interestingly, the OSHA Technical Manual (OSHA, 2003) does mention the deliberations of a National Hearing Conservation Association (NHCA) Task Force (Royster, 1995), the publication of the revised ANSI standard, ANSI S12.6-1997 and its new Method B option, and the existence of the NRR(subject fit) (NRR(SF)) as a new development. But the Agency mentions these developments for informational purposes only. If an employer were to use the NRR(SF) instead of the current NRR, he or she might be subject to a *de minimis* violation of the noise standard, a highly unlikely scenario, but nevertheless, a possibility.

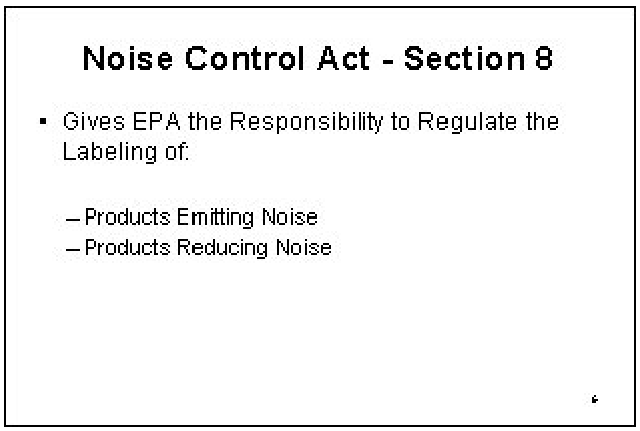
On the basis of the many studies of real-world attenuation values, NIOSH has suggested different amounts of derating for three types of hearing protectors: subtracting 25% from the labeled NRR of earmuffs, 50% from the labeled NRR of foam earplugs, and 70% from the NRR of all other earplugs (NIOSH, 1998).

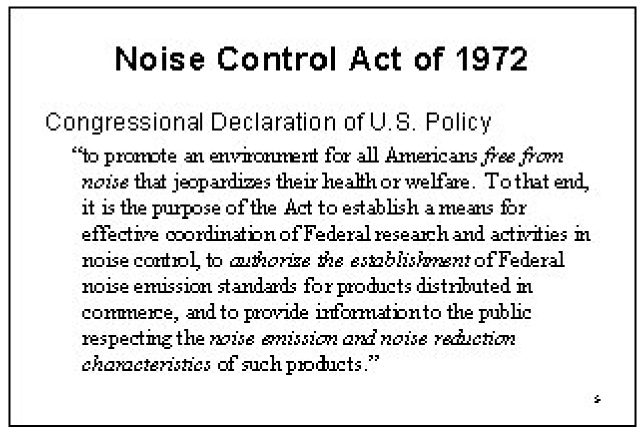
For both the OSHA and NIOSH derating methods, the user is expected to subtract the NRR from the C-weighted TWA in the worker's environment, or lacking that, to use the 7-dB adjustment (meaning subtraction) to the NRR required by Appendix B of the OSHA regulation before subtracting the NRR from the worker's A-weighted TWA.

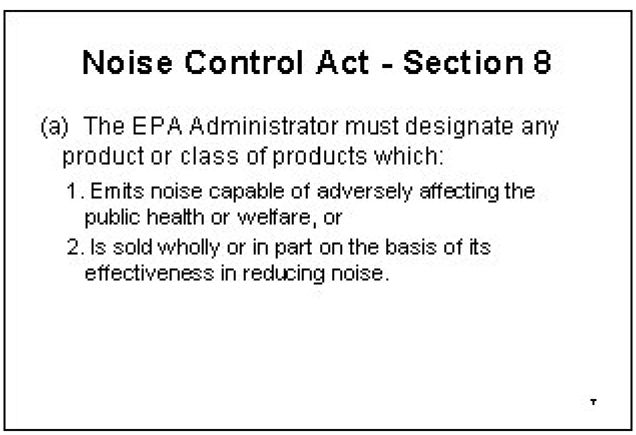
Most employers select their hearing protectors either by subtracting the NRR from some estimate of the worker's TWA, or they just pick protectors with large NRRs and hope for the best. However, some large companies have a policy similar to OSHA's, where they use the NRR minus 7 dB, divided by 2. One large employer which has used this method is the 3M Company .

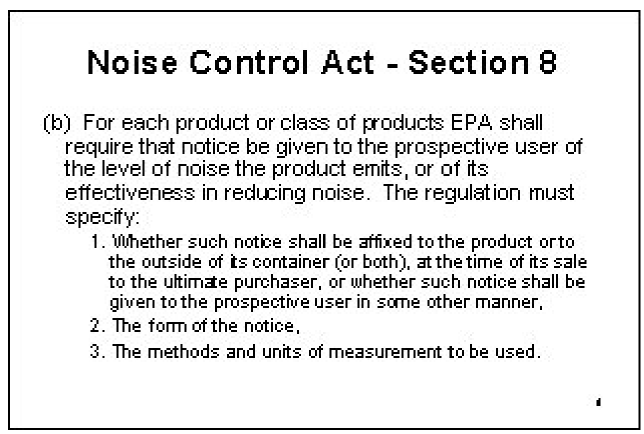
The Noise Control Act

EPA's Office of Noise Abatement and Control was given the responsibility of implementing the requirements of the Noise Control Act (NCA, 1972), which it did with some degree of vigor between 1973 and 1982. Despite the fact that the program was shut down by the Administration in 1982, Congress has never repealed the Noise Control Act. The Act's mandates have not changed, although the program remains largely unfunded.





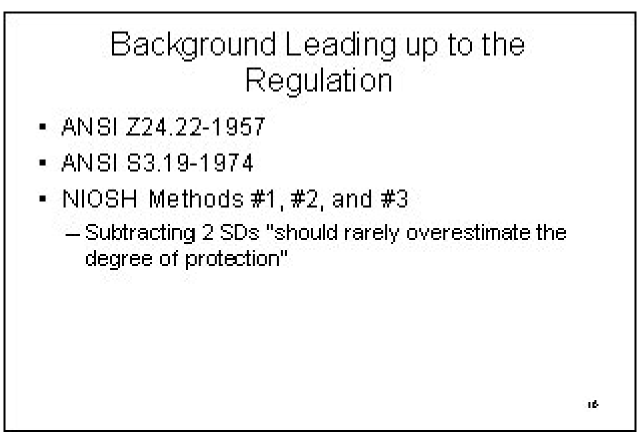




Rationale for Labeling Hearing Protectors:

According to EPA's *Background Document for the Labeling of Hearing Protectors*, the best way to control noise is at its source (EPA, 1977). Section 6 of the Noise Control Act directed EPA to issue regulations for maximum levels of noise emitted by new products. But the Agency recognized that it would be many years before the EPA could regulate all the major sources of noise. Also, the document acknowledged that it was not technically and economically feasible to control all sources to the level needed to prevent adverse effects of noise. In addition, most of the EPA's noise regulations applied only to new products, so the public needed protection against the noise of in-use products. Therefore, providing information regarding the performance of hearing protection devices would assist individuals with an immediate, potentially effective, and relatively easy and inexpensive method of protection against hazardous noise levels.

Background Leading up to the Regulation:



There had been considerable consensus activity in the field before EPA embarked on its regulatory process. ANSI Z24.22, "American Standard Method for the Measurement of the Real-Ear Attenuation of Ear Protectors at Threshold" (ANSI, 1957) had been published in 1957, which was revised to become ANSI S3.19-1974, "American National Standard Method for the Measurement of Real-Ear Protection of Hearing Protectors and Physical Attenuation of Earmuffs." (ANSI, 1974). The revised standard included a physical method for measuring the attenuation of earmuff devices and also the substitution of narrow bands of noise instead of pure tones in the psychoacoustical measurement of hearing protector attenuation. According to EPA, the new standard was not popular because the results generally showed less attenuation than the tests according to the older standard. Also, there was a common perception that the current ANSI standard was too complex and there was a need for simplicity. It was difficult for many people to relate octave-band data to the commonly used A-weighted sound level descriptor. This perception led to the development of proposed single-number rating techniques.

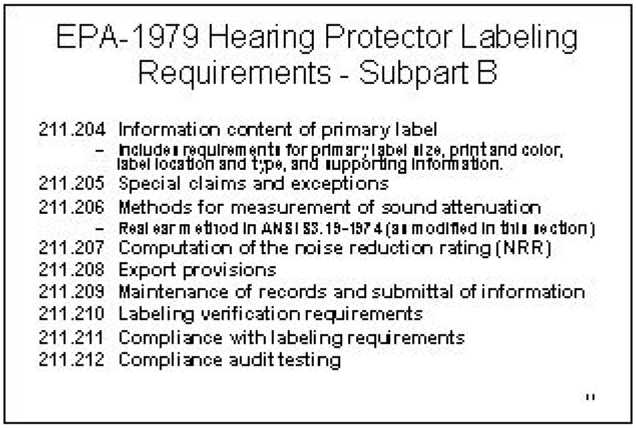
There are always tradeoffs, however, between simplicity and precision. One is the dependence of hearing protector performance on the spectrum of the noise environment. The other is the natural variation among individual responses expressed as the standard deviation.

In 1975, NIOSH put forward three proposed single-number ratings (NIOSH, 1975). Methods #1, #2, and #3 are listed in decreasing order of precision and increasing order of simplicity. The less precise methods include adjustments to guard against overestimating the noise reduction factor. In general, the methods with greater the precision show greater noise reduction factors, but they are more complicated to use. Method #1, the "long method," requires-octave band noise levels as well as A-weighted sound levels. Method #2, originally developed by James Botsford, uses a standard "pink noise" and requires taking the difference between A-weighted and C-weighted noise levels. It incorporates an adjustment of 3 dB to account for spectral uncertainty. Method #3 is the simplest, where all that is needed is the A-weighted noise level, but it incorporates an additional adjustment of 8.5 dB to account for spectral uncertainty.

All three methods use a 2-standard-deviation (SD) adjustment to the mean attenuation value to account for individual variability. According to the NIOSH report, subtracting 2 SDs "should rarely overestimate the degree of protection." (NIOSH, 1975)

EPA Issues its Labeling Regulation:

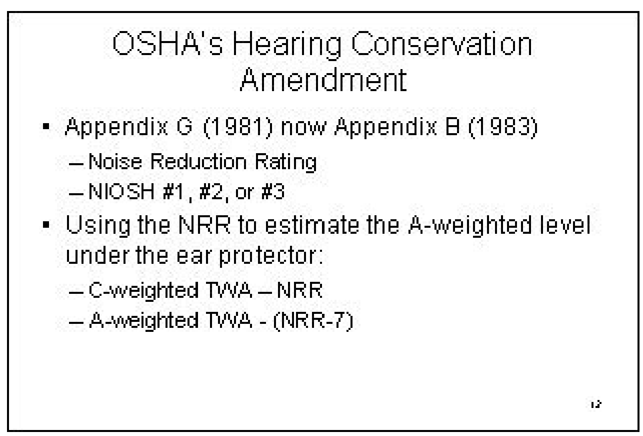
EPA issued a proposed labeling rule in June of 1977 and held public hearings later that year. According to the preamble of the final rule, which was promulgated in 1979, a large majority of the public comments received by EPA favored the proposed labeling program. Most of these comments came from citizens, whereas most of the industry commentors disagreed with various aspects of the program. While EPA modified or clarified some aspects of the proposal, the final rule was promulgated in 1979 with no major changes (EPA, 1979).



Subpart A of the 1979 rule deals mainly with general provisions for the labeling of all noise emitting and noise reducing products, including the label content, format, type, and location, as well as administrative requirements, such as inspection and monitoring, and conditions for exemptions. Subpart B applies specifically to hearing protection devices. The major requirements of the regulation are listed in the figure above.

POST-EPA EVENTS

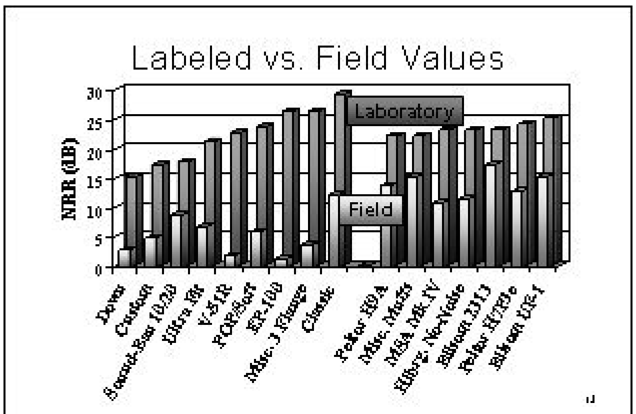
OSHA's Hearing Conservation Amendment:



The NRR received another boost when OSHA issued the hearing conservation amendment to its noise regulation (OSHA, 1981). Appendix G of the amendment (which is Appendix B in the revised version) (OSHA, 1983a) is entitled "Methods for Estimating the Adequacy of Hearing Protector Attenuation." It gives employers a choice between using the NRR or any one of the three NIOSH methods mentioned previously. OSHA recommends the NRR, which the agency describes as a simplification of NIOSH Method #2, as the most convenient method, and it is doubtful that virtually any employers have chosen to use the alternative methods. To estimate the employee's A-weighted exposure level beneath the ear protector, the NRR is to be subtracted from the employee's C-weighted TWA. In the absence of C-weighted measurements, the NRR should be subtracted from the A-weighted TWA after subtracting a 7-dB penalty from the NRR.[1]

Field Studies Of Hearing Protector Attenuation:

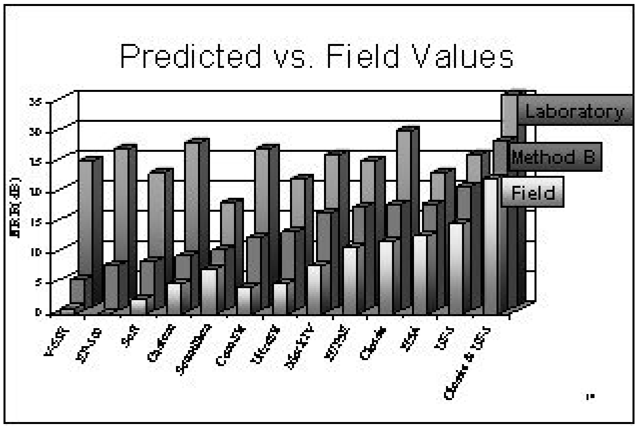
From the mid-1970s through the 1990s, investigators performed numerous studies of the attenuation workers received as they wore hearing protectors on the job. The data derived from these investigations threw cold water on NIOSH's optimistic statement that a rating using a 2-SD adjustment "should rarely overestimate the degree of protection." Field attenuation proved to be about ⅓ to ½ of that realized in the laboratory, even in companies with fairly decent hearing conservation programs.



This figure shows a comparison of labeled NRRs published in North America to real-world attenuation results derived from 22 separate studies (from Berger, 2000). One can see that the disparity between laboratory NRRs and the field "NRRs" is huge, despite the fact that the field data bars reflect the mean minus one standard deviation rather than two standard deviations, as in the conventional method. These data support the use of a method that more closely reflects the real-world picture, such as a rating method derived from the new ANSI standard's Method B. While the current NRR is derived by a method that treats subjects as "test fixtures," the Method B procedure calls for subjects who are naïve

[1] Note that by subtracting the 7-dB correction factor from the NRR, OSHA is actually derating the correction factor as well as the NRR. If instead the 7-dB penalty were added to the A-weighted TWA, the estimated level beneath the protector would be higher.

with respect to the use and testing of hearing protectors and are told to fit the device as best they can by using the same instructions that would be available to them in the field.



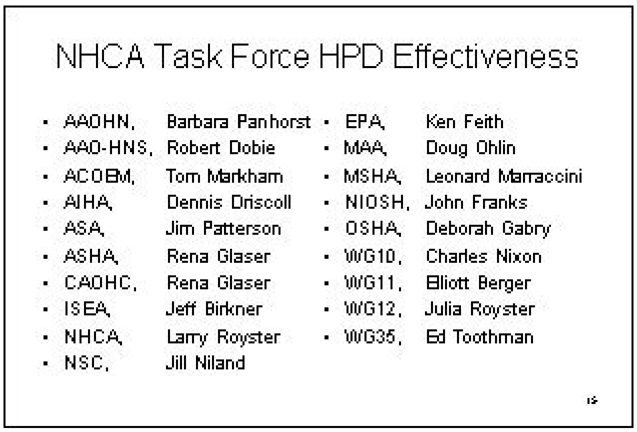
Another reason why a more realistic measure of attenuation is needed is that the NRR is not even very good for *rank-ordering* the attenuation capabilities of hearing protectors. This figure taken from Berger and Kieper (2000) shows how the revised ANSI standard's Method B rank-orders a series of protectors in a manner quite similar to the field studies, even though they still overestimate the field data somewhat. Keep in mind that the labeled NRRs are computed with a 2-SD correction, while the field and Method B data are computed with a 1-SD correction.

<u>ISEA Meeting in April 1993:</u>

Individuals representing industry, government, and professional organizations expressed concern about the status and implementation of the EPA labeling regulation. Consequently, the Industrial Safety Equipment Association (ISEA) called a meeting of interested parties in April of 1993 (reported in Royster, 1995). This meeting stimulated action on the part of several organizations to form a Task Force on Hearing Protector Effectiveness.

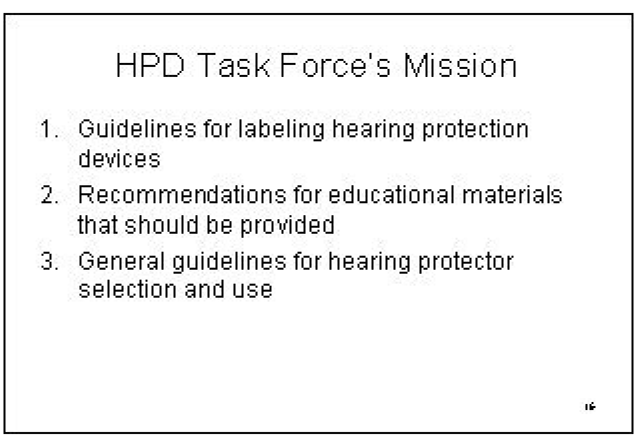
FORMATION OF THE NATIONAL HEARING CONSERVATION ASSOCIATION (NHCA) TASK FORCE (Royster, 1995)

The Task Force met under the auspices of the National Hearing Conservation Association and was chaired by Larry Royster. Initially, there were 15 organizations represented on the Task Force plus four ANSI working groups. The figure below gives the names of these groups and the individuals representing them.



It is important to note that some of the members were participating informally and not as official representatives of their organizations. Consensus was achieved among the members with only 2 negative votes, and NHCA petitioned EPA recommending changes in the hearing protector labeling rule. NHCA was later joined in the petition by several other professional organizations from the Task Force, including the AAOHN, AIHA, ASHA, and CAOHC, plus two organizations not involved in the Task Force, the American Academy of Audiology (AAA), and the American Society of Safety Engineers (ASSE).

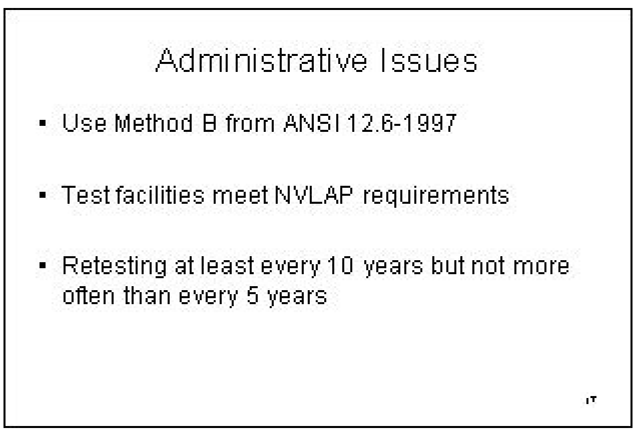
The principal mission of the Task Force was to develop guidelines for labeling hearing protection devices, recommendations for educational materials, and guidelines for hearing protector selection and use.



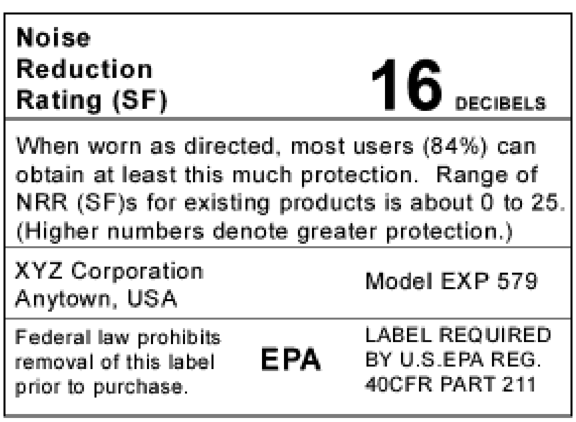
The Task Force issued the following caveat in its report: The most important recommendation is not necessarily the way hearing protection devices are tested or the value of one rating method over another, but the criteria for selecting the hearing protector, which should always include issues of comfort, compatibility with other safety equipment, and personal preference. According to Royster, "The Committee felt very strongly that no *single* HPD characteristic, such as the present NRR or the recommended NRR(SF) should be used in selecting the HPD to be worn by any one individual." (Royster, 1995, p.6) (italics added). The Task Force noted that approximately 90% of the noise-exposed population needs only 10 dB of attenuation to obtain adequate protection.

RECOMMENDATIONS OF THE NHCA TASK FORCE ON HEARING PROTECTOR EFFECTIVENESS (Royster, 1995)

Administrative Issues:



Members of the NHCA Task Force agreed that the current NRR is too high and that the number on the label should better represent hearing protector performance in the field. They favored the adoption of Method B from the draft ANSI standard that was being prepared by ANSI working group S12/WG11. The rating scheme would be the NRR (subject fit) or NRR(SF). The standard was designated then as ANSI S12.6-199x, (a bit of courage reflected in the 1990s designation, knowing how long it takes to develop or revise and ANSI standard), and the standard is now known as S12.6-1997 (ANSI, 1997). The Task Force also recommended that test facilities meet the requirements of the Department of Commerce's National Voluntary Laboratory Accreditation Program



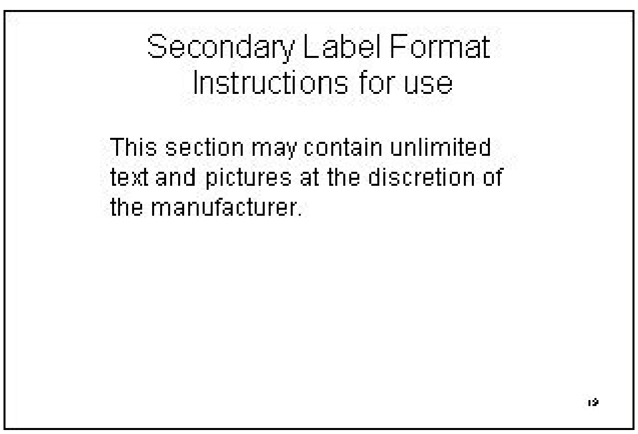
(NVLAP), and that retesting of hearing protectors should take place at least every 10 years but need not be more often than every 5 years.

Primary Label Format:

There are several important differences between the primary label recommended by the Task Force and the current one. First, the Task Force's recommended label uses the NRR(SF) instead of the NRR, and consequently incorporates a 1-SD rather than the 2-SD adjustment. Also new is the indication that real-world attenuation will vary among individuals and that approximately 84 % of the population using the labeled NRR(SF) will achieve at least this much protection. This proposed label states the range of existing NRR(SF)s is approximately 0-25 instead of the current 0-30.

Secondary Label Format:

The Task Force also recommended several additions and changes to the secondary label.



The Task Force recommended more extensive and user-friendly instructions than in the current practice.

In addition to the most critical consideration, which is a comfortable, noise-blocking seal, the NHCA task force identified several other important issues :

1. The HPD's noise reduction: NRR(SF) is only one of the important considerations.

2. Wearer's TWA: Again, the Task Force believed that since most workers' exposures would be 95 dBA or less, an NRR(SF) of 10 should be sufficient.

3. Variations in noise level are of concern. For example, in levels that fluctuate between 70 dBA and 110 dBA, some supervisors require high-attenuating protectors or even double protection to be worn throughout the exposure. The hazards and inefficiencies of this practice are obvious. There needs to be a great deal of education and improved public awareness on this issue. Even a well-used earmuff with an NRR(SF) of 18 would not be appropriate for much of this exposure period.

4. User preference: The hearing protector fitter should be mindful of the worker's needs in that earcanals come in different shapes and sizes, and some workers may not have the finger strength to roll down a foam plug.

5. Communication needs: Again, to over-protect may be counter-productive for the sake of communication and warning signal audibility.

6. Hearing ability: Persons with hearing losses, especially noise-induced hearing losses, have at an added disadvantage when they wear hearing protection devices. Hearing protectors tend to be most efficient at attenuating the higher frequencies. Add this fact to a high-frequency hearing loss and the person is additionally "deafened." It may be especially dangerous to require hearing protectors with high attenuation values in situations where communication is essential. Much education is needed on this topic.

7. Compatibility with other safety equipment: The user needs to achieve a good seal without interference with other types of safety equipment, such as safety glasses or respirators.

8. Wearer's physical limitations; this could included missing or arthritic fingers, among other problems.

9. Climate and other working conditions: For example, plugs tend to be preferred in areas of high humidity, plugs or small-volume muffs in confined spaces. White earplugs could be problematical for use around dairy products, and corded earplugs could become caught in machinery.

10. Replacement, care, and use: This would include recommendations for regular checking and replacement programs.

Table 1. Laboratory attenuation values re: ANSI S12.6-199x (subject fit) along with corresponding HML values and the NRR(SF) (from Royster, 1995).

Test Frequency (Hz)	**125**	**250**	**500**	**1000**	**2000**	**4000**	**8000**	**H**	**M**	**L**	**NRR(SF)**
Mean Atten. (dB)	**17.9**	**19.0**	**21.0**	**24.7**	**29.9**	**35.6**	**34.6**	**25**	**18**	**14**	**16**
S D (dB)	**7.3**	**6.3**	**7.3**	**6.4**	**5.3**	**5.0**	**5.4**				

The Task Force recommends the above type of table for the secondary label and adds the following notes:

1. The data in the table above are representative of a foam earplug. For 2- and 3-position devices, such as earmuffs or semi-inserts hearing protectors, data would also have to be provided for the alternative positions, so the table could contain up to four additional rows.

2. The H, M, and L values refer to the High, Middle, and Low indices from ISO 4869-2, which require both C-weighted and A-weighted sound levels.[2]

Secondary Label Format
How to Use NRR(SF)

The NRR(SF) may be subtracted from an A-weighted sound level or TWA

1. For example, the noise level is 92 dBA.
2. The NRR(SF) is 16 dB.
3. Most users (84%) should be protected to a level of 76 dBA.

Tip: A better estimate of the protected level can be obtained by adding 5 dB to the NRR(SF) and subtracting it from a measurement made using C- instead of A-weighting.

3. How to use the NRR(SF) : The NRR(SF) is designed for use with A-weighted sound levels so that the confusing subtraction of 7 dB is no longer necessary. If the noise environment is predominantly low-frequency, the user may either choose to add the 5 dB and then subtract the adjusted NRR(SF) from the C-weighted noise level, or he or she has the option of using the HML method.

4. Applicability: This section reiterates the amount of protection to be expected *only* if the protector is used as directed, so users will understand the importance of correct insertion and use. One is to be concerned, of course, about the 17% of those in the example who will obtain less than 16 dB, but one might also be concerned about those receiving more than 30 dB, since over-protection could be a problem.

Secondary Label Format
Estimating Noise Reduction for Individual Users

The labeled values of noise reduction are based on laboratory tests. It is <u>not possible</u> to use these data to reliably predict levels of protection achieved by a given individual in a particular environment. To ensure protection, those wearing hearing protectors for occupational exposures must be enrolled in a hearing conservation program. Non-occupational users should have hearing evaluations by an audiologist, qualified physician, or other qualified professional, on a regular basis.

The statement about the relative unimportance of differences between ratings of less than 3 dB is to discourage purchases and users from the hair-splitting mind-set of "bigger is always better."

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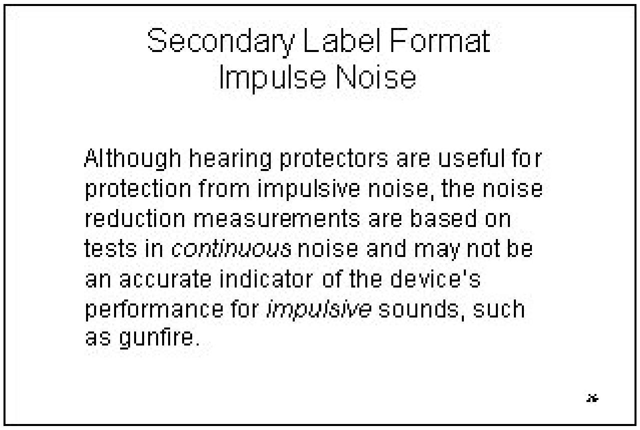
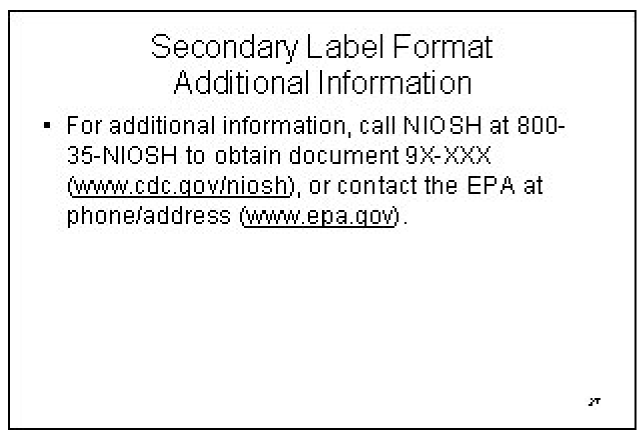
[2] H and M are used in noise environments with primary energy in the mid and high frequencies, where $L_C - L_A \leq 2$dB. M and L are used in noise environments with primary energy in the mid and low frequencies, where $L_C - L_A \geq 2$dB. These levels are arrived at using a range of 8 different octave-band spectra. The rationale behind including them is that hearing protectors usually attenuate less in the low frequencies than they do in the high frequencies and this type of rating gives the user an opportunity to take spectrum into account, particularly for low-frequency noise environments.



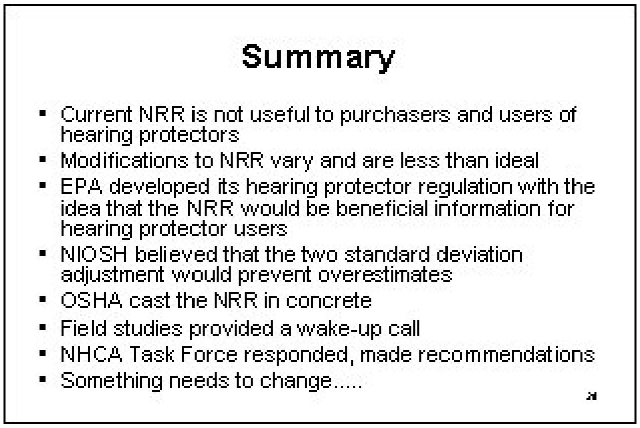
5. Estimating noise reduction for individual users is not possible since these values are based on laboratory tests. Hearing conservation programs or hearing evaluations for non-occupational users are a necessity. The rationale for this caveat should be self-evident. Too many employers are still under the impression that all they need to do is purchase protectors and say, “Here, wear this.”

6. Impulse noise : Although the NRR is based on tests in continuous noise and therefore is not strictly applicable to impulsive noise environments, it is interesting to note that the Task Force members expected at least the same level of protection, and most likely even higher, when protectors are used in impulsive noise.

7. Additional information: Here the Task Force intended that a cartoon pamphlet would be prepared by its members, explaining all features of the Secondary Label and to be made available by NIOSH or EPA.



SUMMARY



In summary, it is clear that the current NRR is not useful to purchasers and users of hearing protectors because it bears virtually no resemblance to the attenuation that is achieved in the field. Moreover, it doesn't even do a good job of rank-ordering the real-world attenuation of protectors.

The modifications used by OSHA and NIOSH are not satisfactory because they are not well supported by test data and they differ between the two Agencies. In fact, the OSHA derating could lead to overprotection in some instances.

EPA meant well when it developed and promulgated its regulation for hearing protectors, but the information supplied by the NRR has turned out not to be beneficial.

The NIOSH belief that the 2-SD adjustment would prevent overestimates has turned out to be untrue.

OSHA's hearing conservation amendment has further solidified the legitimacy of the NRR and, in fact, almost forced people to use it.

Field studies of hearing protector attenuation have provided a wake-up call to the entire profession, to which the inter-organization Task Force convened by NHCA has responded. And now, it is quite clear that something needs to be done, perhaps along the lines of the Task Force's recommendations. The papers presented at this workshop should provide some viable solutions.

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Comparison of the Regulatory Noise Reduction Rating (NRR) and the Required ANSI S3.19 Test Method With Real-World Outcomes and Results From Testing With the New ANSI S12.6B Method

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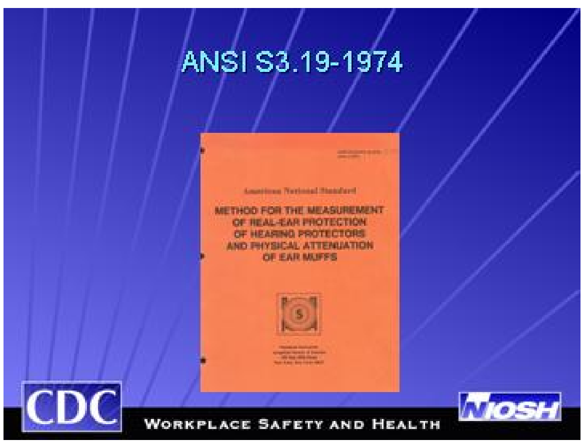
National Institute for Occupational Safety and Health

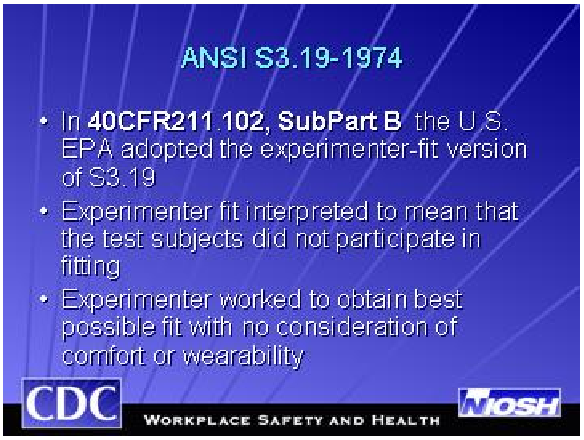
In the previous presentation, Dr. Suter covered the history of ANSI standards for testing hearing protectors, as well as the development of the EPA's rating system and its application by OSHA, including derating schemes used by OSHA and recommended by NIOSH. She also discussed the work of the NHCA Task Force on Hearing Protector Effectiveness. What I will address here are the issues of the present testing method required by the EPA and the potential offered by changing to a newer subject-fit method as defined in ANSI S12.6-1997. My presentation will address only linear, passive hearing protectors, since Dr. Casali's presentation will discuss the many issues related to non-linear devices. Nor will I address the rating system directly, since Dr. Murphy will discuss that matter following my presentation.



Slide 1: ANSI S3.19-1974 (R-1979) is a legacy standard that was adopted by the EPA in its labeling rule. The standard has since been rescinded by ANSI, but lives on in the regulation.

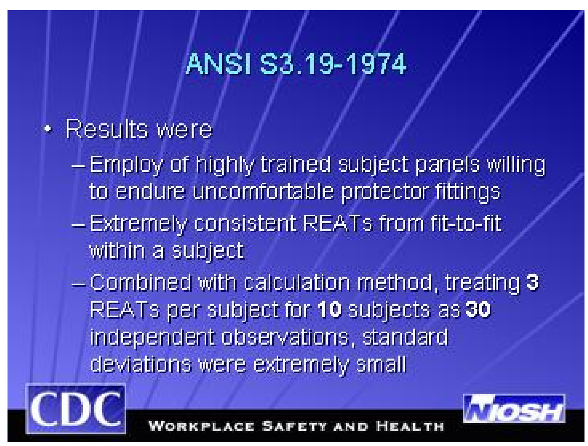
Slide 2: ANSI S3.19 provided two methods for testing hearing protectors: experimenter fit and subject fit. The psychoacoustic procedure is auditory threshold testing for noise bands (diffuse sound field noise-band audiometry) with ears open, then with ears occluded. In the experimenter-fit method, the experimenter is responsible for determining how well the protector is fitted for testing. In the subject-

fit method, the subject is responsible for that determination. The difference between the noise-band thresholds with ears open and ears occluded is Real Ear Attenuation at Threshold (REAT).



Slide 3: In 40 CFR211.102, SubPart B, the U.S. EPA adopted the experimenter-fit version of S3.19. A justification was that the experimenter fit would be what well-trained, well-motivated hearing protector wearers could achieve.

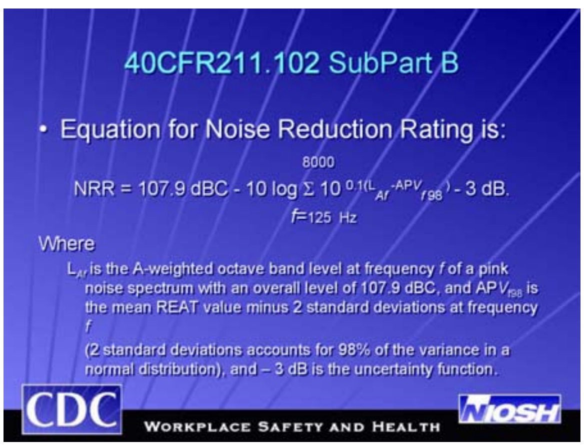
Experimenter fit was interpreted to mean that the test subjects did not participate in the fitting. The experimenter might use a fitting noise and ask the subjects to engage in such tasks as covering their occluded ears with their hands to see if there were differences between the ears, but the subjects did not touch the protectors once they were fit or at all during the ears-occluded audiometry sessions.



Slide 4: The results were:
Testing laboratories recruited subjects who were willing to endure uncomfortable protector fittings and willing to perform the noise-band audiometry diligently. Given the requirements of the standard that test subjects have hearing within normal limits, subject panels were often made up of college students who could be panel members for a period of a few years.

Because of the experience of the experimenter, REATs were extremely consistent from fit-to-fit within a subject and the REAT levels were also very high. When I performed such testing in the early 1980s, we would often create a test panel by screening potential subjects with another protector to get the best panel for the actual test.

For the correct statistical treatment of the data, three REATs from each of the test subjects would be averaged, and these means would have been used to calculate a grand mean and a standard deviation of the subject means. S3.19, however, called for treating each REAT as a separate observation. Thus both the mean REAT and the standard deviation were based on the 30 observations. While this mean would have been no different from the grand mean, a standard deviation calculated with an N of 30 will be different than the correct standard deviation of 10 averages of each subject's three trials. The Noise Reduction Rating has been determined with statistically incorrect standard deviations.

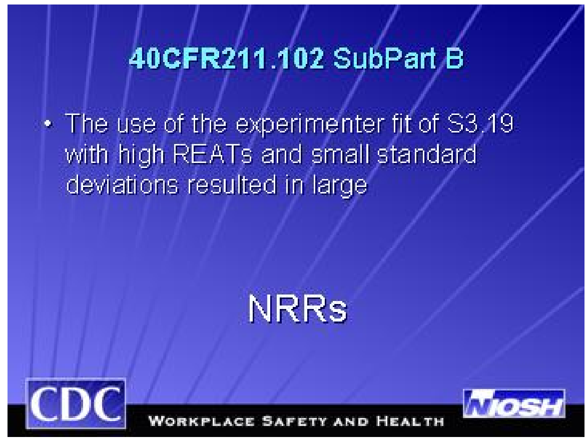


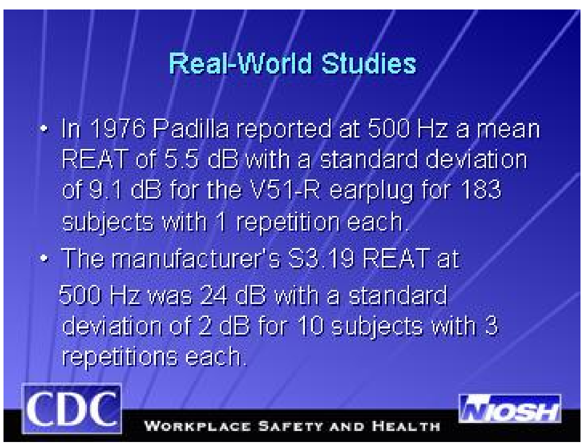
Slide 5: The equation for the noise reduction rating (NRR) is:

$$NRR = 107.9\ dBC - 10 \log \sum_{f=125\ Hz}^{8000} 10^{0.1(L_{Af} - APV_{f98})} - 3\ dB.$$

This equation is similar to that used for any single number rating. What it expresses is that the log-summed A-weighted REATs minus some allowance for variance in the data, in this case 2 standard deviations, are subtracted from a log-summed pink noise. In the case of the NRR, the pink noises are 1/3 octave bands centered at 125, 250, 500, 1000, 2000, 3150, 4000, 6300, and 8000 Hz, which total 107.9 dB. Then 3 dB is subtracted to allow for spectral uncertainty – the uncertainty that the protector will be used in a noise with a spectrum that is not flat. The NRR is intended to be subtracted from the user's C-weighted noise exposure level to determine the A-weighted protected exposure level. If the exposure level is measured in A-weighted decibels, 7 dB are subtracted from the NRR in an effort to account for differences in C- and A-weighted noise measurements. In theory, if users wore the protector as it was tested, 98% would receive the labeled attenuation or greater.

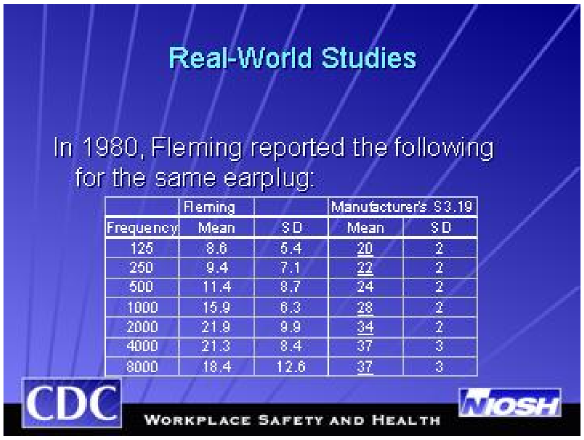
Slide 6: However, the use of the experimenter-fit with experienced subject panels resulted in high REATs and small standard deviations. That, in turn, resulted in large, over-predictive NRRs.





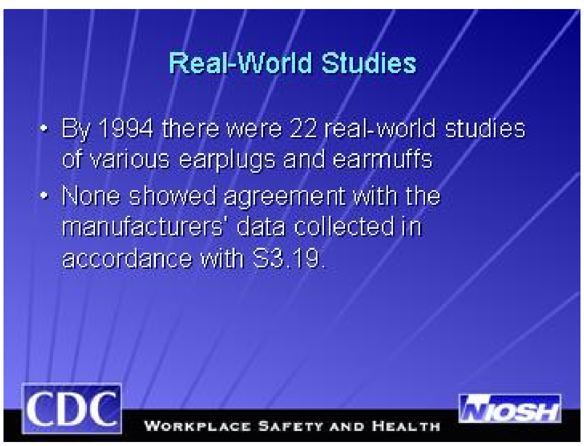
Slide 7: In 1976, Padilla reported the first real-world study of the attenuation of an earplug, the V51-R, which has been around for many years. It is a mushroom-shaped, single-flanged, premolded vinyl earplug. Only one frequency was tested, 500 Hz. The mean REAT was found to be 5.5 dB and the standard deviation for 183 subjects was 9.1 dB. There was one measurement per subject. This was a spontaneous test in that workers were taken off the production line, given a plaque to hold as they walked to the testing facility so that they couldn't touch the earplugs before the test, and tested wearing the protectors. Then, they removed the protectors for the ear-open portion.

The manufacturer's S3.19 REAT at 500 Hz was 24 dB with a standard deviation of 2 dB for a 10-subject panel with three repetitions each. Conclusion? Padilla's workers weren't wearing the protector correctly.



	Fleming		Manufacturer's S3.19	
Frequency	Mean	SD	Mean	SD
125	8.6	5.4	20	2
250	9.4	7.1	22	2
500	11.4	8.7	24	2
1000	15.9	6.3	28	2
2000	21.9	9.9	34	2
4000	21.3	8.4	37	3
8000	18.4	12.6	37	3

Slide 8: In 1980, Fleming studied the same earplug with 9 subjects and found the following: At 500 Hz, the mean REAT was 11.4 dB with a standard deviation of 8.7 dB, which was not statistically different from Padilla's 5.5 dB mean REAT and standard deviation of 9.1 dB. Fleming's data were statistically different from the manufacturer's S3.19 data at each test frequency.

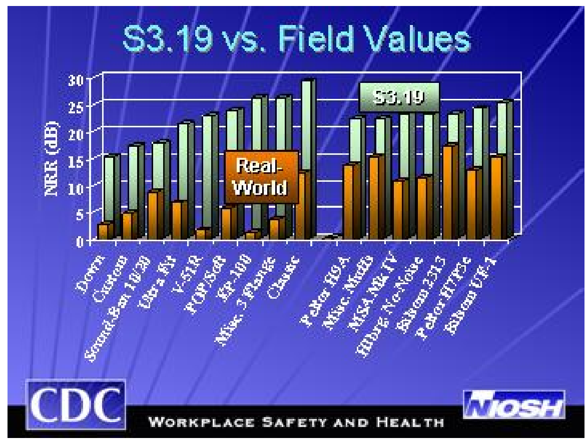


Slide 9: By 1994 there were 22 real-world studies of various earplugs and earmuffs. Some of these were spontaneous studies, as with Padilla and Fleming, and some of these were scheduled. In a scheduled study, the test subject appears at the test site, dons the hearing protector as he or she wears it normally, and is tested in a controlled environment that meets the diffuse sound-field requirements of the standard. S3.19 and S12.6 have essentially the same requirements, except that S3.19 requires a reverberant sound field with maximum and minimum reverberation times at each test frequency, while S12.6 has only a maximum reverberation time for each test frequency. In spite of the face validity of the spontaneous test – prohibiting the test subject from touching the hearing protector from the time of leaving the work area until being tested in the ears-occluded condition - there are no statistically significant differences between data collected in spontaneous and scheduled tests. This casts doubt, for at least this

situation, on the notion that the test subject will fit protectors better under supervision than during normal day-in and day-out use.

None of the studies showed agreement with manufacturer's S3.19 data. In fact, all REATS and resultant NRRs were statistically lower for the real-world tests than for the S3.19 tests.

Slide 10 (from Berger, 2000): Not only were the real-world NRRs lower than the S3.19 NRRs, there is no correlation between the differences. That is, it is not possible to develop a formula that would universally allow correction between real-world data and S3.19 data for all devices. This slide shows the comparison of real-world NRRs to S3.19 NRRs for the 9 earplugs and 7 earmuffs that were tested in the 22 studies.



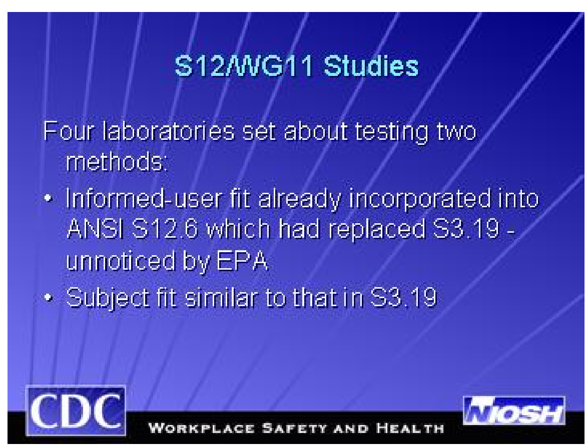
In spite of the lack of correlation between the two outcomes, OSHA applies a universal 50% derating to the NRR when determining whether a hearing protector would provide adequate attenuation to allow a hearing-protector based hearing conservation program to be implemented in lieu of a program based on engineering noise control. However, OSHA does not apply a derating when determining whether a given protector is adequate for a given worker in a given noise.

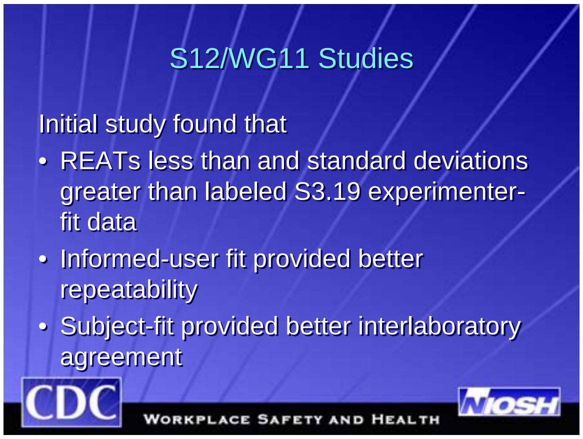
NIOSH has attempted to apply a derating factor that reflects the fact that the difference in real-world vs. S3.19 NRRs is smaller for earmuffs and slow recovery foam earplugs than it is for other protectors. Consequently, NIOSH applies a variable derating scheme: 25% for earmuffs, 50% for slow-recovery foam earplugs, and 70% for all other earplugs. The derating is applied to determine whether a given protector should be adequate for a worker in a given noise. NIOSH does not recommend that hearing protectors be used in lieu of engineering noise control and therefore does not recommend a derated NRR for the purpose of determining whether noise control-based interventions can be avoided.

NIOSH has not applied a derating for custom-molded earplugs, recognizing that these devices are only as good as the impression that is taken to make the device. With a good impression, they can be extremely effective with high noise reduction, or with a poor impression than can merely be ear jewelry, offering little or no noise reduction.

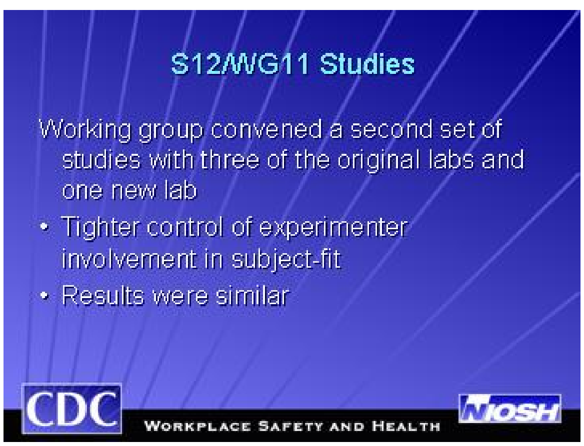
Slide 11: ANSI Standards Accreditation Committee S12 directed working group S12/WG11, chaired by Elliott Berger, to begin the development of a new test method that would provide a better predictor of hearing protector performance in the real-world . The working group solicited the cooperation of four laboratories to conduct self-funded studies of various methods. The laboratories were the EarCal Laboratory at E·A·R/Cabot, which is now Aearo, the Auditory Systems Laboratory at Virginia Tech, USARL at Ft. Rucker, and NIOSH in Cincinnati.

Slide 12: The four laboratories set about testing two methods, the informed-user fit which was already incorporated in ANSI S12.6 as the experimenter-supervised fit, and a subject-fit method similar to that in S3.19. No S3.19 experimenter-fit tests were done in this study. A rigorous protocol was developed and each lab followed the protocol carefully.





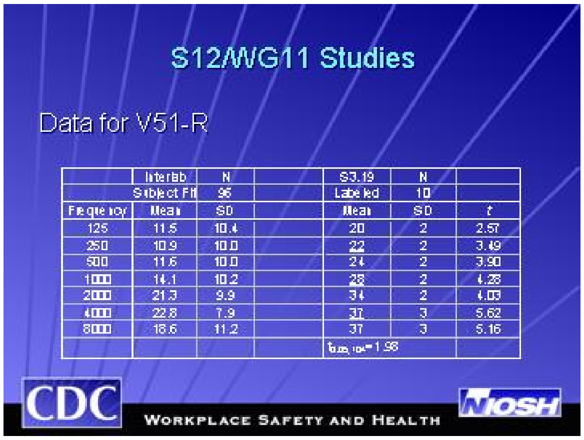
Slide 13: The initial study found that for both procedures the REATs were lower and the standard deviations were greater than the S3.19 values reported on the hearing protectors' labels. The protectors were the V51-R, the EP100, the E-A-R Classic, and the Bilsom UF-1 earmuff. The informed-user (experimenter-supervised) fit provided better repeatability than did the subject-fit method, and the subject-fit method provided better interlaboratory agreement or reproducibility. When this series of studies began, the expectation was the informed-user fit would be the better procedure. This was similar to the experimenter-supervised fit of version of S12.6 then current, which was intended to provide an "optimal" data set. The fact that the subject-fit procedure provided better interlaboratory reproducibility was a surprise, as was the fact that the subject-fit data were close to the real-world outcomes reported in the literature.



Slide 14: Consequently, the working group convened a second set of studies. Virginia Tech was unable to participate in the second interlaboratory study and was replaced by the Armstrong Laboratory at Wright-Patterson Air Force Base.

There was tighter control of the experimenter involvement in the subject-fit method – the experimenter was limited to reading a script and could provide no assistance outside of what was in the script. Thus, the subject-fit method became a test of the protector and its packaging since the subject was limited to the instructions provided by the manufacturer for fitting the device correctly.

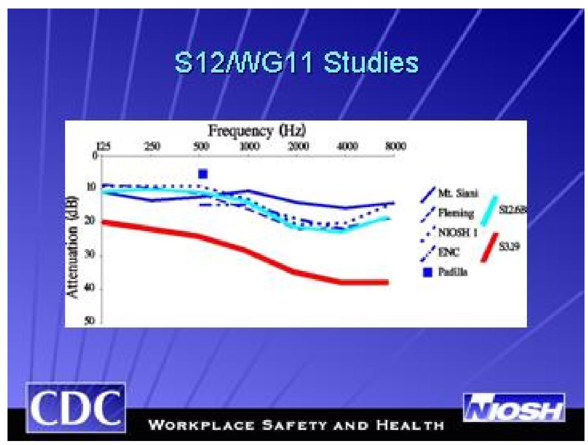
The test results were similar to the earlier study with the subject-fit method providing lower REATs and larger standard deviations, along with better agreement with real-world data and better interlaboratory reproducibility than the informed-user fit.

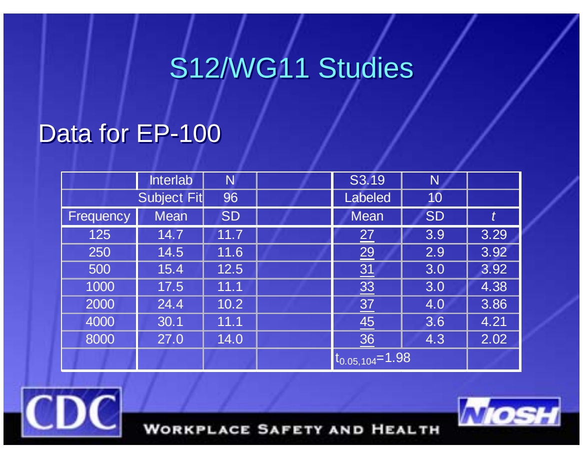


	Interlab	N		S3.19	N	
	Subject Fit	96		Labeled	10	
Frequency	Mean	SD		Mean	SD	*t*
125	11.5	10.4		20	2	2.57
250	10.9	10.0		22	2	3.49
500	11.6	10.0		24	2	3.90
1000	14.1	10.2		28	2	4.28
2000	21.3	9.9		34	2	4.03
4000	22.8	7.9		37	3	5.62
8000	18.6	11.2		37	3	5.16
				$t_{0.05,104}$=1.98		

Slide 15: This table shows the data from the second interlaboratory study for the V51-R earplug compared to the manufacturer's reported S3.19 data. In all cases the differences where statistically significant.

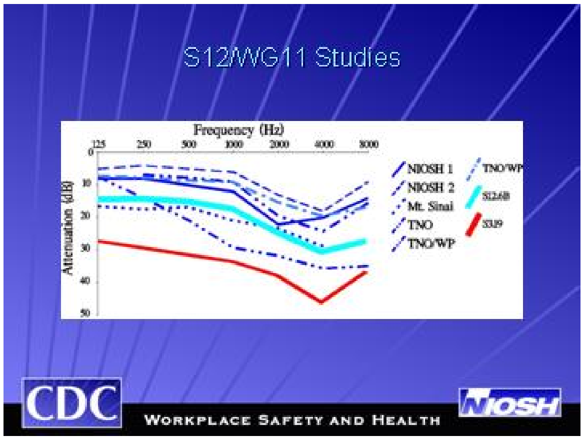
Slide 16: This graph displays comparisons for the V51-R earplug's mean REATs from the 5 real-world studies the mean subject-fit REATs from the second interlaboratory study (now incorporated in ANSI S12.6 as Method B), and the manufacturer's reported mean S3.19 REATs. The S3.19 mean REATs are far greater than the others, while the S12.6B REATs fall within those of the real-world studies and are not statistically significantly different from the real-world mean REATs.



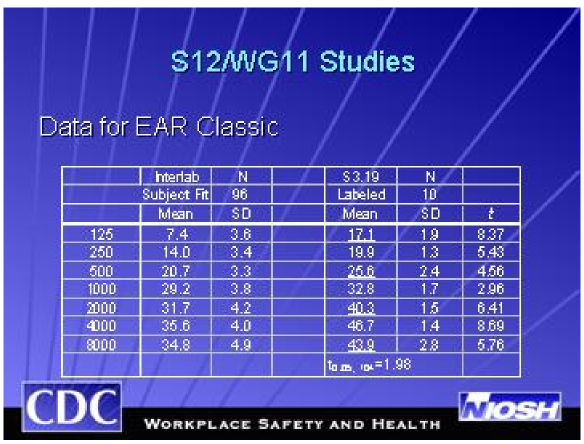


	Interlab	N		S3.19	N	
	Subject Fit	96		Labeled	10	
Frequency	Mean	SD		Mean	SD	*t*
125	14.7	11.7		27	3.9	3.29
250	14.5	11.6		29	2.9	3.92
500	15.4	12.5		31	3.0	3.92
1000	17.5	11.1		33	3.0	4.38
2000	24.4	10.2		37	4.0	3.86
4000	30.1	11.1		45	3.6	4.21
8000	27.0	14.0		36	4.3	2.02
				$t_{0.05,104}$=1.98		

Slide 17: This table shows the data for the second interlaboratory study for the EP100 earplug compared to the manufacturer's reported S3.19 data. In all cases the differences where statistically significant.

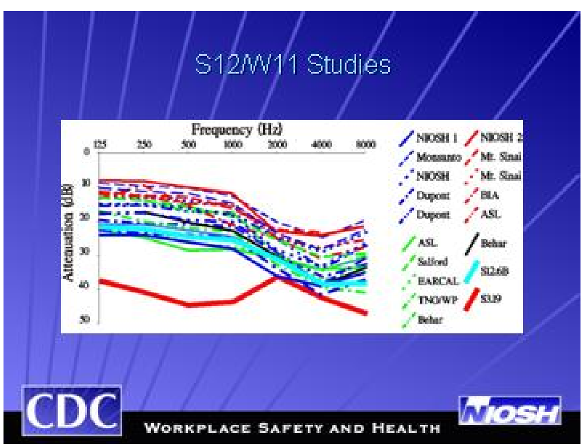


Slide 18: As with the V51-R, the manufacturer's reported S3.19 mean REATs for the EP100 are greater than the mean S12.6B REATs, and the mean S12.6B REATs are similar to and not statistically different from the mean real-world REATs for the 6 studies, with the exception of some frequencies for the second NIOSH study. The NIOSH field studies were conducted with large circumaural earmuffs while the others were conducted in a diffuse sound filed in a laboratory setting.

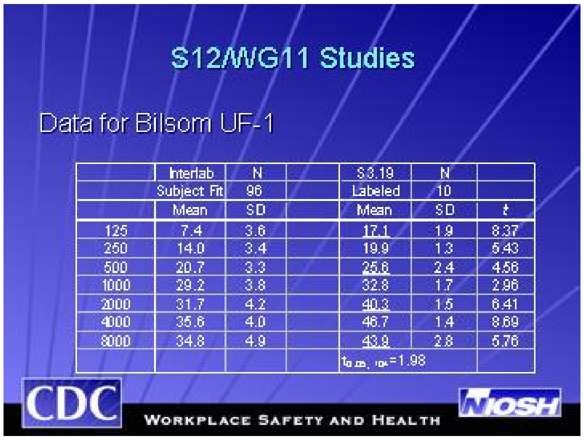


	Interlab	N		S3.19	N	
	Subject Fit	96		Labeled	10	
	Mean	SD		Mean	SD	t
125	7.4	3.6		17.1	1.9	8.37
250	14.0	3.4		19.9	1.3	5.43
500	20.7	3.3		25.6	2.4	4.56
1000	29.2	3.8		32.8	1.7	2.96
2000	31.7	4.2		40.3	1.5	6.41
4000	35.6	4.0		46.7	1.4	8.69
8000	34.8	4.9		43.9	2.8	5.76
				$t_{0.05,\,104}$=1.98		

Slide 19: This table shows the data for the second interlaboratory study for the E-A-R Classic earplug compared to the manufacturer's reported S3.19 data. In all cases, the differences were statistically significant.



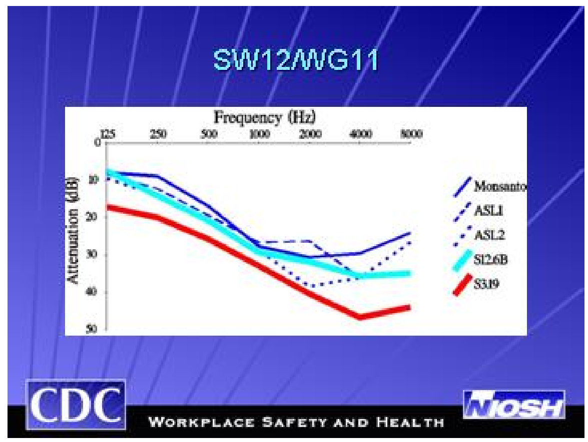
Slide 20: As with the V51-R and the EP100, the manufacturer's reported S3.19 mean REATs for the E-A-R Classic earplug are greater than the mean S12.6B REATs, and the mean S12.6B REATs are similar to and not statistically different from the mean real-world REATs for the 16 studies with a few exceptions for single frequencies.

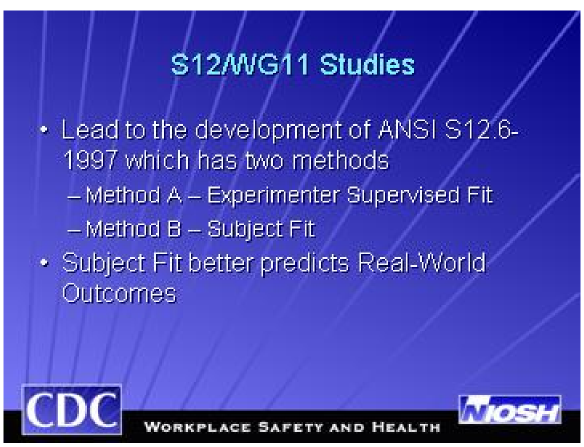


	Interlab	N		S3.19	N	
	Subject Fit	96		Labeled	10	
	Mean	SD		Mean	SD	t
125	7.4	3.6		17.1	1.9	8.37
250	14.0	3.4		19.9	1.3	5.43
500	20.7	3.3		25.6	2.4	4.56
1000	29.2	3.8		32.8	1.7	2.96
2000	31.7	4.2		40.3	1.5	6.41
4000	35.6	4.0		46.7	1.4	8.69
8000	34.8	4.9		43.9	2.8	5.76
				$t_{.05, 104}$=1.98		

Slide 21: This table shows the data for the interlaboratory study for the Bilsom UF-1 earmuff compared to the manufacturer's reported S3.19 data. In all cases the differences were statistically significant.

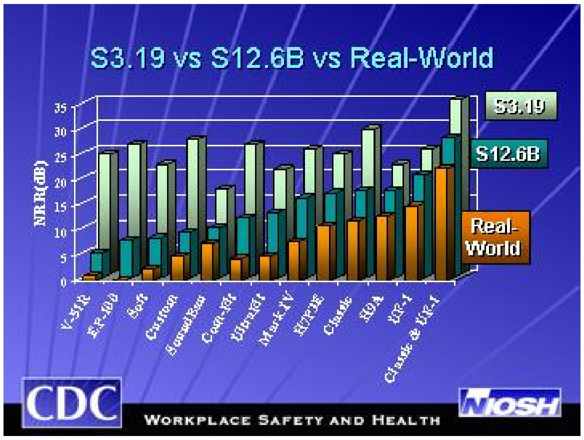
Slide 22 (from Berger and Kieper, 2000): As with the V51-R, the EP100, and the E-A-R Classic, the manufacturer's reported S3.19 mean REATs for the Bilsom UF-1 earmuff are greater than the mean S12.6B REATs, and the mean S12.6B REATs are similar to and not statistically different from the mean real-world REATs for the 3 studies.





Slide 23: In 1996, the working group revised ANSI S12.6 to include two methods: The experimenter-supervised fit remained unchanged from the earlier version of S12.6, and the subject-fit method was added as method B, hence the notation of the method as S12.6B.

The subject-fit method better predicts real-world outcomes and provides data with the best interlaboratory reproducibility. The mean REATs are lower, the standard deviations are higher, and any rating system that is based on the subtraction of a multiple of the standard deviation from the mean REAT will be lower than for either the experimenter-fit method of S3.19 or the experimenter-supervised fit of S12.6A. This applies to the NRR as well as to the SNR and HML of the ISO 4869 standard used throughout the European Union.



Slide 24: In terms of real-world data, while the S12.6B mean REATs are generally higher than the real-world data indicate, the S12.6B data are, in most cases not statistically different from the real-world data and they are correlated with the real-world data in that the rank ordering of real world NRRs with S12.6B NRRs is almost perfect. By contrast, the experimenter-fit S3.19 data are statistically different from and not correlated with the real-world data. This graph displays data for all of the devices tested by the working group interlaboratory study plus 8 other protectors, as well as a combination fit of the E-A-R Classic plug and the Bilsom UF-1 muff.

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Berger, E.H. (2000). "Hearing Protection Devices," Chapter 10 in E.H. Berger, L.H. Royster, J.D. Royster, D.P. Driscoll, and M. Layne, **The Noise Manual: Fifth Edition.** Fairfax, VA: American Industrial Hygiene Assoc., p. 421.

Berger, E.H. and Kieper, R.W. (2000). "Ongoing experience with laboratory-based subject-fit REAT methods for measuring hearing protector attenuation." **J. Acoust. Soc. Am., 108**(5, pt.2) p. 2619.

Deriving a New NRR from the ANSI S12.6B Method, Interlaboratory Reproducibility of Data, and Precision of the Data

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Division of Applied Research and Technology

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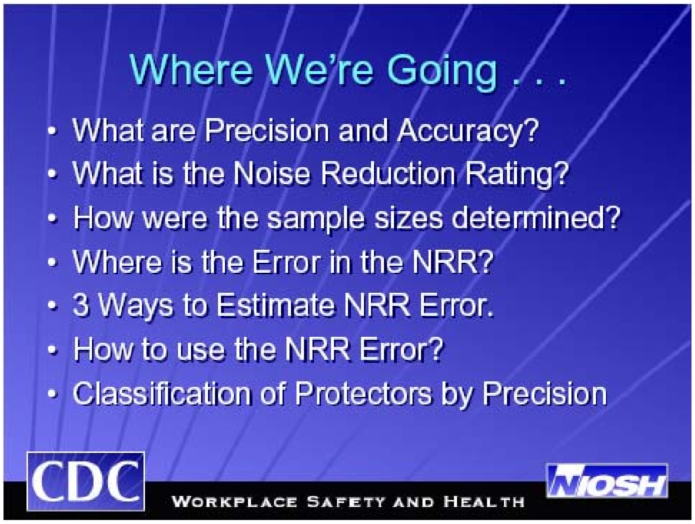
I am privileged to be speaking this morning about the ANSI S12.6 Method B interlaboratory reproducibility of data and the precision of that data. This talk will review the analysis of interlaboratory reproducibility and will extend those concepts to other methods for estimating the error in the Noise Reduction Rating (NRR). Three methods for estimating the NRR error will be developed and explained. Some of this presentation will be technical, however, with proper motivation and explanation, the essence of the concepts should become apparent.

Before continuing, the title of the presentation deserves some translation. In fact, this presentation seeks to answer the question, “When have enough subjects been tested?”

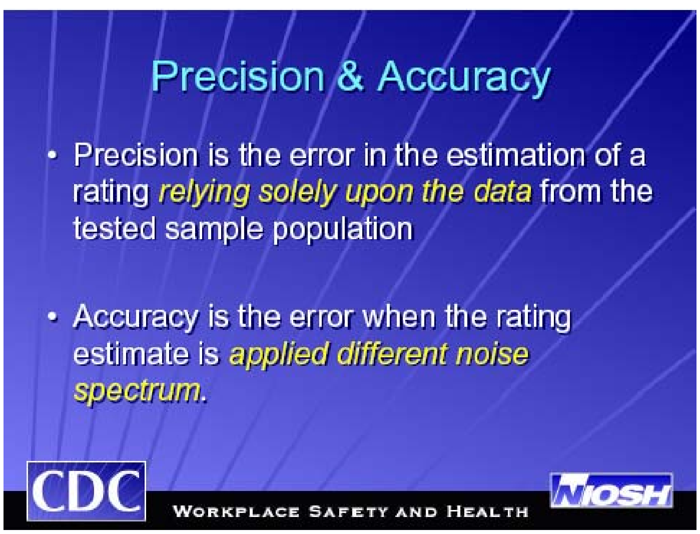
(Reference ANSI S12.6-1997; Royster et al., 1996; Murphy et al., 2003)



Several topics will be covered. First the definitions of Precision and Accuracy will be given and their relationship to hearing protection will be discussed.

Next, A brief review of hearing protector ratings and testing procedures will be given.

Then the development of the subject sample size requirements in ANSI S12.6 Method B will be explained. Following that, three methods for estimating the error in the noise reduction rating will be developed and applied to the interlaboratory data. Finally, a classification scheme for hearing protection ratings based upon precision will be presented.



First, the meanings of precision and accuracy as they apply to hearing protector ratings need to be set forth.

The Precision of a hearing protector rating is the error in the estimation of a rating that is derived solely from the tested sample population.

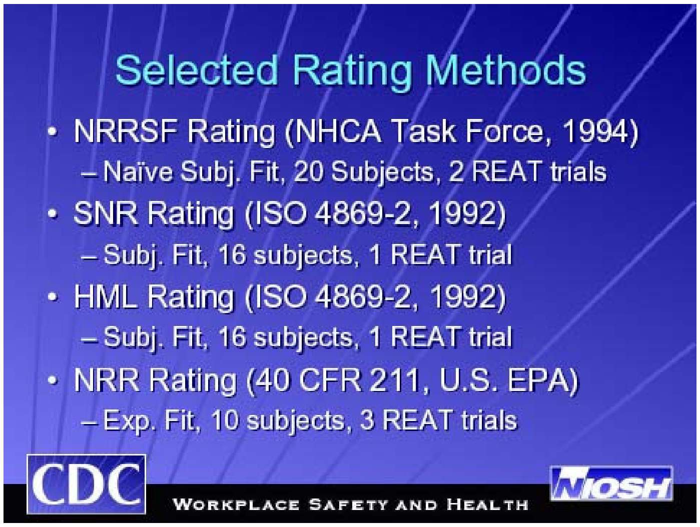
The Accuracy of a hearing protector rating is the error in applying the rating estimate to a different noise spectrum.

These definitions can be clarified with an example from marksmanship. Imagine clamping a rifle to a bench rest and shooting a set of 10 shots. The spread of those ten shots about the center of the group is a measure of the precision of that rifle. A heavier barrel with better rifling and stiffening ribs will make the barrel less prone to vibration.

The grouping will be come smaller and the rifle more precise.

Unfortunately, if you miss the target, Precision without Accuracy is useless.

Similarly, a protector can have very tight attenuation distributions, indicative of a highly controlled testing protocol or a well-designed protector. The rank-ordered comparison of real-world attenuation of hearing protectors, subject-fit and laboratory real ear attenuation at threshold (REAT) data demonstrate that laboratory data tend to be very precise but way off target (Suter, 2003; Berger, 2003). If the test procedure and rating method are not accurate, then ultimately the rating is meaningless. This presentation will focus on how to estimate the precision. Other papers will address the issue of accuracy for different noise spectra.

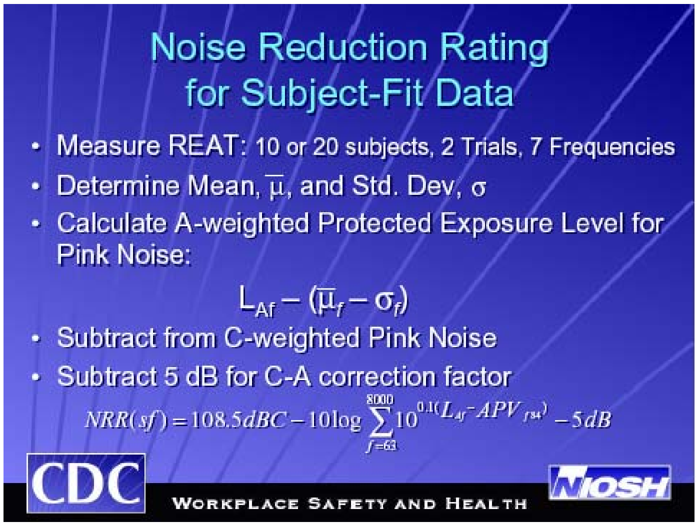


A brief review of selected hearing protector rating methods is necessary.

The Noise Reduction Rating Subject-Fit, NRR(SF), was developed by ANSI Working Group S12/WG11 and adopted by the Task Force on Hearing Protector Effectiveness of the National Hearing Conservation Association (NHCA). The ANSI working group developed a rating based upon testing 20 subjects twice to estimate the real ear attenuation at threshold for a protector. The subjects were to be naïve with respect to protector use and testing. This method incorporated a mean minus one standard deviation to estimate the protection of 84% of the users that would wear a device (Royster, 1995).

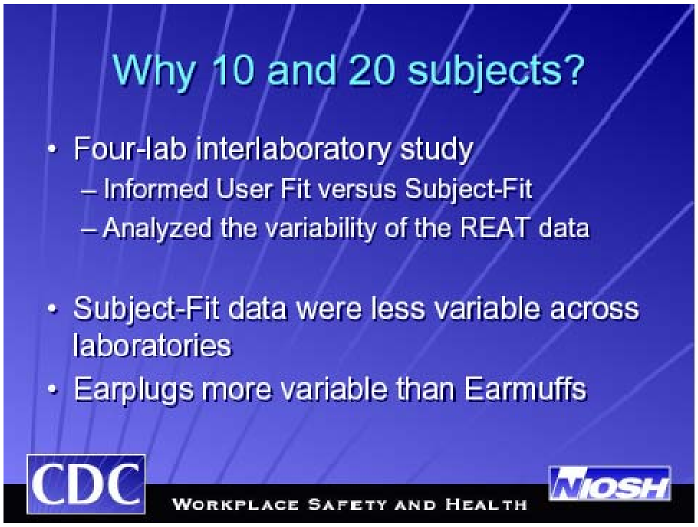
The next two methods, Single Number Rating (SNR) and the High-Middle-Low (HML) ratings are the European methods approved by the ISO in 1994 (ISO 4869-1, 1990; ISO 4869-2, 1994). The SNR method provides one number that is subtracted from a C-weighted noise to estimate the A-weighted exposure level of a person wearing a protector. Similarly, the HML method requires the user to know the difference between the C-weighted and A-weighted sound pressure levels before applying the rating. HML is more accurate than the SNR method when applied to a variety of noise spectra for the purpose of estimating the protected exposure level. Both methods are calculated from 16 subjects performing one REAT trial and allowing them to have some level of experience with the use of protectors.

The NRR has been the subject of criticism almost from its inception (EPA, 1978). The NRR uses 10 experienced subjects, has the experimenter fit the protector, and measures the REAT for three trials. The NRR must be derated before applying it to the problem of estimating a worker's exposure level (OSHA, 1999). The experimenter-fit results are representative of the best possible performance of a hearing protector.



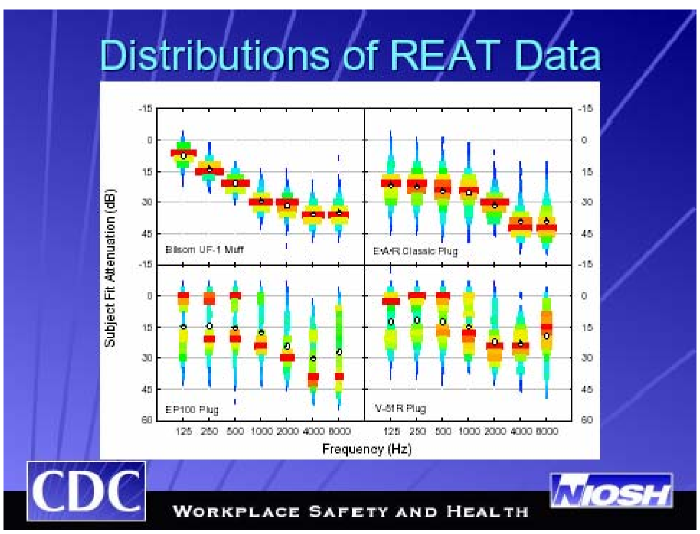
For those who are unfamiliar with hearing protector ratings, we will review the Noise Reduction Rating Subject-Fit method. The manufacturer sends a product to a testing laboratory. The lab must recruit a panel of subjects, (10 for earmuffs and 20 for earplugs or semi-inserts), who have no experience with protector use and testing. The unoccluded and occluded hearing thresholds are measured for each subject after they have been qualified for testing. Each subject is measured twice at seven frequencies. After the panel is completely tested, the lab must calculate the means and standard deviations at each frequency of the real ear attenuation at threshold. From these values, the overall A-weighted protected exposure level is determined and subtracted from the C-weighted Pink noise. For the NRR(SF), a correction factor of 5 dB is subtracted. When it is all said and done, this formula describes the process. Most protector rating schemes utilize a similar formula. This is an important point since this talk examines the error in using this formula. The C- and A- weighted reference spectrum, 108.5 dBC and L_{Af}, and the C-A correction factor are the components that are varied when assessing the accuracy of the rating metric (Royster, 1995; Franks et al., 2000).

How did ANSI S12.6-1997 arrive at the threshold of testing 10 subjects for earmuffs and 20 subjects for all other devices? In the early 1990s, an interlaboratory study was conducted between four labs, NIOSH, EARCal, WPAFB, and USAARL. The study

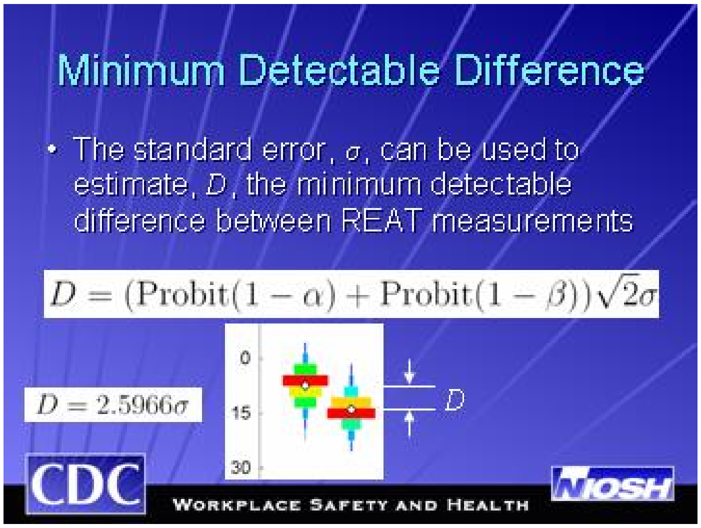


tested four hearing protectors with two protocols: Informed-User-Fit, and Subject-Fit (Royster et al. 1996; ANSI S12.6-1997).

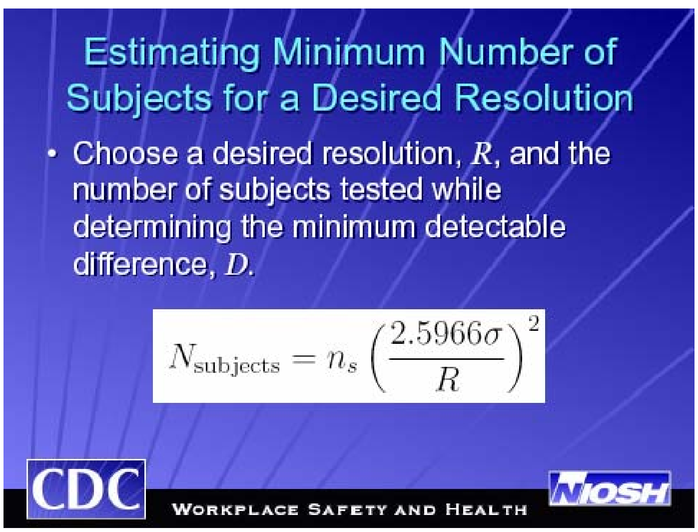
Statistical analysis demonstrated that Subject-Fit data were less variable across laboratories than the Informed-User-Fit data. The analysis also showed that the attenuation provided by earplugs was more variable than that provided by earmuffs (Murphy et al. 2003).



This figure shows the distributions of REAT data for the Subject-Fit trials from the interlaboratory study. Two points are evident: The REAT distributions for the Bilsom and E-A-R Classic are unimodal and for the most part symmetric about the mean value, the diamond symbol. For the V-51R and EP100 premolded earplugs, the distributions are bimodal in the low frequencies and widely spread at the higher frequencies (Murphy et al., 2002; Murphy et al., 2003).

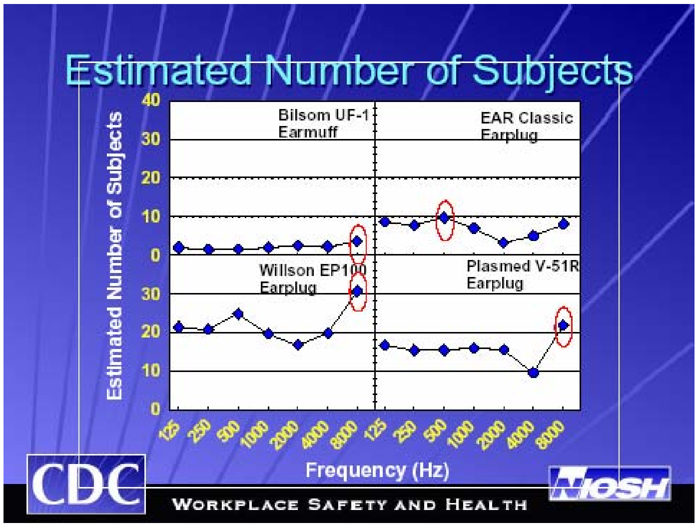


From the statistical analysis of the data across laboratories, subjects, and trials, an error term, sigma, was estimated at each frequency for the four protectors. From these error terms, assumptions of statistical certainty were made for the purpose of determining the minimum detectable difference between two distributions of data. The minimum detectable difference is the distance between the centers of the distributions (Murphy et al., 2003).

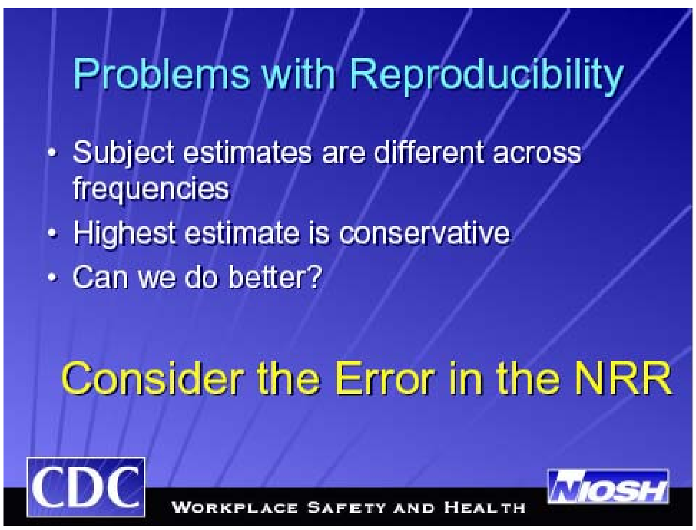


Once the minimum detectable difference has been determined and the desired resolution chosen, the minimum number of subjects for testing can be calculated. Annex C of ANSI S12.6-1997 uses a desired resolution of 6 dB to estimate the sample sizes for testing different types of hearing protectors. The n_s in this formula is the number of subjects actually tested and the $N_{subjects}$ is the estimated number of subjects to achieve a desired resolution of R (ANSI S12.6-1997; Murphy et al., 2003).

In this figure the interlaboratory subject-fit data have been analyzed and the estimated numbers of subjects have been plotted for each protector and frequency for a desired resolution of 6 dB, number of tested subjects is equal to 20 and number of trials is equal to 2. For the UF-1 earmuff, the estimated number of subjects was less than 4. For the



Classic earplug, the estimated number of subjects was less than 10. For the V-51R and EP100 plugs, the estimated numbers of subjects were about 23 and 32, respectively. Some problems with this analysis exist (Murphy et al., 2003).

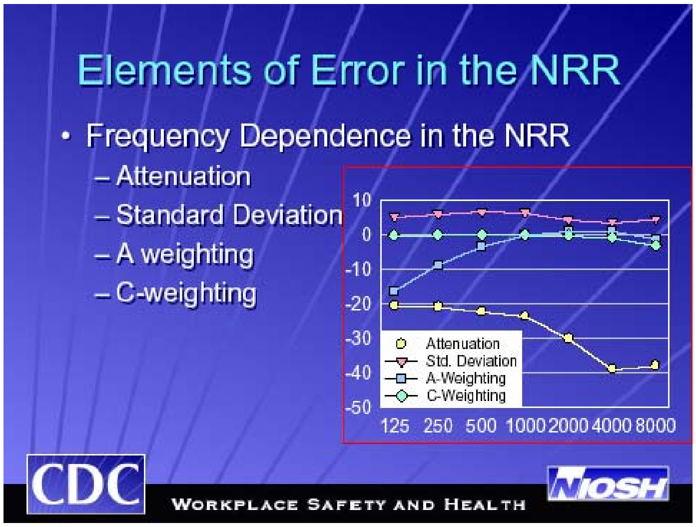


Using the interlaboratory reproducibility, the estimated numbers of subjects were plotted for each frequency in the previous slide. The analysis does not show how to combine the subject estimates across frequencies. Without that information, the most conservative estimate was the maximum number of subjects at any frequency. For a resolution of 6 dB, at least 32 subjects need to be tested for the EP100 earplug.

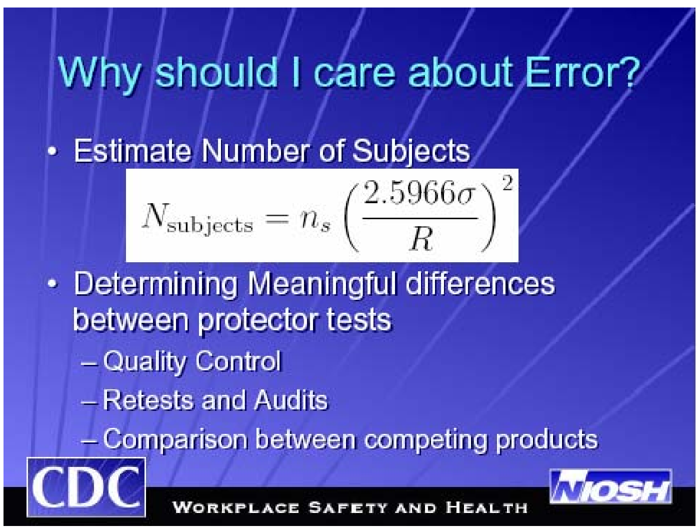
Can a better estimate be developed?

Yes, if one considers the error in the NRR.

The NRR calculation involves summing energy and attenuations across frequencies and distills down to four components that are frequency dependent. The protector's attenuation typically increases with frequency. The standard deviations tend to be



constant within a few decibels. The A-weighting curve deemphasizes the lower-frequency bands of the reference spectrum and the C-weighting of the reference spectrum is relatively constant except at the higher frequencies. These terms will jointly influence the error contribution.

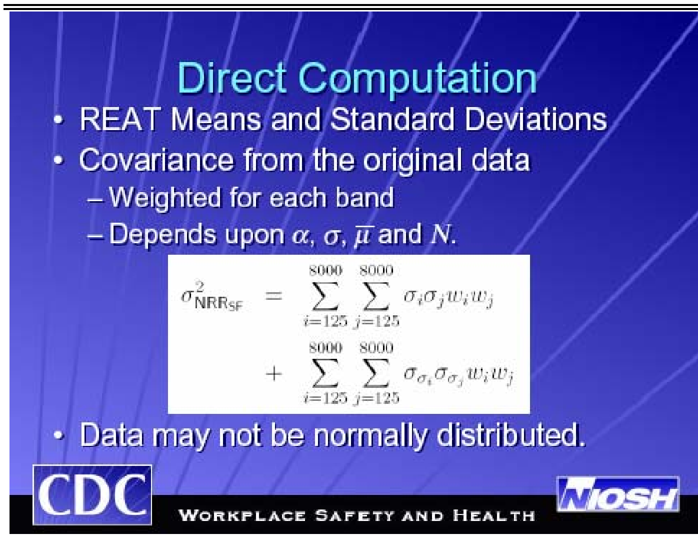


So why should one care about the error?

First, as has been shown previously, the number of subjects necessary to achieve a desired resolution can be estimated. Using the prior formula, if one knows the error, sigma, then the desired resolution needs only to be chosen to know whether sufficient Subjects have been tested.

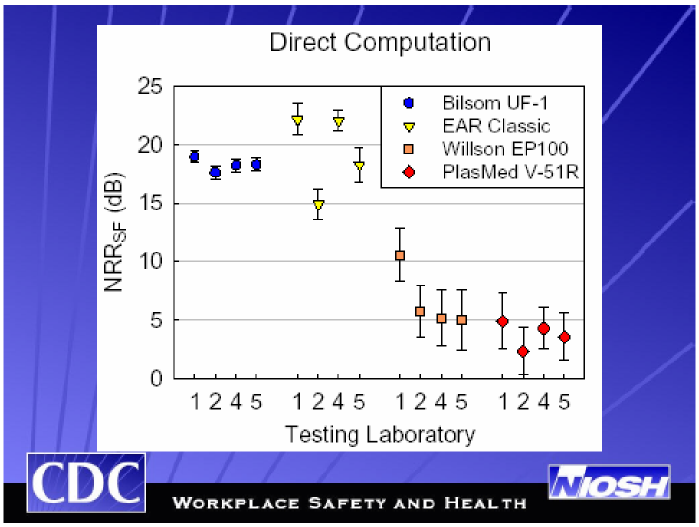
More importantly, the error can be used to determine meaningful differences between protector tests. The applications might include quality control within a manufacturing facility, retesting the product for labeling and audit purposes, and making comparisons between competing products on the market. The current mode of comparison is usually performed on the basis of the NRR magnitude. If product X has an NRR of 21, then it must do a better job than product Y which has an NRR of 20. No thought has been given to characterizing the protector based upon the precision of the rating. An intelligent consumer might look at the standard deviations provided on the secondary label and be able to make some sense of them. And if the user is an acoustician, they will know how to take that rating and perform the octave-band calculation to get their exposure level, and they will consider the comfort factor for an extended period of wearing the protector. Sadly this is rarely the case.

Recently, NIOSH has evaluated three methods to estimate the error in the NRR. The first is a direct computation using the means and covariance of the REAT data. The second is a Monte Carlo method that simulates data based upon the means and covariance of the REAT data. And finally, a bootstrap method in which one samples the original REAT data to form new data sets that are used to estimate the NRR multiple times. Each of the methods has good and bad points that are a function of the assumptions used in their calculation.



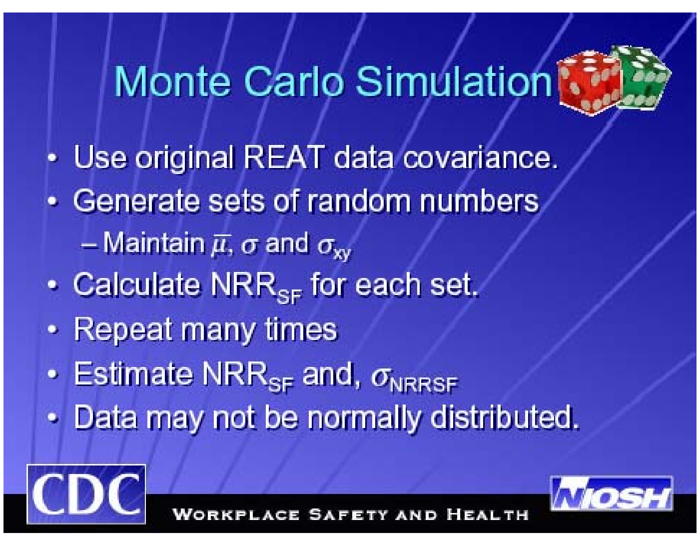
The REAT data can be characterized by the mean attenuation at each frequency and the covariance matrix for the entire set of measurements for the tested subject sample. The covariance is simply the variation of the attenuation at one frequency with the attenuation measured at another frequency (Bevington, 1969). When a subject achieves an excellent fit, the attenuations will generally be greater across frequencies than for a subject who achieves a poor fit. Thus, the covariance matrix can be used to better assess the error. From a derivation of the variance of the NRR(SF), we find an equation of the following form. What is interesting about this result is that the individual frequencies are weighted according to their contribution to the overall protected sound pressure level.

The primary shortcomings of this derivation are that it assumed the REAT data are normally distributed and that it must be derived for each particular rating method.



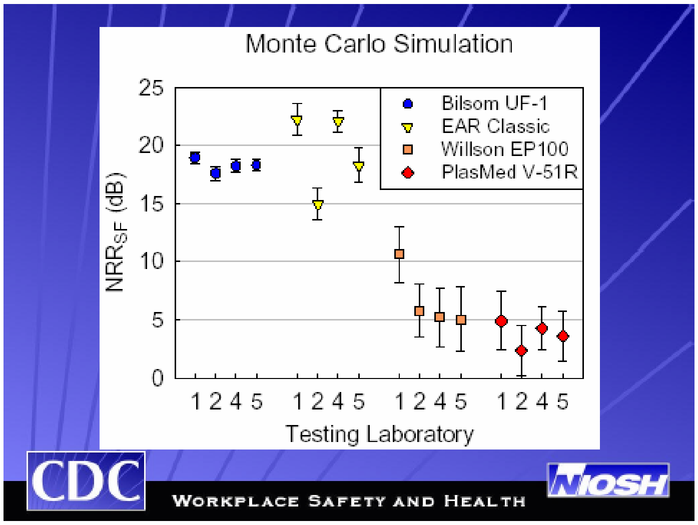
The Subject-Fit data from the interlaboratory study were analyzed using the means and covariance to estimate the error bars. The error bars about the NRR(SF) for the UF-1 earmuff are small, about 0.5 dB. The error bars about the E-A-R Classic plug ratings are about 0.9 to 1.5 dB. The error bars for the EP100 range from 2.1 to 2.6 dB and the errors for the V-51R are 1.8 to 2.4 dB.

Further analysis of the data was performed to determine whether or not the differences in the NRR(SF) measurements in the different labs were statistically significant. Only for the E-A-R Classic were these data different from one another. Lab 2 was significantly different from Labs 1 and 4, but not Lab 5. The remainder of the protectors exhibited no significant difference across labs. Please note that even though the EP100 exhibited a difference of 6 decibels between Labs 1 and 5, the difference is not significant.



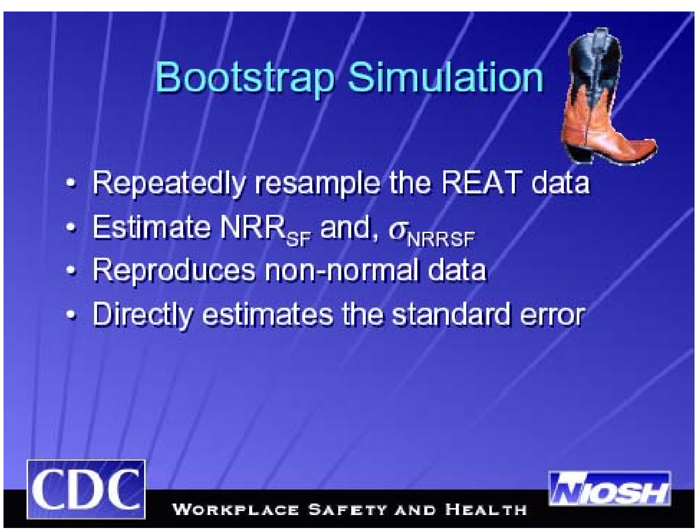
For the Monte Carlo simulation,

a set of random numbers is generated that has the same mean and standard deviation as the original REAT data (Press et al., 1986). The NRR(SF) is computed for that set of data and the result is stored. The process is repeated several thousand times to guarantee convergence of the mean and the standard deviation of the NRR(SF).



The method makes an assumption that the subjects are randomly drawn from a normally distributed population. For some protectors, the REAT distributions were not normal but bimodal. Bimodality has a small, unpredictable effect on the NRR(SF) calculation. A better model of the distribution of the data is the topic for continued research. As we examine the errors for the Monte Carlo method, they are approximately 5% larger than the errors for the direct method. The NRR(SF) calculations are the same, and there are no discernable differences in the results.

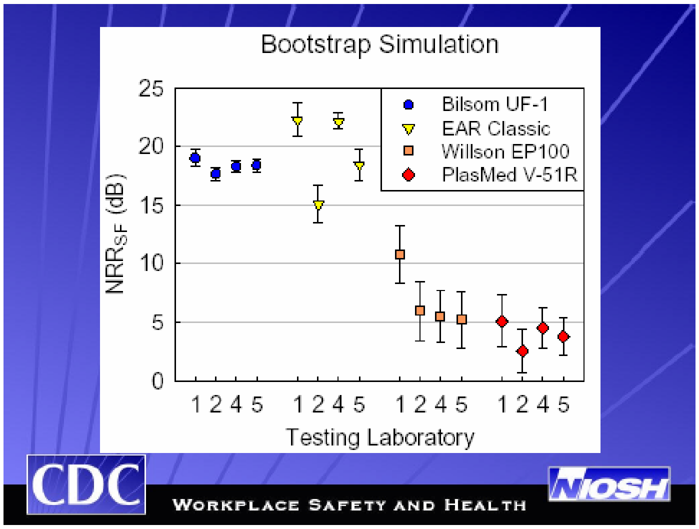
The Bootstrap simulation is a unique approach both to model the REAT data and to



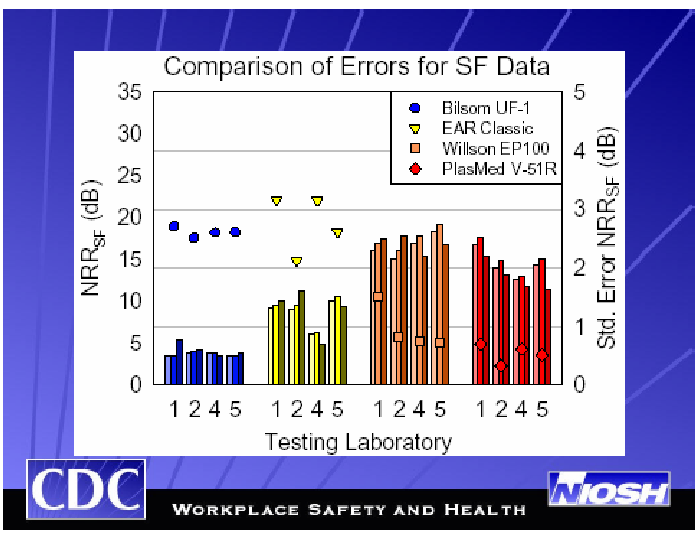
estimate the error inherent in the hearing protector rating. One assumes that the subjects can be randomly sampled such that they have an equal probability of being selected for each throw of the dice (Efron and Tibshirani, 1993)

. This sampling strategy is called Sampling with Replacement. The number of subjects drawn is the same as in the original sample. In the case of the

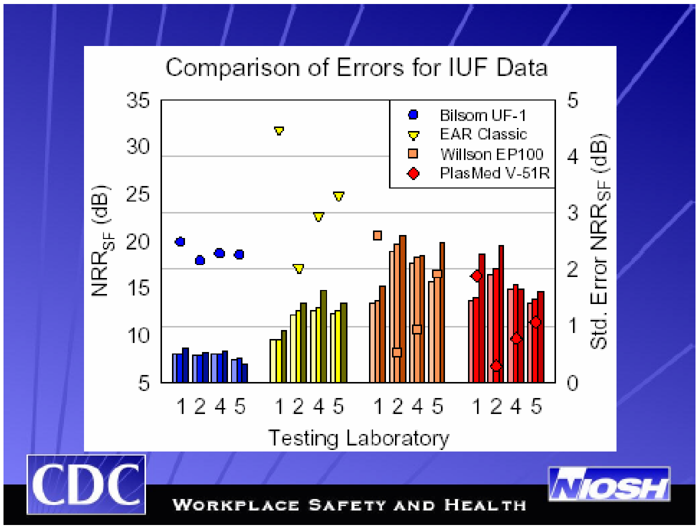
Interlaboratory study, each lab tested 24 subjects, so each random sample will select 24 subjects.



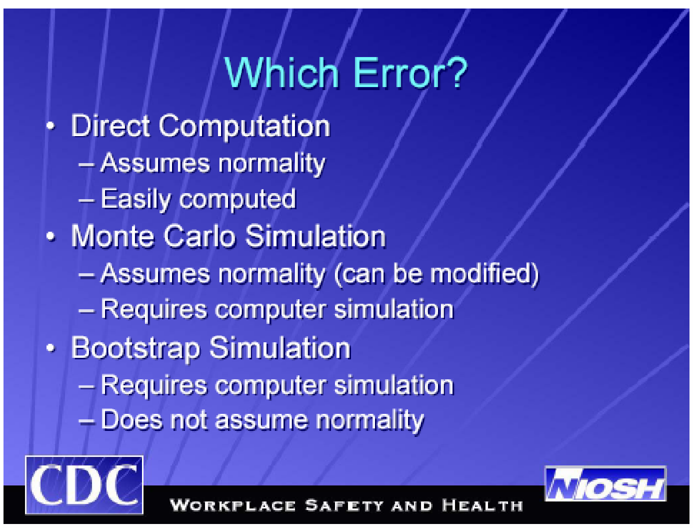
The Bootstrap errors are slightly greater than the Direct method and sometimes greater than the Monte Carlo method's errors. The results incorporate the bimodal character of the data because the actual data are used in the calculation.



In this figure, the NRR(SF) calculations (left axis) have been combined with a bar chart for the errors shown on a different scale on the right hand axis. The errors for the Direct method are the lightly shaded bars; the errors for the Monte Carlo method are the medium shaded bars and the Bootstrap errors are the darkly shaded bars. One should recognize that the errors from each method are comparable. The UF-1 earmuff errors are less than 1 decibel. The E-A-R Classic errors were less than 2 dB. The EP100 earplug errors were all above 2 dB and less than 3 dB. The V-51R errors were above 1.5 dB and less than 2.5 dB.



The same analysis was performed on the Informed-User-Fit data from the four-lab study. In this case, errors using the bootstrap method are slightly greater than those using the other methods. For the earmuff, the Informed-User-Fit errors were comparable to the Subject-Fit errors. For the earplugs, the errors overall were less than those for the subject-fit data.

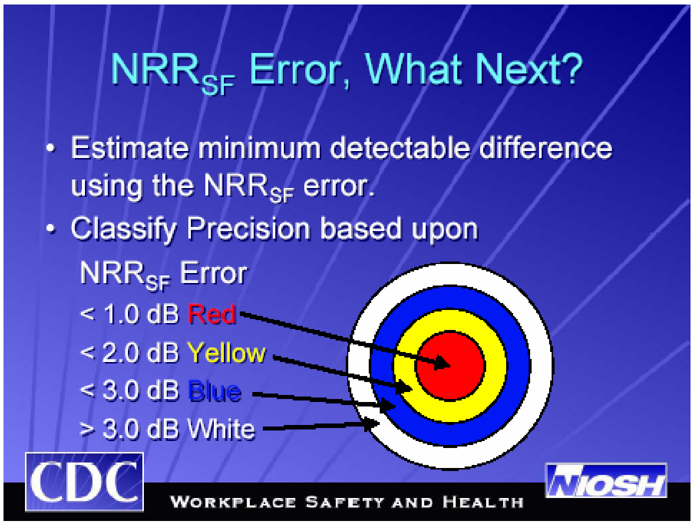


After looking at the errors, which method should be used? At this point, the results are comparable for the different methods. The direct method assumes normality of the data and may be incorrect for non-normal data. Its advantage is that it can easily be computed and can be programmed into a spreadsheet.

The Monte Carlo method also assumes normality in the data, but could be modified for non-normal distributions. It requires computer simulation using a high-level language.

The Bootstrap method does not assume any structure in the data because it uses the original data to generate its results. The bootstrap also requires a computer simulation using a high-level language.

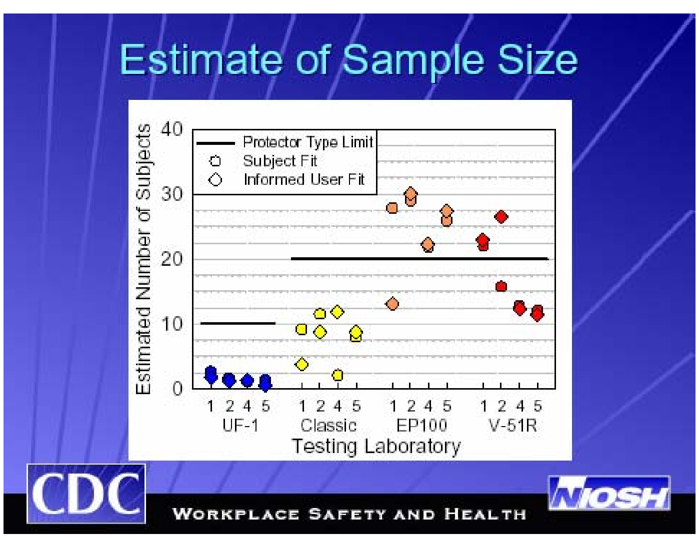
At this point, the bootstrap seems to be the best method for estimating the error. The other methods work, but may need further development to assure that the results are always accurate.



Now that the effects of the standard error on the hearing protector rating have been examined, how might the precision be used?

From the earlier formula, the minimum detectable difference can be determined and the number of subjects to test can be estimated.

The precision of the protector could be classified. The highest precision protectors with errors less that 1 dB could be classified as red. Those protectors with errors greater than 1 dB but less than 2 dB could be yellow. Errors greater than 2 dB and less than 3 dB would be blue, and any device greater than 3 dB would receive a white classification. The class scheme could easily be Type 1 through Type 4.



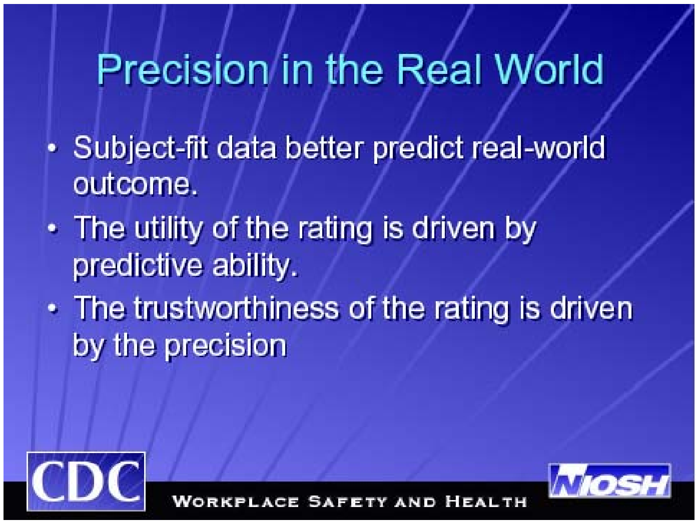
This figure presents the estimates of the sample sizes for the interlaboratory study based upon the bootstrap errors and the minimum detectable difference of 6 decibels. Remember that this difference is the distance between two distributions to be able to distinguish them. For the Bilsom UF-1 earmuff the number of subjects was less than 3 for both the Subject- and Informed-User-Fit data. The E-A-R Classic required less than 12 subjects for all the labs. The EP100 exhibited the poorest results with Lab 2 requiring 30 subjects to achieve a 6-dB minimum detectable difference. Finally, the V-51R earplug required less than 27 subjects for Lab 2. Several of its measurements were less than the suggested 20 subjects.

So, when does precision matter?

In high-noise environments, the hearing protection must be matched to the worker's noise exposure. If the protection is inadequate, the worker will be at an increased risk of developing a hearing loss. Current practices utilize double protection which pairs an earmuff with an earplug. The muff typically will have higher precision than the earplug. If both devices were high precision, then the worker has greater assurance of adequate protection.

Two aspects of over-protection in a noisy environment must be considered: the ability to communicate and the audibility of warning sounds. If workers are unable to communicate due to overprotection, they are likely to remove or defeat the attenuation of the protector, which increases their noise exposure. Increased noise exposure means increased risk of hearing loss. Similarly, if workers cannot hear warning sounds, such as backup alarms, they put their lives instead of their hearing at risk.

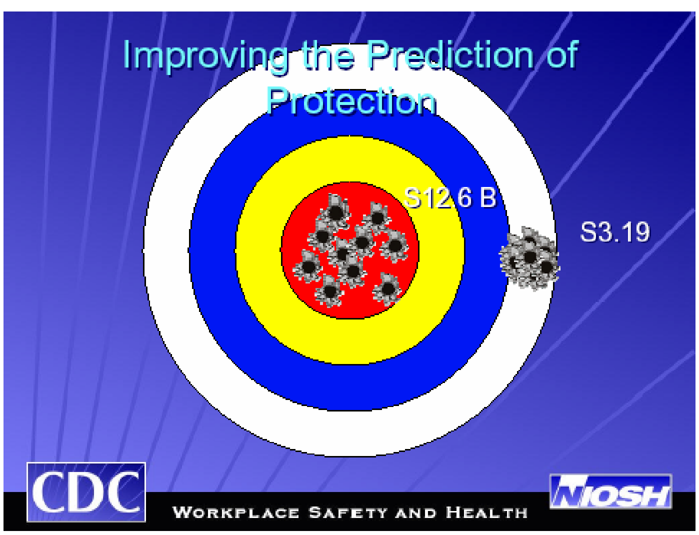
The bottom line for employers is that they need to better characterize the noise exposure profiles of their workers to best match protection with exposure. If employers choose low-precision protectors, then their workers are at greater risk of developing hearing loss.



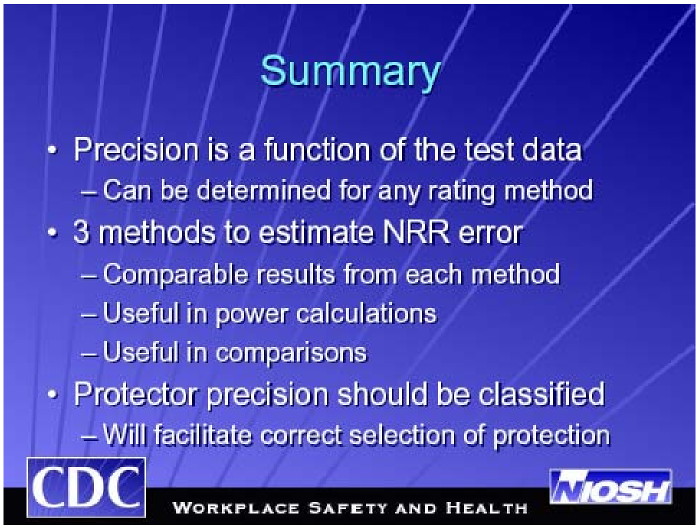
Precision can applied to the difficult issues of hearing loss prevention. From this paper and others, the Subject-Fit data have proven to better predict real-world attenuation measurements than have the ANSI S3.19 Experimenter-Fit data.

The utility of the rating is driven by its predictive ability. That OSHA requires and NIOSH recommends derating the current Noise Reduction Rating, should be evidence that Experimenter-Fit data do a poor job of predicting real-world performance. Moving to Subject-Fit data should improve the ability to predict the protected noise exposure levels for workers in the protected condition.

The precision of the data drives the trustworthiness of the rating. Some precision will be sacrificed when using Subject-Fit data, especially for earplugs and semi-aural devices. Testing a larger pool of subjects will improve the precision of the rating, in effect tightening the confidence limits for the rating and decreasing the minimum detectable difference.



If the target of a hearing protector rating is to predict how well protected a worker might be, then this revision to the earlier example should be considered. Currently, ANSI S3.19 laboratory data are poor predictors of real-world performance (Berger et al. 1998). The data are very precise but way off target. If the United States shifts its regulations to using Subject-Fit data, then some precision is sacrificed for the sake of accuracy.



In summary, the precision of a rating is a function of the original REAT data measured for the sample pool of subjects. Precision is an inherent property of the data and can be determined for any method. The accuracy of a hearing protector rating method depends upon the noise spectrum, where the protector will be used, and its ability to describe real-world performance.

Statistical analysis has been developed to estimate the numbers of subjects necessary to achieve a level of statistical certainty. That analysis was limited by its inability to combine results across frequencies. The formulas would continue to be useful if we knew the error in the protector rating.

Three methods have been briefly presented to estimate the error in the rating: the Direct, Monte Carlo, and Bootstrap methods. Each method yielded comparable results, but currently the Bootstrap has the most potential to be applied to any rating method. The error in the protector rating can be useful in power calculations to predict how many subjects need to be tested. The error will also permit meaningful comparisons between tests and devices.

Finally, some applications of the concept of precision to the practical problem of hearing loss prevention have been presented. Precision is function of the actual REAT testing data rather than the color of its plastic or the type of foam from which it was manufactured.

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"Augmented" HPDs:
Active Noise Reduction, Level-Dependent, Sound Transmission, Uniform Attenuation, and Adjustable Devices -- Technology Overview and Performance Testing Issues

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BACKGROUND

Conventional Passive HPDs

So-called "conventional" hearing protection devices (HPDs) constitute the vast majority of HPDs, which generally consist of earplugs that seal the ear canal by insertion into it, ear canal caps that seal the canal at or near its rim, and earmuffs that encircle the outer ear. These devices achieve attenuation of noise strictly by passive means without the use of dynamic mechanical elements or electronic circuitry. Attenuation is accomplished through one or more avenues, including the use of construction materials with high sound transmission loss properties, liner materials which absorb and dissipate sound, trapped air volumes which provide acoustical impedance, and compliant materials which establish an acoustical seal against the skin. When properly selected for the situation, and fit to and correctly worn by the user, conventional HPDs yield adequate protection in most industrial, military, and recreational environments. However, due to the very nature of the attenuation that they provide, concomitant deleterious effects on hearing quality and auditory performance sometimes arise.

It is important to recognize that conventional HPDs reduce noise at the ear solely by passive means, and the attenuation provided is the same regardless of incident sound level. That is, the devices are "level-independent or amplitude-insensitive." Although the devices are currently tested at the threshold of hearing using real-ear attenuation at threshold standards (ANSI S3.19-1974; Experimenter-Fit), the attenuation achieved at threshold remains the same (or linear) throughout most of the dynamic range of noises normally encountered in industry. Exceptions include extremely high-level impulses, such as gunshots, which may modify the behavior of the HPD on the human head, an example being the separation of an earmuff cushion from the side of the head as a high-caliber weapon’s pressure wave passes it. It is also noteworthy that most conventional HPDs have spectral attenuation curves that increase (more attenuation) as a function of sound frequency. An example for three earmuffs appears in Figure 1.

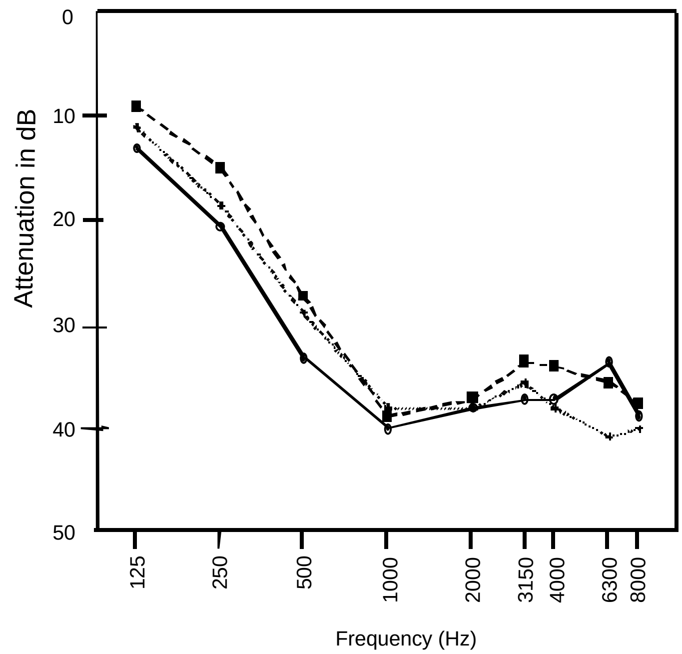

Figure 1. Attenuation of three conventional passive earmuffs.

A major impetus for the development of augmented HPDs has been the occasional negative influence that conventional HPDs have on the hearing ability of users. They have often been implicated in compromised auditory perception, degraded signal detection, and reduced speech communication abilities. Depending upon situational demands, these effects can create hazards for the wearer, or at the very least, resistance to use by those in need of hearing protection. Nonetheless, to combat the damaging effects of high intensity noise to hearing, the promulgation in 1971 of the OSHA Noise Standard and in 1983 of the OSHA Hearing Conservation Amendment, has caused the use of HPDs to proliferate in U.S. industrial workplaces, and similar occupational noise requirements have been enacted in many other countries. Likewise, HPDs have been a staple of personal protection equipment in the U.S. military for many years, starting in the early 1950s. Recently, there is an indication that HPDs are becoming more popular among the general public, for example, for reduction of noise annoyance on airplanes and for engaging in loud recreational activities, such as target shooting, power tool operation, and noisy spectator events.

<u>Conventional Passive HPDs: Effects on Hearing Ability for Speech and Signals</u>

Users may reject hearing protection if it compromises their hearing to an extent where sounds no longer appear natural, signals cannot be detected, or speech cannot be understood. In some cases, too much attenuation may be provided by an HPD for a particular noise situation, and the user's hearing is unnecessarily degraded.

Overall, the research evidence on normal hearers generally suggests that conventional passive HPDs have little or no degrading effect on the wearer's understanding of external speech and signals in ambient noise levels above about 80 dBA, and may even yield some improvements with a crossover between disadvantage to advantage between 80 and 90 dBA. However, they do cause increased misunderstanding and poorer detection as compared to unoccluded conditions in lower sound levels, where HPDs are not needed for hearing defense but may be used for reduction of annoyance. In intermittent noise, HPDs may be worn during quiet periods so that when a loud noise occurs, the wearer will be protected. However, during those quiet periods, conventional passive HPDs typically reduce hearing acuity. In certain of these cases, the family of **level-dependent HPDs** can be beneficial, those that provide minimal or moderate attenuation during quiet but increased attenuation as noise levels increase.

Theoretically, conventional passive HPDs may improve signal detection and/or speech understanding in high-level noises in that the HPD lowers the total incident energy of both speech/signal and noise, reducing the cochlear distortion that occurs at high sound levels. "Acoustic glare" is thereby reduced and the neural ear operates under more favorable conditions in which its filters remain "sharper," and better discrimination thus occurs. However, predicting the influence of any type of HPD on speech intelligibility or signal detection in noise is a complex issue that depends on many factors, including the listener's hearing abilities, occlusion of the talker's ears, whether or not the talker is in noise, the HPD's attenuation, noise levels and spectra, reverberation time of the environment, facial cues, and the content and complexity of the message (Casali and Berger, 1995).

At ambient noise levels greater than about 85 dBA, most studies have reported slight improvements in speech intelligibility with certain HPDs (e.g., Casali and Horylev, 1987; Howell and Martin, 1975), while others attempting to simulate actual workplace conditions have reported small decrements, especially when the talker is also wearing protection, and as such reducing his or her vocal output (Hormann et al., 1984). Noise- and age-induced hearing losses generally occur in the high-frequency regions first, and for those so impaired, the effects of HPDs on speech perception are not clear-cut. Hearing-impaired individuals are usually at a disadvantage when wearing HPDs since their thresholds for mid-to-high frequency speech sounds, which are already elevated, are further raised by the protector. Though there is not consensus among studies, certain reviews have concluded that sufficiently hearing-impaired individuals will usually experience additional reductions in communication abilities with conventional HPDs worn in noise (Suter, 1989). In some instances, HPDs with electronic sound restoration circuits, sometimes called **active sound-transmission** HPDs, can be offered to hearing-impaired individuals to determine if their hearing, especially in quiet-to-moderate noise levels below about 85 dBA, may be improved while still providing a measure of protection. Results with these devices, however, are mixed (Casali and Wright, 1995).

Conventional passive HPDs cannot differentiate between speech (or nonverbal signal) energy versus noise energy at a given frequency, and selectively pass the desired sounds. Therefore, these devices do not improve the speech-to-noise ratio, which is the most important factor for achieving reliable intelligibility. As shown in Figure 1, conventional HPDs attenuate high-frequency sound more than low-frequency sound, thereby reducing the power of consonant sounds, which are important for word discrimination. Also, by allowing low-frequency noise to pass through, they further degrade the intelligibility of speech through the upward spread of masking. Certain augmented HPD technologies help to overcome the weaknesses of conventional HPDs in low frequency attenuation; these include a variety of **active noise reduction (ANR)** devices, which, through electronic phase-derived cancellation of noises below about 1000 Hz, improve the low frequency attenuation of passive HPDs. Concomitant benefits of ANR-based HPDs may include reducing the upward spread of masking by low-frequency noise over speech and signal bandwidths, as well as reducing noise annoyance in certain environments dominated by low frequencies, such as jet aircraft (Casali and Gower, 1993; Nixon, McKinley and Steuver, 1992).

Because the attenuation of conventional HPDs increases as a function of increasing frequency, this creates an imbalance in the listener's hearing of relative amplitudes of different pitches. It causes broadband acoustic signals to be heard as spectrally different from normal, in that they take on a more bass tone (Casali and Berger, 1996). In other words, the spectral quality of a sound is altered, and sound interpretation, which is important in certain jobs that rely on aural inspection, may suffer as a result. This is one of the reasons why **uniform (or flat) attenuation** HPDs have been developed as an augmentation technology.

Some of the high-frequency binaural cues (especially above about 4000 Hz) that depend on the pinnae are altered by HPDs, and judgments of sound direction and distance may be compromised. Earmuffs, which completely obscure the pinnae, radically interfere with localization in the vertical plane and also tend to cause horizontal plane errors in both contralateral (left-right) and ipsilateral (front-back) judgments (Suter, 1989). Earplugs may result in some ipsilateral judgment errors, but generally cause fewer localization problems than muffs. Exceptions exist, however, in that at least one high-attenuation earplug has been observed to disrupt localization in a magnitude similar to muffs (Mershon and Lin, 1987). In an effort to compensate for the lost pinnae-derived cues for sound localization that are typically destroyed with application of an earmuff, **dichotic sound transmission** HPDs can be utilized. These devices have an external microphone on each earmuff cup, which transmits a specified passband of the noise incident upon each microphone to a small loudspeaker under the earmuff cup. Binaural cues, at least to some degree, are thus maintained with these devices, assuming their between-ear gain controls are properly balanced and their microphones are sufficiently directional.

User Complaints and Other Problems

In practice, especially in the industrial and other occupational environments, HPD users voice many complaints associated with hearing protection, often using these complaints as a reason for not wearing their protectors. Complaints are myriad, but the subset that is commonly related to the influence of HPDs on hearing ability is as follows:

- "I can't hear warning signals in the vicinity."
- "The machine noise cues that I listen to for feedback sound strange with protectors on."
- "I missed hearing my co-worker shouting LOOK OUT."
- "It's inconvenient to take my protector off so I can hear whenever my machine is on a quiet cycle."
- "I need to hear others near me on the police firing range but I can't remove my protector because I don't know when the next shot will be fired."

Safety professionals often face a dilemma in selecting HPDs for the workforce that provide adequate attenuation for the noise threat at hand, but also do not provide so much attenuation that the worker cannot hear important signals and speech communications. This dilemma is sometimes termed "underprotection" versus "overprotection." To emphasize the magnitude of this dilemma in a legal sense, the view of the injured worker, acting as a plaintiff, is sometimes as follows: "The hearing protector provided inadequate noise attenuation for defending my ears against the damaging effects of noise, so I lost my hearing over time." Or, "The hearing protector provided more attenuation than needed for the noise that I was in, and therefore was the proximate cause of the accident when I could did not hear the forklift's backup alarm and was run over." While these are extreme statements, they may indeed be valid in certain circumstances if an HPD is not properly "matched" to a worker's needs, the noise exposure, and any hearing critical requirements inherent in a job. In civil court, these arguments potentially provide a theory on which a legal foundation for recovery of damages may be based.

To reduce worker complaints, and to some extent mitigate the issue of underprotection versus overprotection, certain features have been developed and integrated into HPDs. These advancements can be collectively termed "augmentations," hence the term "augmented HPDs." For example, through the use of electronics or passive acoustical networks, the attenuation of these devices can be tailored to prevailing ambient noise levels or job demands. High-pass, low-pass or band-pass filters can be incorporated to aid speech communication and signal detection. Flat-attenuation devices allow more natural hearing, which is an important consideration for some users, such as musicians. By reducing excessive low-frequency noise, active noise reduction (ANR) devices can reduce noise annoyance and sometimes reduce the masking of speech, even in situations where hearing protection may not be required for preventing noise-induced hearing loss. The goal of all these features is to foster the use of hearing protection by producing devices that are more acceptable to the user population and amenable to the work environment, as well as to afford better hearing under a "protected" state. However, while these goals are noble, they are not always realized in practice.

HPD Attenuation Measurement

Insertion Loss (IL) versus Noise Reduction (NR). To understand how HPDs are tested and rated for their performance, it is first necessary to gain an appreciation for the basics of laboratory attenuation measurement techniques. While almost all measurement techniques are applicable to conventional, passive HPDs, some of these techniques are amenable to certain augmented HPDs but not to others. When HPD attenuation performance is quantified using microphone-based *(i.e. physical)* measurements, two approaches are commonly used. In each case, two distinct measurements are needed to quantify the performance of the HPD: one to indicate the noise level to which the wearer would be exposed *if the HPD were not worn* and the other to indicate the noise level to which the wearer would be exposed *if the HPD were worn*. The two approaches differ in the number of microphones used to perform the measurements, the locations of the microphones, and the time sequence of the measurements.

The first of these methods is referred to as **insertion loss (IL)**, where a single stationary microphone is used and two measurements are performed, one with the HPD in place and one without the HPD. The **attenuation** is the difference between the two measurements, hence the phrase "insertion loss," which is the reduction (or loss) in the noise level after the insertion of a barrier (the HPD) between the noise source and the measurement location. In Figure 2, this would be represented by the difference in the levels measured at locations A and A′ (IL = A – A′). The microphone can be located in an acoustical test fixture or in the concha or ear canal of a human test subject or acoustical manikin.
[1]

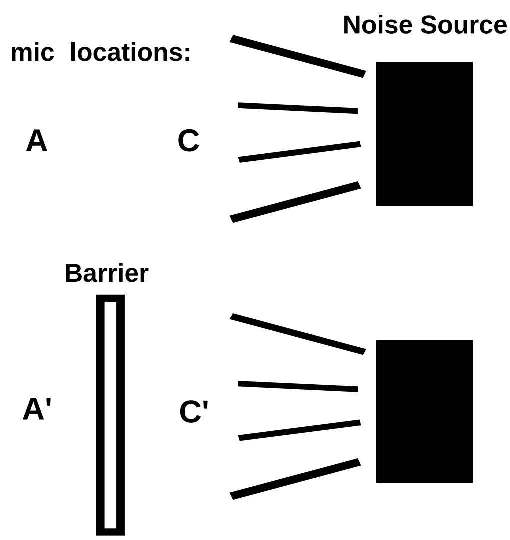

Figure 2. Microphone locations for noise reduction (NR) and insertion loss (IL) measurements.

Noise reduction (NR), on the other hand, utilizes two microphones with the measurements made *simultaneously* on the interior and exterior of the HPD. This would be represented by the difference in the levels measured at locations A′ and C′ in Figure 2 (NR = C′ – A′). As with insertion loss, NR measurements may be made using test

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[1] As discussed below, because real-ear test procedures also represent two distinct threshold measurements performed at different times with and without an HPD in place, they are also referred to as insertion loss measurements.

fixtures, manikins, or human subjects. If human subjects are used, the measurements obtained at C′ must be corrected for the transfer function of the open ear (Mauney, Casali and Burks, 1995).

Real-Ear Attenuation at Threshold (REAT). Most HPD attenuation data (and all attenuation data required for EPA labeling purposes) are obtained using human subjects in a binaural threshold shift methodology referred to as Real-Ear Attenuation at Threshold (REAT).[2] As implemented in the current HPD test standards of the American National Standards Institute (ANSI S3.19-1974 and ANSI S12.6-1997), subjects track their thresholds for 1/3 octave bands of noise at the center frequencies of 125, 250, 500, 1000, 2000, 3150, 4000, 6300, and 8000 Hz with and without a hearing protector in place. The difference between the two thresholds (the threshold shift due to the presence of the HPD) represents the insertion loss of the hearing protector. This methodology is recognized as the most accurate method available in that it can account for individual differences in the fit of devices across the subject sample, as well as the human bone conduction effect, which, as a flanking path, constitutes the ultimate limiting factor in HPD attenuation. However, there are also disadvantages associated with REAT, one of which is the overestimation of low-frequency attenuation of devices due to physiological noise. This is caused by the fact that the HPD enhances low-frequency bone conduction and results in inflated occluded thresholds. Other disadvantages are inter- and intra-subject variability and the need for an extremely quiet test environment. Also, REAT cannot be used to assess certain augmented HPD technologies, for example, attenuation which changes non-linearly with noise level or the attenuation of impulse noise. This means that the data obtained for augmented devices are not representative of the device's performance in the conditions for which they were designed. This is a major problem with the current EPA labeling rule, in that the use of ANSI S3.19-1974 does not accommodate certain augmented HPDs. Thus, these devices cannot be properly labeled for their performance in certain noise environments.

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[2] Because this procedure relies on humans as the "transducers," this procedure is often incorrectly referred to as a *subjective* procedure, but a more appropriate term is *psychophysical* procedure.

ANSI S3.19-1974, specifically the Experimenter-Fit protocol, is currently required by the EPA for HPD labeling purposes (CFR, 2002). However, there has been recent support from hearing conservation groups in the U.S., such as the National Hearing Conservation Association, for replacement of this requirement with ANSI S12.6-1997, using the Method B Subject-Fit protocol (Royster, 1995). Data from several "proving" experiments, conducted through the cooperation of multiple HPD testing laboratories, have demonstrated that Method B of ANSI S12.6-1997 produces HPD attenuation data that are more representative of the attenuation performance achieved by workers in companies with active, quality hearing conservation programs (Berger et al., 1998). Method B of ANSI S12.6-1997 also was shown to provide good reproducibility between laboratories. Thus, the validity (real-world correspondence) and reliability of data produced from Method B has been supported by empirical data. The same cannot be said for the older S3.19-1974 standard and its Experimenter-Fit protocol.

Microphone in Real-Ear (MIRE). The microphone-based counterpart to REAT is Microphone in Real-Ear (MIRE). This methodology is standardized in ANSI S12.42-1995 and MIL-STD-912 and is referred to as *objective* or *physical* since the measurements are microphone-based. As the name implies, small microphones, connected to a spectrum analyzer, are placed in human subjects' ears at or near the opening of the ear canal, and insertion loss measurements are performed using relatively high levels of a broadband noise stimulus (usually pink or white noise). This procedure is easily implemented with earmuffs and some supra-aural devices, but can be difficult or impossible to implement with earplugs or semi-insert HPDs due to the need for wires running underneath the HPD, which can break the seal. Advantages of MIRE testing are that the results are not contaminated by physiological noise as are REAT results, the process is much quicker than REAT testing, and since the measurements are performed at elevated noise levels, there is no requirement for extremely quiet ambient noise conditions. Also, because real human heads are used as test fixtures, MIRE measurements can account for individual differences in the fit of the devices across the subject sample just as REAT measurements do. However, MIRE measurements cannot account for bone conduction, and thus may overestimate attenuation at mid-to-higher frequencies. They also require special equipment consisting of miniature microphones, microphone power supplies, and spectrum analyzes).

Manikins, Head and Torso Simulators (HATS), and Acoustical Test Fixtures (ATFs). Another *objective* method of measuring the attenuation of HPDs is the use of acoustical test fixtures, such as the one specified in ANSI S12.42-1995 or manikins, such as KEMAR (ANSI S3.36-1985 (R1996)), or similar devices manufactured by Brüel & Kjær or HEAD Acoustics. As in MIRE, this method is microphone-based, using 1/2" or 1" precision measurement microphones usually situated at the end of an artificial ear canal or within a special coupler. Like MIRE, ATF-based tests utilize elevated levels of broadband noise for the test stimulus and lend themselves easily to measuring the performance of earmuffs. However, it is difficult to test earplugs or semi-insert devices with an ATF. The use of ATFs has advantages similar to those associated with MIRE, with the added benefit that manikins and ATFs can be used in elevated noise environments in which it would be unsafe to place a human test subject. The disadvantages include those already associated with MIRE. In addition, there are validity issues associated with the fact that transfer functions to the human head and ear have not been quantified, the acoustic isolation of HATS "skull and torso" is ill-defined, and unlike MIRE, HATS and ATFs do not account for individual differences in the fit of the devices across a selection of subjects. However, for very high noise environments, this methodology is the only one possible due to the risks to human subjects.

AUGMENTED HPDS:
DESIGN, PERFORMANCE, AND TESTING ISSUES

In 1996, Casali and Berger proposed a simple classification scheme for categorizing augmented hearing protectors into a dichotomy of **passive** (non-electronic) and **active** (electronic) devices, with subgroups under each. This classification, with modifications to include more recent technologies, is shown in Table 1.

Table 1. A Classification of Augmented HPD Technologies (Casali and Berger, 1996).

- Passive (Non-Electronic) HPDs
  - Uniform (flat) Attenuation Devices
  - Level-Dependent (Amplitude-Sensitive) Devices
  - Adjustable (as to attenuation) Devices
- Active (Electronic) HPDs
  - Level-Dependent (Amplitude-Sensitive) Sound-Transmission Devices, also called Sound Restoration Devices
  - Active Noise Reduction (ANR) Devices
  - Adjustable (as to hearing-assistive, filtering) Devices

Uniform Attenuation Devices

The attenuation of conventional passive HPDs generally increases as frequency increases. While sounds are reduced in level, they are also changed in a non-uniform manner across the spectrum so that the wearer's hearing of the sound spectrum is distorted. Since many auditory cues depend on spectral shape for informational content (e.g., pitch perception by musicians), conventional HPDs may compromise these cues. In an attempt to counter these effects, flat- or uniform-attenuation HPDs such as the ER-15 Musician's earplug or the ER-20 Hi-Fi™ earplug have been developed (see Figure 3). These devices utilize acoustical networks to provide essentially flat attenuation over the range of frequencies from 125 to 8000 Hz, as shown in Figure 4. Because these devices provide the same level of attenuation regardless of noise level, they are accommodated by REAT tests, including ANSI S3.19-1974 and S12.6-1997.

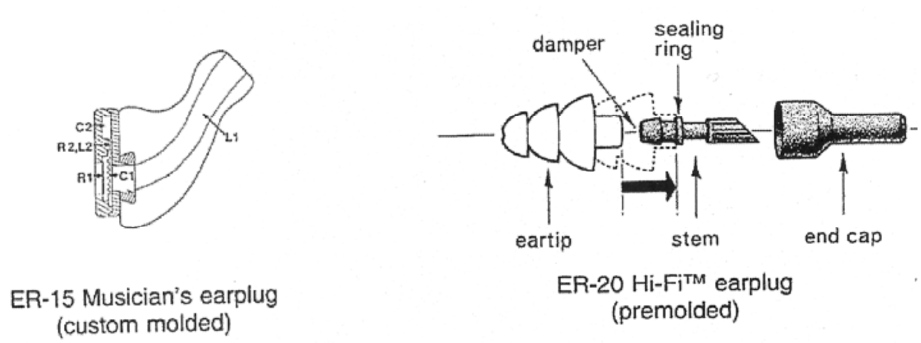

Figure 3. Flat-attenuation earplugs, from Berger and Casali (1996).

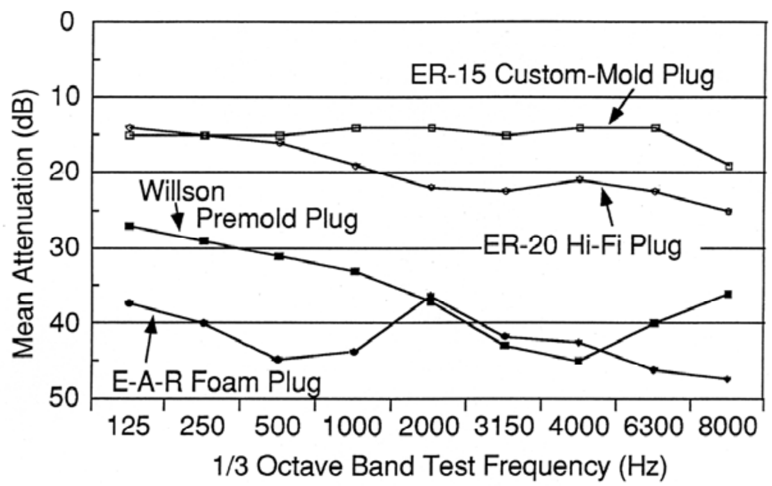

Figure 4. Attenuation characteristics of the two flat-attenuation earplugs shown in Figure 3 as well as those for standard premolded and foam earplugs, from Berger and Casali (1996).

Level-Dependent Devices

Level-dependent (or sometimes called **amplitude-sensitive**) HPDs are designed to change their attenuation characteristics as the ambient noise level changes, increasing their attenuation as the noise level increases. Such devices may be passive, relying on acoustical networks or mechanical valves for their unique attenuation characteristics, or they may be electronic. While most of these devices are based on earmuff designs, like the EAR Ultra 9000™, there are a few level-dependent earplugs, such as the Gunfender™

(Mosko and Fletcher, 1971). Typically, these devices offer minimal if any attenuation at low to moderate noise levels, but as ambient noise levels increase, their attenuation increases to some maximum level.

Passive Level-Dependent Devices. In passive level-dependent HPDs, a dynamically-functional valve or sharp-edged orifice provides a controlled leakage path into the HPD. At low noise levels, the passive attenuation of the device behaves as that of a **leaky protector**, offering little attenuation below about 1000 Hz. This minimal attenuation is all that is available to protect the wearer's hearing at sound levels below about 110 dB. Since such devices are intended to be used primarily in intermittent impulsive noise, this should not be a problem as long as the "off" periods are relatively quiet (below about 85 dBA). At elevated sound pressure levels (above about 110-120 dB, as might occur during a gunshot), the valve is designed either to close or the flow through the orifice changes from laminar to turbulent, effectively closing the orifice and increasing the attenuation of the device. An additional advantage is that some orifice-based devices offer roughly flat attenuation.

Typical broadband attenuation characteristics of an orifice-type passive, level-dependent HPD are shown in Figure 5. As one can see, the non-linear attenuation characteristics of the HPD begin when the incident SPL reaches a level of about 110 dB, but the attenuation does not reach a maximum until the incident SPL exceeds 160 dB. Clearly, these devices do not lend themselves to use in most industrial situations characterized by continuous noise at much lower levels.

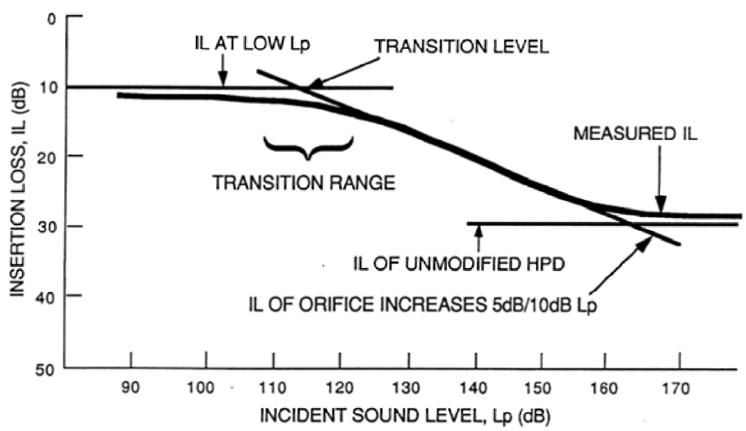

Figure 5. Typical broadband attenuation characteristics of an orifice-type, passive level-dependent HPD, from Allen and Berger (1990).

Active/Electronic Level-Dependent Devices. These electronically-augmented devices, typically earmuff-based, incorporate a microphone and output-limiting amplifier to transmit external sounds to earphones mounted within the earcups. The electronics can be designed to pass and boost only certain sounds, such as the critical speech band or critical warning signal frequencies. Typically, the limiting amplifier maintains a predetermined gain, which in some cases is user-adjustable, often limiting the earphone output to about 82-85 dBA. When the ambient noise reaches a cutoff level of 115 to 120 dBA, the electronics cease to function and at this point the device essentially becomes a passive HPD. This is illustrated schematically in Figure 6.

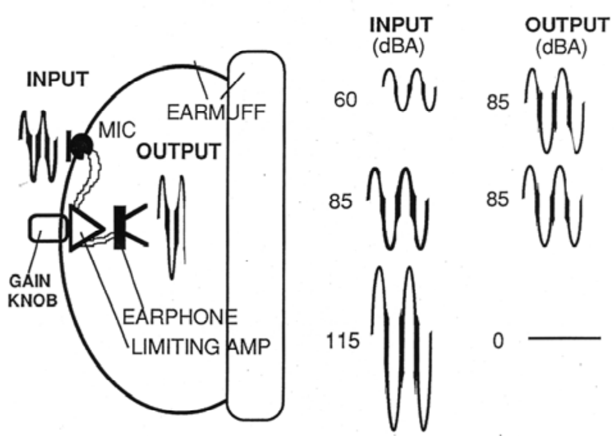

Figure 6. Example of the operating characteristics of an electronic level-dependent sound-transmission earmuff.

Ideally, a level-dependent sound-transmission HPD should exhibit a flat frequency response and distortion-free amplification without spurious electronic noise across its passband, as well as high signal-to-noise ratios (S/N) at levels below its predetermined cutoff level. The cutoff level itself should be safe, to ensure that transmitted sound does not overexpose the wearer. The cutoff should be fast, meaning little or no delay, and should exhibit a sharp attenuation transition without transients. The passband of the electronics should be adequate to accommodate desired signals, but not so wide as to pass unnecessary and undesirable noise to the listener. There should be two external microphones, one for each ear permitting dichotic listening to aid in sound localization, and they should be minimally affected by wind or normal movement of the head. Such devices have the potential for improving the hearing of hearing-impaired listeners in quiet or moderate noise levels, acting much like a hearing aid. However, normal-hearing listeners may not realize similar benefits due to the potential for the residual electronic noise to mask desired signals. Like their passive counterparts, some of these devices are well suited for impulsive noise, but less so for sounds with long on-durations, which can produce objectionable distortion artifacts.

Ideal and typical performance for active sound transmission systems are illustrated in Figure 7. The gain for the system at low sound levels may be set anywhere from a negative value, which in essence provides a degree of noise reduction, to a positive value. An example of a device with a 6-dB positive gain is shown in Figure 7. The maximum attenuation that the active sound-transmission device can provide occurs at levels at and beyond the level at which the electronic circuitry has cut off. Then the earmuff continues to provide the passive attenuation of its earcups as shown by the right-most diagonal line labeled "off." Presuming that the microphone and cable penetrations through the cup are properly designed and acoustically sealed, the performance of the system with the electronics cut off should be approximately the same as the equivalent passive earmuff without the electronics and transducers.

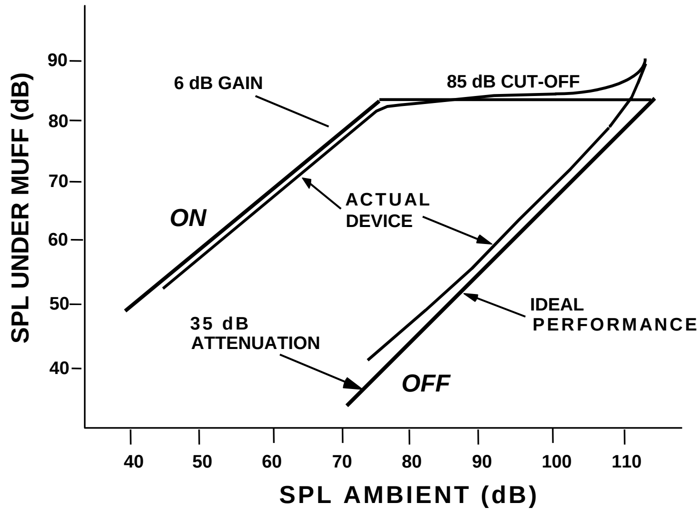

Figure 7. Ideal versus typical performance characteristics of an electronic level-dependent sound-transmission earmuff, from Maxwell, et al. (1987).

REAT Testing Issues: Active and Passive Level-Dependent HPDs. Because REAT tests of passive level-dependent devices are performed at the listener's threshold of hearing, REAT attenuation data are valid only for a device's performance in quiet. Although attenuation at higher sound pressure levels *should* be higher, it is not represented in REAT data. The situation is reversed for active level-dependent HPDs. REAT attenuation is valid only for a device's performance with its electronics turned off, otherwise, electronic hum and amplification would affect the thresholds. Such attenuation data are valid only when HPD is functioning as a passive attenuator, and this yields "best-case" attenuation. With the sound transmission circuit turned on, attenuation will likely be lower because of electronic pass-through sound.

Testing Needs for Level-Dependent HPDs. Because the noise levels are so high at which passive level-dependent devices are most effective (greater than 110 - 120 dB), tests conducted to quantify their attenuation characteristics cannot ethically use human test subjects, even those using MIRE techniques where the subjects may wear earplugs. The only methods currently available for this purpose involve ATFs or HATS. The attenuation performance of passive level-dependent HPDs must be quantified as a function of transient pressure pulse onset-to-peak (“attack”) time and peak-to-ambient (“decay”) time for a “standard” rapid burst, such as that produced by gunfire. Any standardized test protocol should utilize both Type A (damped) and Type B (undamped) impulses, as shown in Figure 8, because the HPD’s attenuation performance may change as a result of the oscillatory behavior of the incident pulse wave. Quick response time performance is of critical importance in these nonlinear devices. In addition to the needs outlined above for passive level-dependent devices, electronic level-dependent HPDs also require quantification of the frequency response of the microphone-amplifier-earphone circuit, the distortion characteristics of the electronics, and any change in performance with degraded batteries. Finally, electronic level-dependent HPDs must be tested against both impulsive and steady-state noises at levels from 85 dBA up to the design limits of the protector.

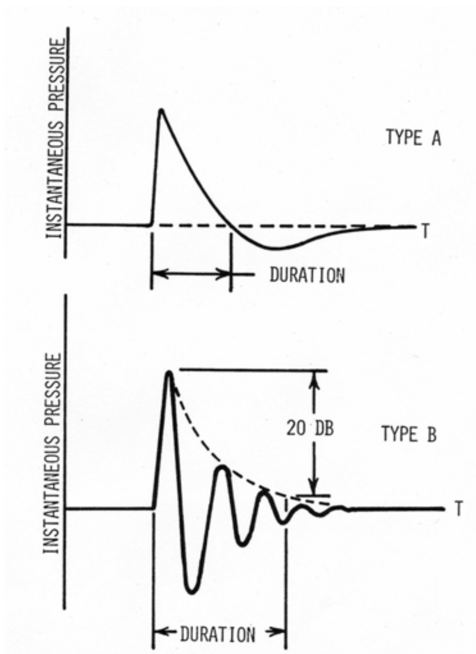

Figure 8. Damped (Type A) and undamped (Type B) impulses, from Minnix (1978).

Two examples of studies on level-dependent HPDs are useful to illustrate specific performance issues with these augmented devices. Neither of these issues would be dealt with by the current REAT standard tests.

Murphy and Franks (2002) reported on a study in which they evaluated the attenuation of six different electroacoustic earmuffs and one assistive listening device (a hearing aid) using an acoustic manikin (HATS). The electroacoustic earmuffs were the Bilsom 707 Impact II™, Bilsom Targo Electronic™, Howard Leight Thunder™, Howard Leight Leightning™, Peltor Tactical 6S™, and Peltor Tactical 7™, which were tested against gunfire from 10 weapons: eight handguns of various calibers and two 12-gauge shotguns. The devices were tested at three gain settings: off, unity, and maximum gain. The authors found that peak attenuation ranged from about 22 dB to 34 dB across devices, that attenuation was only slightly dependent upon the gain setting of the electronics, and that peak attenuation differences between maximum gain vs. gain off settings were within about 3 dB for most devices.

Casali and Wright (1995) utilized a Peltor T7-SR™ level-dependent sound-restoration earmuff in a signal detection study where masked thresholds were determined as subjects responded to a vehicle backup alarm. With the earmuff's gain set to a subjectively-preferred level, subjects listened for the backup alarm in continuous pink noise presented at levels of 75, 85, and 95 dBA. After each test, the subject-selected gain control settings were determined using a KEMAR manikin. A MANOVA was applied to dBC, dBA, and 1000-Hz noise measurements made under the earmuff, with gain status (on or off) as one independent variable. The gain-on vs. gain-off differences were largest (5 dB) at 1000 Hz, but overall, the contribution of the gain to the noise exposure, as measured by noise dose, was negligible. This result is illustrated in Figure 9, showing the percentage of 8-hour noise dose as well as the sound level under the protector for the gain-on vs. gain-off conditions.

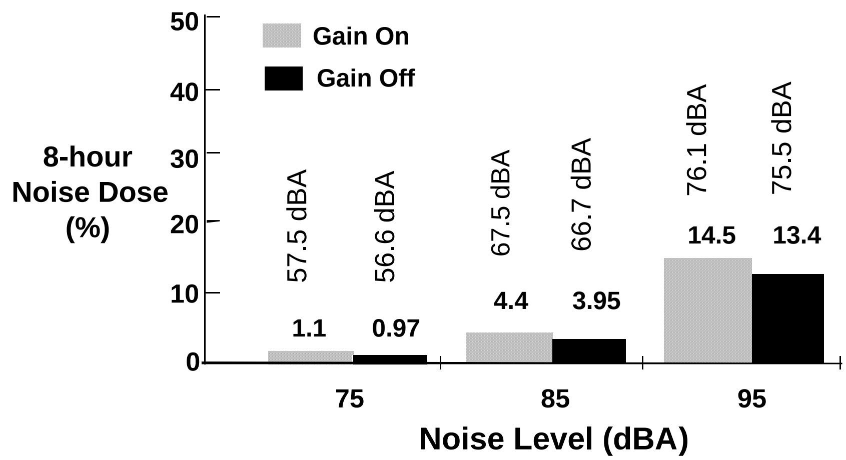

Figure 9. Eight-hour noise dose produced under Peltor T7-SR™ level-dependent sound-restoration earmuff, for subjects' gain settings and gain off setting, in 3 noise levels, from Casali and Wright (1995).

When testing either passive or electronic level-dependent HPDs against impulsive noise, the need exists for a standardized method or device for reliably producing consistent, repeatable impulses. While some researchers use gunfire (e.g., Murphy and Franks, 2002), the impulses produced vary with weapon type, weapon manufacturer, caliber, and ammunition manufacturer. Even impulses produced with a single weapon vary from firing to firing. A more consistent alternative is needed, and two examples follow:

Zera (2002) describes a device which can reliably produce impulses in the range of 145-170 dB, as shown in Figure 10. In this device, a cylinder with one end closed by a metal foil or elastomer diaphragm is pressurized. When the pressure reaches a predetermined level, depending upon the desired sound pressure level of the impulse, a needle punctures the diaphragm, creating the sound impulse. The earmuff being tested is situated on an acoustical test fixture or HATS located beside the cylinder. To enable quantification of the earmuff's attenuation using a single impulse, two microphones are used, one underneath the earmuff and one exterior to the earmuff (a *noise reduction* measurement as described earlier).

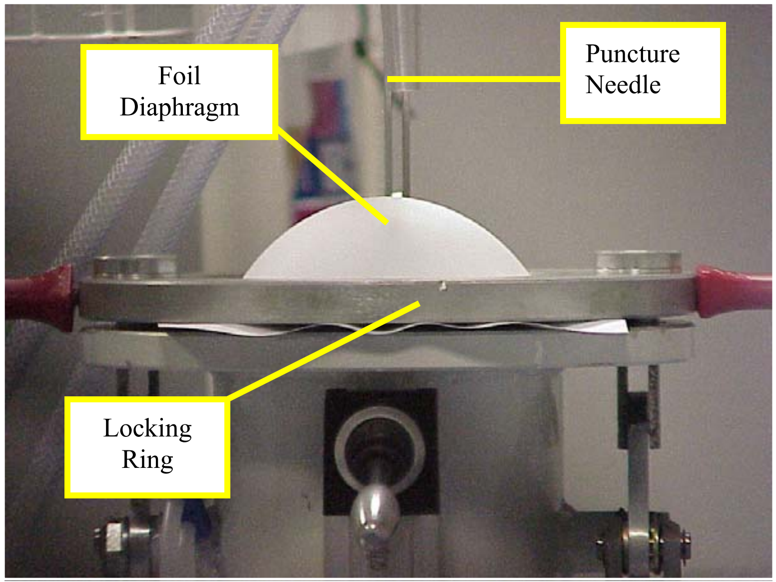

Figure 10. Diaphragm-type impulse generator, from Zera (2002).

A second approach to this problem is described by Vergara, Gerges, and Birch (2002). Their device is a 12 m shock tube in which a pressure impulse is created at one end, which then travels down the length of the tube, ultimately reaching the earmuff on an ATF/HATS located in a removable test section near the opposite end of the tube. This device, illustrated in Figures 11 and 12, can produce controlled high-amplitude impulses above 140 dB. As with Zera's device, noise reduction measurements are obtained on the test HPD.

(a) Pressure wave generator, exterior

(b) Exterior of shock tube

Figure 11. Exterior view of a pressure wave generator and 12 m shock tube, from Vergara, Gerges, and Birch (2002).

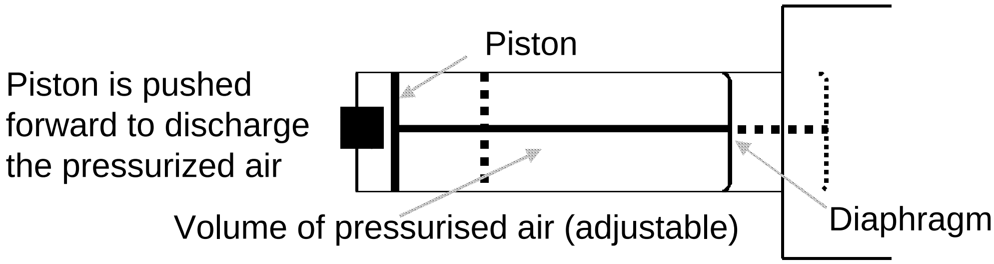

Figure 12. Schematic diagram of a shock tube pressure wave generator, from Vergara, Gerges, and Birch (2002).

A Misinterpretation Relating to Level-Dependent HPDs that Stems from the EPA Labeling Regulation. The EPA labeling requirement (40 CFR Part 211) for devices sold for hearing protection purposes label states that: "Although hearing protectors can be recommended for protection against the harmful effects of impulsive noise, the NRR is based on the attenuation of *continuous* noise and may not be an accurate indicator of the protection attainable against *impulsive* noise such as gunfire." (See CFR, 2002). This statement was included because level-dependent devices were felt by manufacturers to be *under-rated* by the NRR. That is, their NRR rating was based on attenuation at threshold, not at high ambient noise levels where their attenuation increased. However, based on the authors' experience, as well as those of others involved in research and practice with HPDs (Berger, 2003), there is a common misconception that results from this statement. The misinterpretation is that HPDs do not work well in impulsive noise, which is not true, except in extremely high levels (>170 dB) where earmuffs may separate from the head when the blast overpressure moves by the head. In fact, the NRR is a reasonable indicator of the attenuation of impulses by a given HPD. This statement calls for a revision in any new labeling regulation.

Active Noise Reduction HPDs

Active Noise Reduction (ANR) relies on the principle of destructive interference of equal amplitude, but 180 degree out-of-phase sound waves at a given point in space; in the case of hearing protectors, the cancellation is established at the ear. Although the first ANR headset appeared as a working model in 1957 (Meeker, 1957), it has only been in the past decade that major advances in miniature semiconductor technology and high speed signal processing have enabled ANR-based HPDs and communication headsets to become viable products.

ANR has been incorporated into two types of personal systems: 1) those designed solely for hearing protection, and 2) those designed for one- or two-way communications. Both types are further dichotomized into open-back (supra-aural) and closed-back (circumaural earmuff) variations. In the former, a lightweight headband connects ANR microphone/earphone assemblies surrounded by foam pads that rest on the pinnae. Because there are no earmuff cups to afford passive protection, the open-back devices provide only active noise reduction, and if there is an electronic failure, no protection is provided. Closed-back devices, which represent most ANR-based HPDs, are typically based on a passive noise-attenuating earmuff, which houses the ANR transducers, and, in some cases, the ANR signal processing electronics. In the event of an electronic failure of the ANR circuit, the closed-back HPD is advantageous due to the passive attenuation established by its earcup.

Analog ANR Devices. A generic block diagram depicting the typical components of an analog electronics, feedback-type, muff-based ANR HPD appears in Figure 13. The example shown is a closed-loop, feedback system which receives input from a sensing microphone, which detects the noise that has penetrated the passive barrier posed by the earmuff. The signal is then fed back through a phase compensation filter that reverses the phase. It then goes to an amplifier, and finally becomes output, as an "anti-noise" signal through an earphone loudspeaker to effect cancellation inside the earcup. Although most ANR devices have been built in earmuff or supra-aural headset configurations, earplug examples have been prototyped but are not yet commercially offered. In contrast to the common ANR closed-loop feedback configuration, open-loop, feed-forward systems are also available; these are typically of the lightweight headset (open-back) variety.

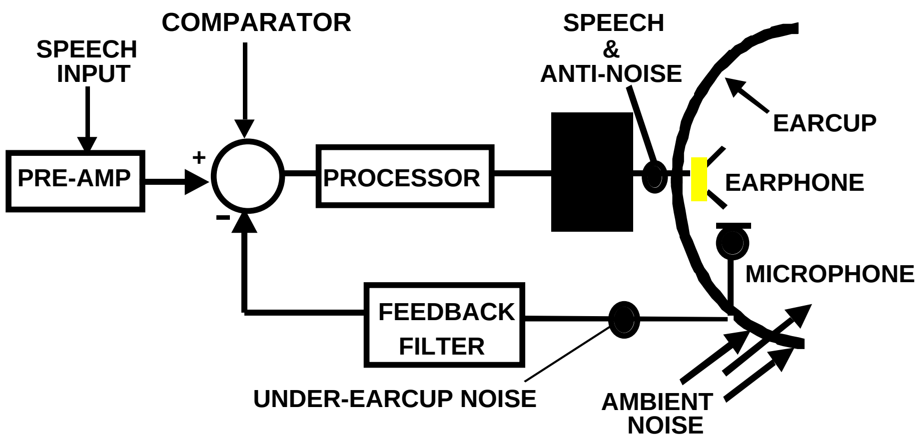

Figure 13. Schematic diagram of a typical analog ANR headset, from Casali and Berger (1996).

Due to the phase shifts that can be attributed to transducer location differences, as well as the possibility of throughput delays in signal processing, establishing the correct phase relationship of the cancellation signal and noise becomes more difficult as the bandwidth of the noise increases. For this reason, ANR has typically been most effective against low-frequency noise. For example, with contemporary analog ANR devices, maximal attenuation values of about 22 dB are typically found in a range from about 100 to 250 Hz, dropping to essentially no attenuation above about 1000 Hz (Nixon, McKinley and Steuver, 1992; Casali and Robinson, 1994). Noise enhancement, typically of 3 to 6 dB, but in some cases more, occurs in the midrange frequencies (about 1000 to 3000 Hz) with some analog ANR devices (Robinson and Casali, 1995).

Digital ANR Devices. With advances in the speed, power, reliability, and miniaturization of digital signal processing components, digital technology has demonstrated promise for improving the capabilities of ANR-based HPDs, particularly the precise tuning of the control system via software for optimizing the cancellation of specific sound frequencies. The advantages of digital technology lie mainly in its capability to perform complex computations with high precision because electronic components are less affected by temperature variations and remain more stable, and performance tolerances can be held very tight. Some ANR HPDs incorporate hybrid analog/digital designs.

A block diagram of the major components of a digital ANR system, showing one earphone, appears in Figure 14. A residual microphone transduces the noise at the ear providing the input to the digital controller, allowing it to continuously create an anti-noise signal which is presented via the headset speaker to minimize the noise at that ear. The internal operation of the controller can be best described starting at the output of the adaptive filter. The adaptive filter generates the anti-noise signal that is passed through an equalizing filter (designed to match the acoustics of the headset), creating a signal that approximates the acoustical anti-noise as would be heard by the residual microphone. Subtracting this signal from the residual noise signal then recreates an approximation of the original noise that would be at the ear if the ANR were turned off. The regenerated reference signal is then input to a classical "Least Mean Square" adaptive filter, which compares the regenerated reference signal to the residual signal and continuously updates its internal parameters so as to minimize the energy in the residual signal (Denenberg and Claybaugh, 1993). While analog devices generally work best against steady-state low-frequency noise, digital devices have been shown to reduce noise at frequencies as high as 2000-3000 Hz, and can be tuned to cancel periodic noises as well, such as an emergency vehicle siren (Casali and Robinson, 1994).

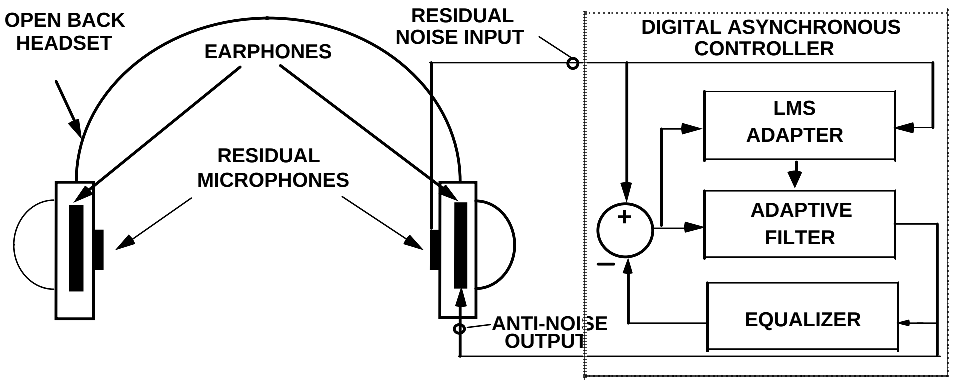

Figure 14. Schematic diagram of a typical digital supra aural ANR HPD, adapted from Denenberg, and Claybaugh (1993).

ANR HPD Testing and Labeling Issues. At present, standardized attenuation data and NRR ratings are not available for ANR hearing protectors. MIRE testing using ANSI S12.42-1995 can be used to measure the passive (ANR off) and total (ANR on) attenuation of the device. The active component of the attenuation can then be computed using the following relationship:

Active component = MIRE total – MIRE passive

REAT or MIRE testing can be used to quantify the passive component of the total attenuation for labeling purposes, but the choice of method can affect the data. MIRE attenuation at low frequencies is lower than REAT attenuation due to the physiological noise masking effects on occluded thresholds that occur during REAT testing. Looked at in another way, one could say that REAT overestimates the low-frequency attenuation of HPDs. In addition, MIRE, unlike REAT, does not account for the bone conduction path[3]. Finally, passive attenuation is often decreased in the middle frequencies (from about 1000-3000 Hz) when the ANR circuit is turned on and the electronics may produce or amplify noise which increases the noise level under the protector.

Issues with ANR HPDs relating to the NRR. Because ANR works only with specific noises, like siren noise or continuous low-frequency noise for analog devices, the nature of the REAT test stimulus (1/3 octave bands of noise pulsed at approximately 2 Hz) makes it incompatible with these devices. While it might be possible to build an ANR HPD that would cancel REAT test stimuli, the data would not be representative of the device's performance against most other types of noise. Likewise, attempting to test an ANR device in the active mode with traditional REAT procedures would not produce useful attenuation data, due in part to the masking effects of the earphone-produced noise and possibly, cancellation of the test stimulus signal. Furthermore, NRR ratings cannot generally be calculated from MIRE data since within- and between-subject variability is such an integral part of the process. However, this problem can be overcome to some degree by performing multiple measurements, where each measurement represents a unique fit of the device, across multiple subjects.

Based on anecdotal information, it appears that some ANR manufacturers feel that they are being penalized by the lack of legally-accepted test procedures and labeling guidelines since it precludes them from selling their products as industrial or consumer devices for protecting the ear against noise hazards. However, other manufacturers, based on the fact that they target their sales to applications other than industrial markets, like the military, general aviation, consumer noise annoyance, do not want an NRR. However, an important question must be asked: In the absence of attenuation data, will the typical consumer really know <u>not</u> to use the ANR device as a hearing protector?

The argument has also been made that ANR devices do not need an NRR. ANR devices work best in low-frequency-biased noise, characterized by dBC minus dBA (C-A) values greater than 5-6. As one can see in Figure 15, most industrial noises have C-A values less than about 4-5. Some argue that since ANR devices do not lend themselves to typical industrial noises, they do not require an NRR or similar labeling requirements.

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[3] Bone conduction, as a flanking path, limits the performance of <u>all</u> HPDs and thus is an important factor when quantifying their attenuation.

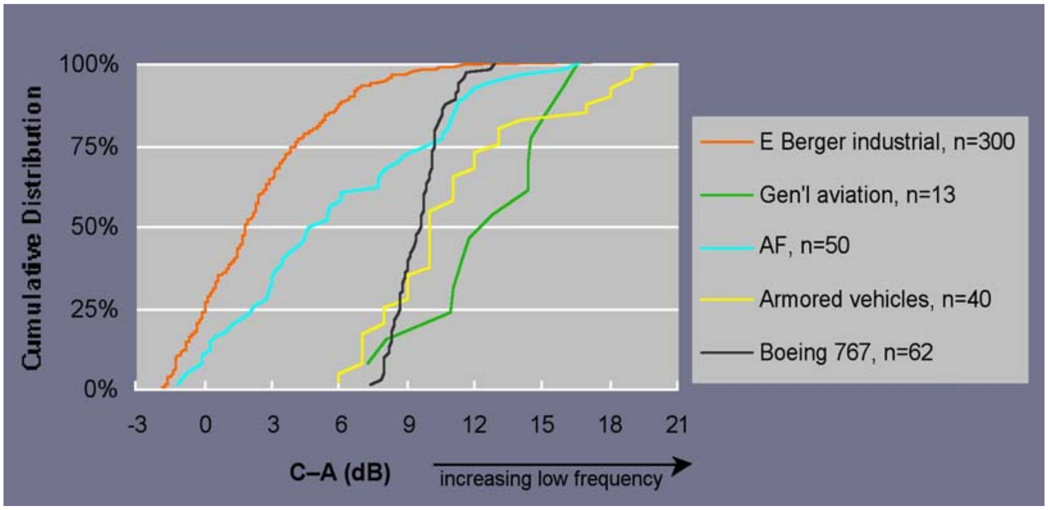


Figure 15. dBC minus dBA values for various noises, from Gauger (2002).

ANR Attenuation Performance: MIRE and REAT. Typical REAT and MIRE attenuation for a closed-back circumaural ANR earmuff is shown in Figure 16 (Robinson and Casali, 1995). Readily apparent in the figure is the difference between the MIRE and REAT attenuation at 125 and 250 Hz. As mentioned earlier, this difference is due to physiological noise masking the test stimulus during the REAT test. Also evident in the figure is the slight reduction in total attenuation at 1000 and 2000 Hz when the ANR device is turned on.

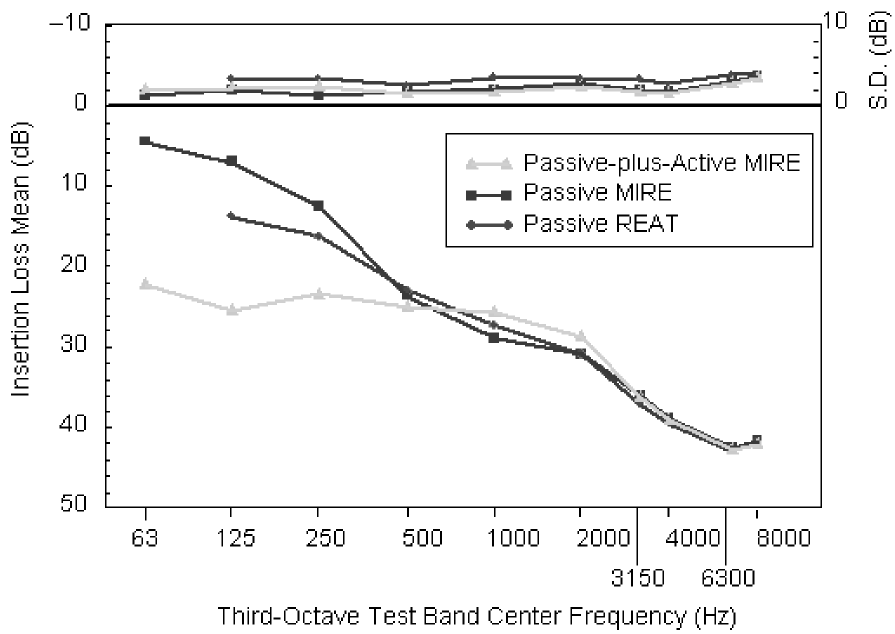


Figure 16. Attenuation of the NCT PA-3000 closed back ANR headset, from Robinson and Casali (1995).

Similar data for an open-back (supra-aural) ANR headset appears in Figure 17 (Robinson and Casali, 1994). In this case, the device offers essentially no passive attenuation, only active attenuation at frequencies below 1000 Hz.

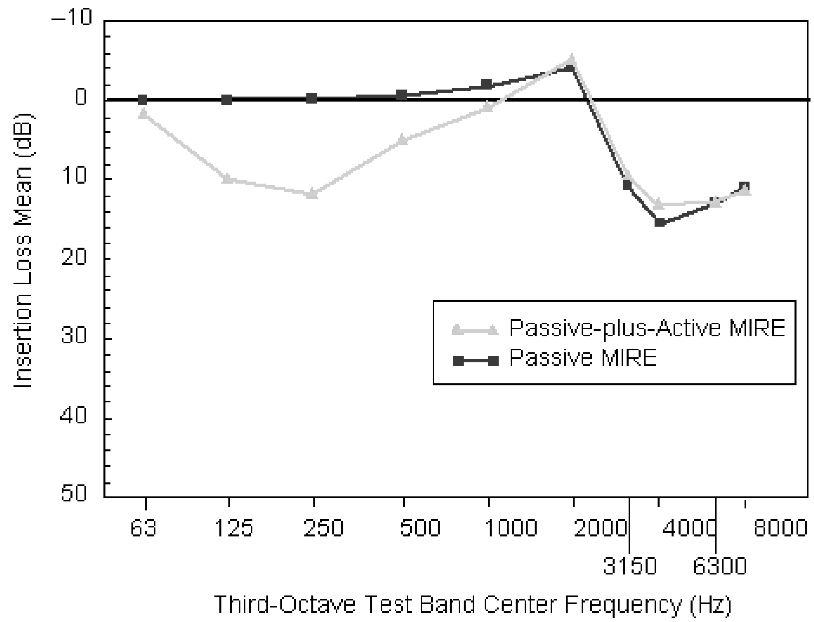


Figure 17. Attenuation of the NCT PA-1000 open back ANR HPD, from Robinson and Casali (1994).

Finally, the total (MIRE) attenuation of two closed-back circumaural ANR earmuffs are compared to the passive (REAT) attenuation of a foam earplug in Figure 18 (Casali and Berger, 1996). As one can see, even well-designed large-volume ANR earmuffs offer considerably less attenuation than a well-fitted (and less expensive) foam earplug. Clearly, ANR devices must distinguish themselves for characteristics other than simply attenuation. While Figure 16 illustrates the total (MIRE) and passive (both REAT and MIRE) attenuation, the active component of the device can be separated from the total attenuation simply by subtracting the MIRE passive attenuation from the MIRE total attenuation. This is illustrated in Figure 19. Here, it is clearly evident that the active circuits contribute to the noise level at the ear at 1000 and 2000 Hz.

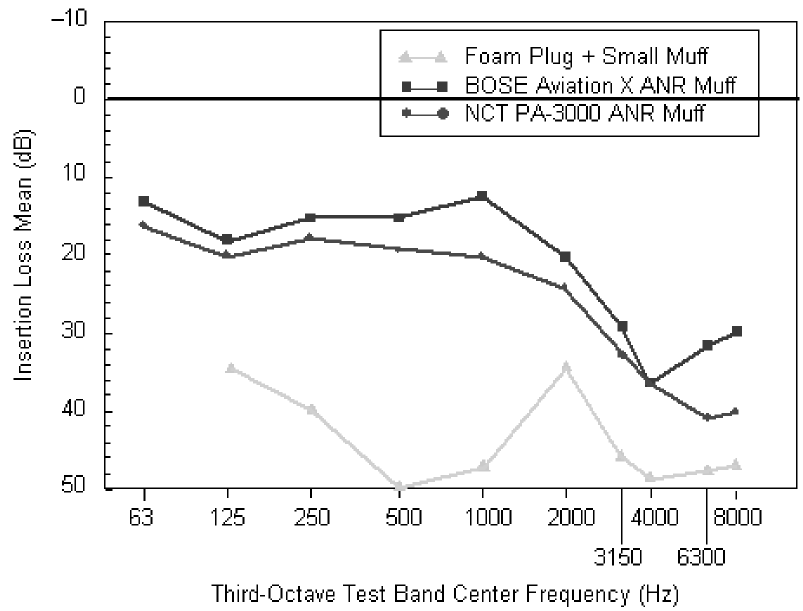


Figure 18. Comparison of the MIRE attenuation of two closed back ANR HPDs with the REAT attenuation of double passive HPDs (earmuff over foam plug), adapted from Casali and Berger (1996), with modifications.

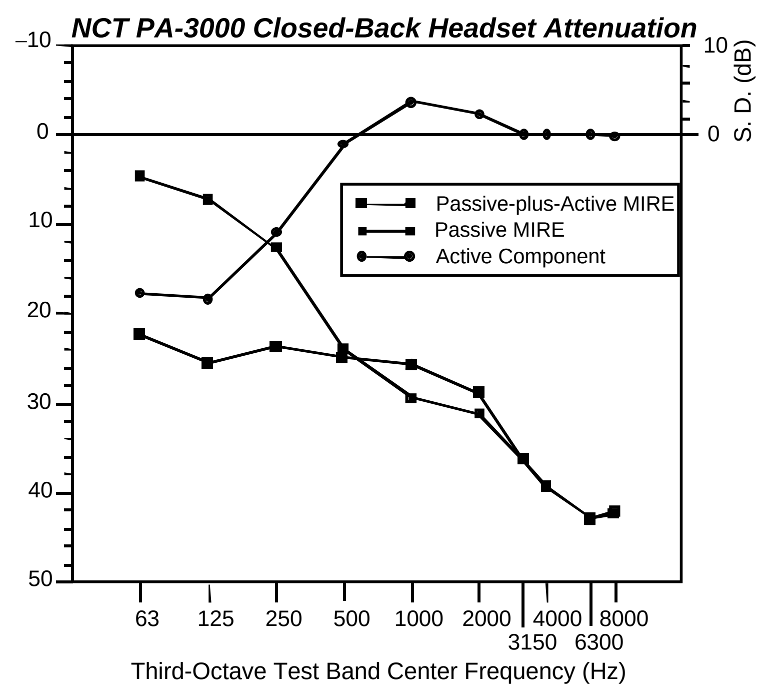


Figure 19. MIRE active, passive and total attenuation of the NCT PA-3000 ANR headset, from Robinson and Casali (1995).

These two factors have lead some ANR manufacturers to target their devices to very specific applications, going so far as to tune their devices to particular noises. An example of this is illustrated in Figure 20 (Urquhart, Robinson, and Casali, 2001), showing the performance of a supra-aural (open back) ANR headset designed to be used in a U.S. Army Standard Integrated Command Post Shelter (SICPS). The ANR electronics were tuned specifically for the noise found in these shelters, and the device works quite well at frequencies from 80 to 630 Hz. The way in which this attenuation reduces the noise reaching the ears of the wearer in the SICPS shelter is illustrated in Figure 21. As one can see, the ANR device reduces the low frequency noise considerably, most likely reducing annoyance and fatigue and potentially improving speech intelligibility by reducing the upward spread of masking.

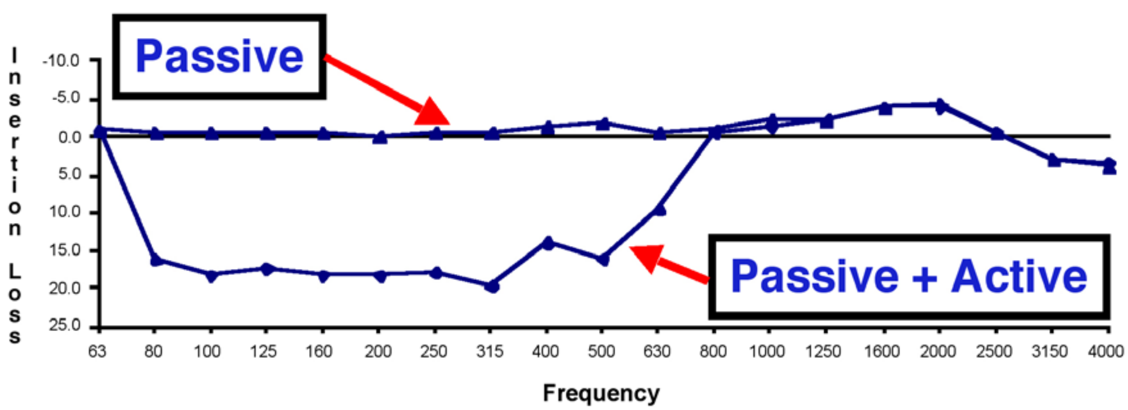


Figure 20. Attenuation of a prototype supra-aural NAR headset intended to be used in U.S. Army SICPS, from Urquhart, Robinson, and Casali (2001).

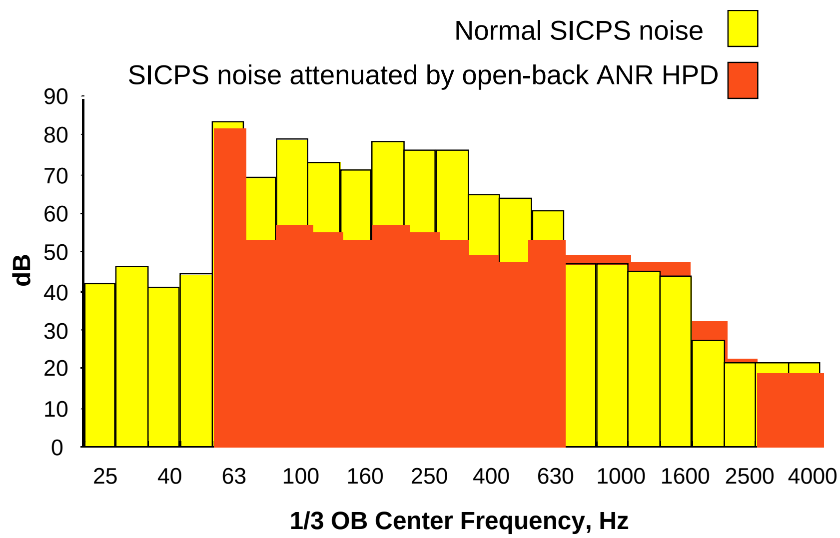


Figure 21. Reduction in noise exposure occurring for SICPS crew using the prototype supra-aural ANR headset, from Urquhart, Robinson, and Casali (2001).

Current ANR HPD/Headset Applications. ANR devices cannot currently be sold as *hearing protectors* (except for their passive attenuation only) due to the lack of appropriate ANR testing standards and labeling regulations. However, they are being used for various purposes in both the public and private sector. For example, ANR headsets are sold to airline passengers to reduce noise annoyance. They are also sold as personal stereo headsets, communications headsets for commercial, military and civilian aviation, and they are used to combat severe noise environments in armored vehicles in the military. Special-purpose ANR devices are also available for telephone operators and telemarketers, to reduce patient noise exposure in MRI machines, and even to reduce siren noise for emergency vehicle crews. As stated previously, there is still disagreement among ANR HPD manufacturers about the potential for the application of ANR to industrial noise markets, and, therefore, whether an NRR-like rating is really necessary since relatively few industries are characterized by noise with applicable C-A values (see Figure 15 above and Figure 22 below).

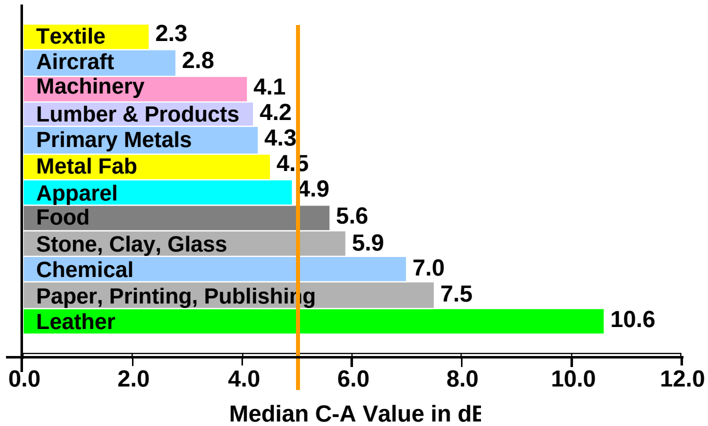


Figure 22. Examples of C – A values for various U.S. industries, from Karplus and Bonvallet (1953).

Adjustable Attenuation HPDs

To help overcome the problem of "overprotection" in moderate noise environments, earplug designs have recently been developed that allow the user some level of control over the amount of attenuation achieved. These devices incorporate a leakage path that is user- or technician-adjustable by setting a valve which obstructs a channel through the body of the plug, or by selecting from a choice of available filters or dampers.

A Dutch earplug, Ergotec Varifoon™, is an example of an adjustable-valve design, which is constructed from an acrylic custom-molded impression of the user's earcanal. According to the manufacturer's data, below 500 Hz the attenuation adjustment range is approximately 20 to 25 dB, with a maximum attenuation of about 30 dB at 500 Hz. At higher frequencies, the range of adjustment decreases, while the maximum attainable attenuation increases slightly. At any valve setting, the Varifoon™ provides frequency-dependent attenuation which increases with frequency. An example of a selectable-filter design is the Sonomax SonoCustom™, manufactured in Canada. The Sonomax device is still in development at the time of this publication, so attenuation data are not yet available.

There are two important distinctions between passive adjustable-attenuation HPDs and the passive level-dependent HPDs discussed earlier. The former require setting by the user to effect attenuation changes, and the attenuation, once selected, is essentially independent of incident sound level. Level-dependent devices, on the other hand, react automatically to changes in incident sound levels and the user typically has no control over the change in attenuation.

Issues in Applying REAT Standards to "Adjustable" Attenuation HPDs. For adjustable attenuation passive devices, the issues are only slightly more complex than for the flat-attenuation passive devices discussed earlier. For devices with discrete settings (e.g., the SonoCustom™) REAT tests can be conducted for each discrete level of adjustment (or for each damper/filter insert) and an NRR is determined for each setting. However, this is time- and labor-intensive, and thus can be expensive for the manufacturer. Continuously-variable devices (e.g., Varifoon™) are more problematic because they can only be tested *reliably* at the extremes of their adjustment range (fully open and fully closed). As such, there is no way to reliably quantify the protection afforded by these devices at any intermediate setting. Finally, some of these devices are sold as a system that includes training for the end-user, individual "tuning," and fit-testing. All of these factors impact attenuation performance, but the test standards and labeling requirements do not reflect the influence of these features.

This class of device affords flexibility in product development in that they can be fitted with "modular" augmentations. User-adjustable devices are easily adapted to changing noise environments. Filter-based devices can be tuned for specific environments or tuned to pass speech or other critical bands necessary for specific jobs. As this technology matures, the potential exists for additional active or electronic augmentations to be incorporated into the devices, noise suppression, electronic filtering, closed-loop attenuation control, hearing assistive circuits, and automatic gain control. When this occurs, each augmentation will most likely require different testing and labeling procedures.

Physical (Microphone-Based) Measurements: Which HPDs may require them?

Based on the previous discussion of various test methods and HPD augmentation technologies, it is possible to construct a table that assigns specific technologies to specific test methods. This has been done in Table 2.

Table 2. Attenuation test methods and applicability to specific augmented HPD types.

Microphone-in-Real-Ear (MIRE)

- Level-dependent earmuffs
- ANR earmuffs or supra-aural devices
- Adjustable attenuation earmuffs (also REAT)

Microphone-in-Acoustical-Test-Fixture (ATF)

- Level-dependent earmuffs (for high level impulses)
- ANR earmuffs or supra-aural devices
- ANR or level-dependent earplugs
- Adjustable attenuation earmuffs or earplugs (also REAT)

Microphone-in-Head-and-Torso-Simulator (HATS)

- Same as for ATF

SPECIFIC LIMITATIONS WITH REAT (S3.19-1974; S12.6-1997) AND MIRE (S12.42-1995) TECHNIQUES

ANSI S12.6-1997, the most current REAT test standard, states expressly in its *Abstract* that it applies only to “conventional passive hearing protection devices.” In addition, the *Forward* states that it “does not pertain to physical attenuation measurements using acoustical test fixtures or microphones mounted in human ear canals.” Other Standards, ANSI S12.42-1995 or MIL-STD-912, address MIRE measurements.

There are, however, quantifiable reasons why REAT or MIRE testing is inappropriate for testing certain aspects of ANR and level-dependent devices. The first of these deals with the levels at which the devices must be tested. After all, the performance limitations of an HPD cannot be established without exceeding those limits. As stated earlier, the levels at which passive and electronic level-dependent devices must be tested (greater than 110 - 120 dB) are inconsistent with use of humans as test subjects. It would be unethical to expose human test subjects to test stimuli at these levels, even if the subjects were double-protected, because it could do them physical harm.

The second issue has to do with the acoustic characteristics of the test stimulus. The REAT test stimuli specified in both ANSI S3.19-1974 and ANSI S12.6-1997 are pulsed 1/3-octave bands of noise presented at the listener’s threshold of hearing. The standard test stimulus for MIRE testing is broadband pink noise. These stimuli are inconsistent with the types of noises for which some ANR and most passive or electronic level-dependent devices are designed. Generally, ANR works best to cancel low-frequency steady-state noise. Some specifically-tuned ANR devices exist which can cancel tonal noise, even high-frequency noise which is steady-state or has a known, measurable period. Likewise, passive level-dependent devices are intended to block relatively high levels of impulsive noise above about 110 – 120 dB. None of these devices would do well at attenuating the standard REAT or MIRE stimuli. If such tests were conducted, the results would not represent the devices’ true functional capabilities. At this stage of knowledge, one is left to conclude that such devices must be tested using test stimuli that represent the noises for which the devices were designed, e.g. engine/drivetrain/airfoil noise, gunfire or explosive impulses, and narrow-band modulated siren noise, etc., which complicates the issues of instrumentation, test environment, and procedures. Such tests are outside the current scope of existing REAT or MIRE standards.

A convincing example of the need to test special-purpose HPDs using the noise stimuli for which they are designed is a study conducted by Casali and Robinson (1994) in which the authors evaluated a supra-aural Noise Cancellation Technologies (NCT) ANR headset designed specifically to cancel emergency-vehicle siren noise. The headset was tested against three different siren sounds (Wail, Yelp, and Hi-Lo) presented at multiple sound levels. The spectra of the three siren sounds are presented in Figure 23. While all three sounds had similar spectra, there were sufficient differences in their periods that each had a distinct sound. Also, the peak energy of all three siren sounds is at 1000 Hz and above, well above the normal limits of ANR-based devices.

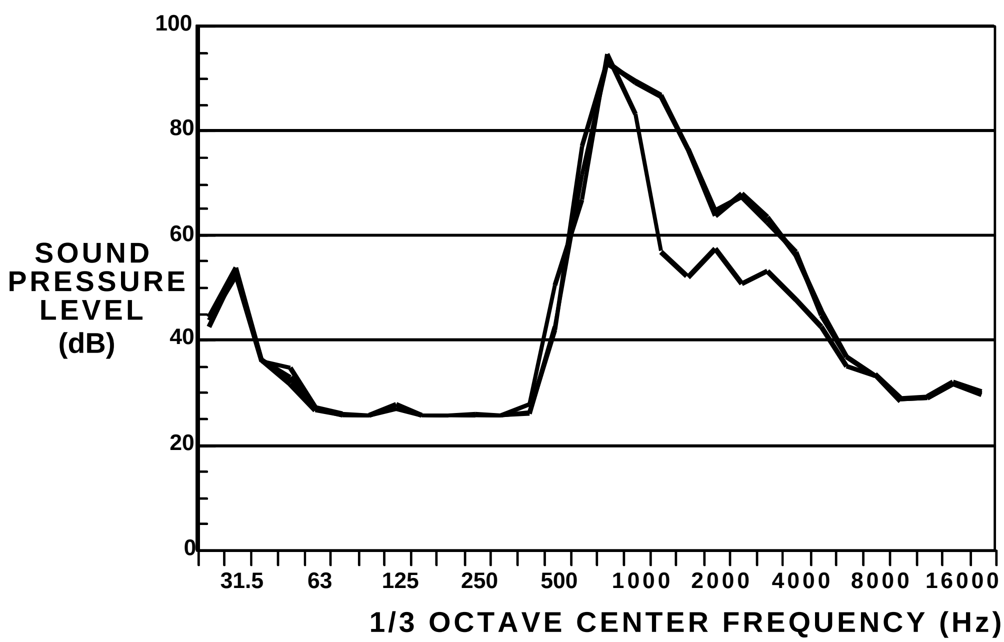
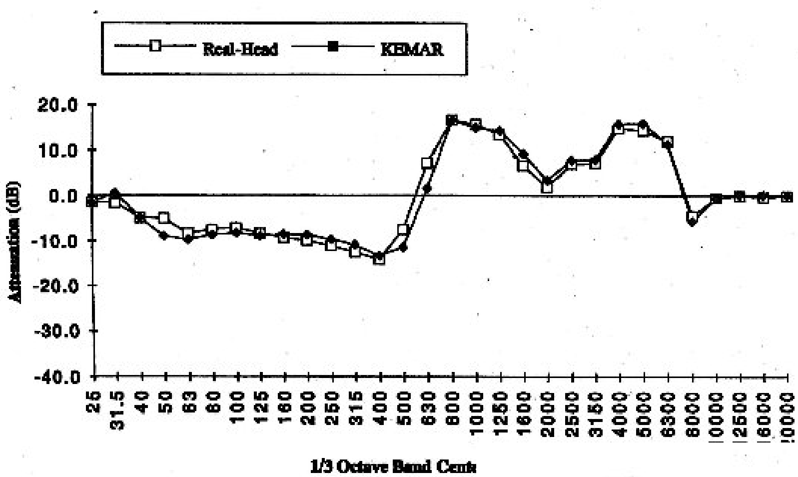
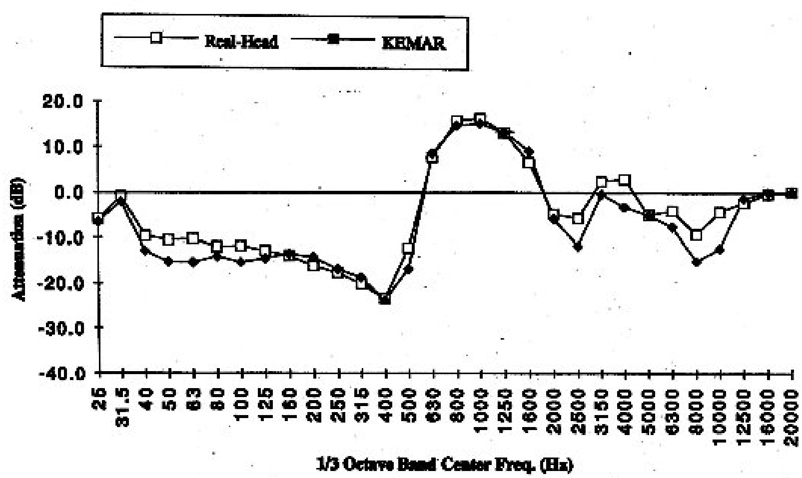


Figure 23. Spectra of three sirens used to evaluate the NCT siren–canceling headset, from Casali and Robinson (1994).

Figure 24 shows the attenuation of the NCT headset for two levels of the Wail siren using MIRE techniques. While the headset performed quite well, achieving active attenuation of nearly 20 dB at frequencies as high as 6300 Hz, it is clearly evident by comparing the two graphs, that the attenuation afforded by the headset is not constant with siren level. Instead, as the level of the siren increases, the attenuation of the headset decreases (see Figure 24 (b)). To fully characterize the performance of such an HPD requires multiple tests at noise levels ranging from the minimum levels expected to the point at which the device either saturates, fails, or shuts down.[4]



(a) Wail at 90 dB(Linear)



(b) Wail at 100 dB(Linear)

Figure 24. Attenuation of the NCT siren-canceling headset when tested using the Wail siren at: (a) 90 dB and (b) 100 dB from Casali and Robinson (1994).

[4] While MIRE techniques were used in this test, the excitation stimulus (siren noise) was not as specified in the two MIRE test standards.

HOW DO MIRE AND REAT RESULTS COMPARE WHEN TESTING CONVENTIONAL HPDs?

As stated earlier, REAT tends to overestimate the low-frequency attenuation of HPDs when compared to MIRE protocols. While the differences are real and measurable, the question arises as to how significant they are when the attenuation spectra are used to calculate a single-number rating such as the NRR. In part to answer this question, Casali, Mauney, and Burks (1995) performed both REAT and MIRE tests on six earmuffs. To remove the effect of re-fitting the muff, both REAT and MIRE tests were performed for <u>each</u> fitting of the earmuffs. In addition, both insertion loss (IL) and noise reduction (NR) MIRE measurements were performed, with the NR data corrected for the transfer function of the open ear. To allow NRRs to be calculated for each test and device, 10 subjects were tested in three trials as required by existing REAT test standards (see Figure 25).

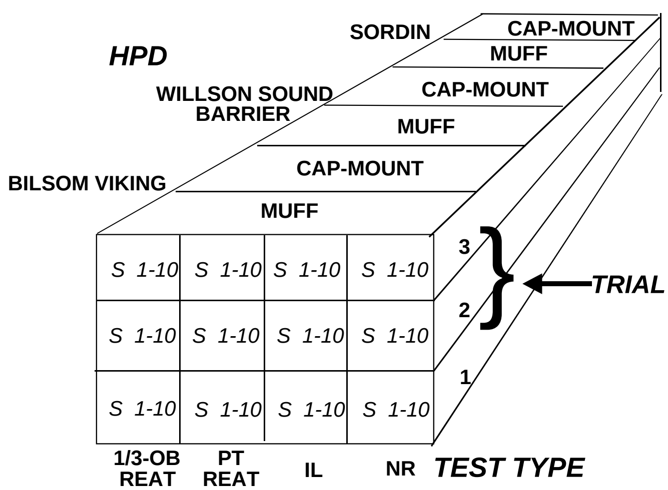


Figure 25. Illustration of the experimental design used by Casali, Mauney, and Burks (1995).

The spectral attenuation and NRRs for two representative examples of the earmuffs appear in Figures 26 thorough 29. It is evident that there were no differences between NRRs calculated using either MIRE method. In addition, the differences between the

NRRs calculated using the MIRE data and the REAT data were small, in fact, insignificant from a practical standpoint. These results suggest that MIRE data can be used to generate an NRR-like rating for at least some augmented hearing protectors.

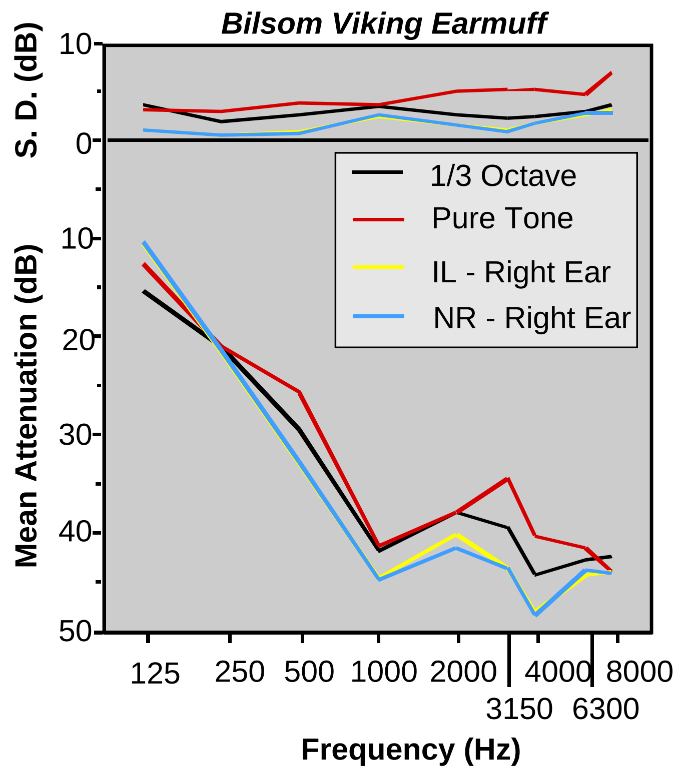


Figure 26. Spectral attenuation of the Bilsom Viking earmuff tested using REAT, MIRE-IL, and MIRE-NR, from Casali, Mauney, and Burks (1995).

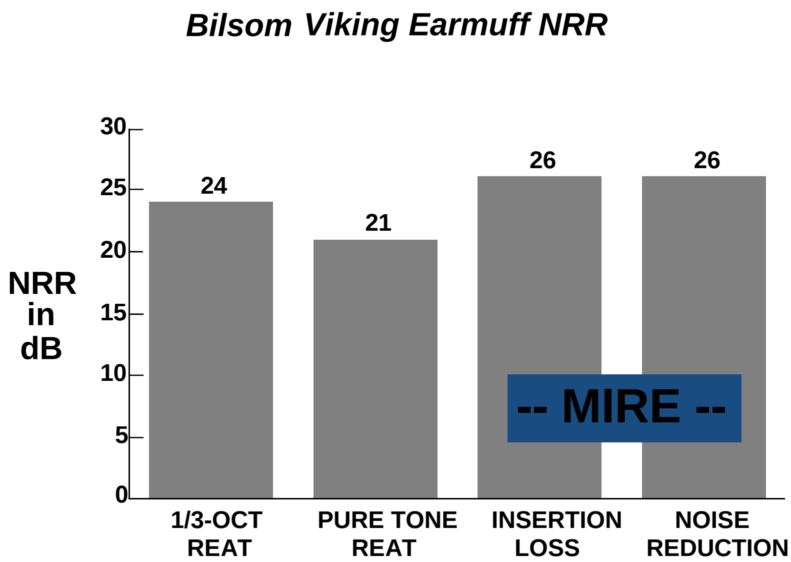


Figure 27. NRRs calculated for the Bilsom Viking earmuff tested using REAT, MIRE-IL, and MIRE-NR, from Casali, Mauney, and Burks (1995)

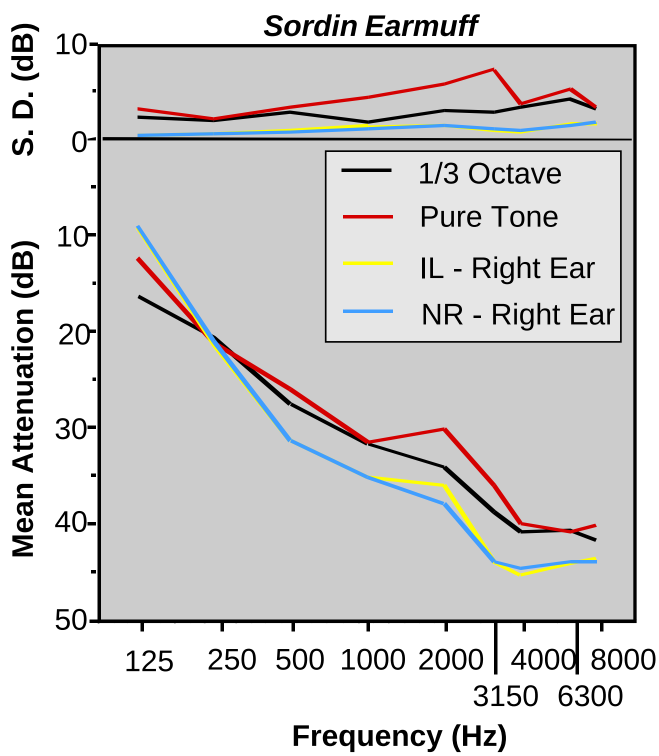


Figure 28. Spectral attenuation of the Sordin earmuff tested using REAT, MIRE-IL, and MIRE-NR, from Casali, Mauney, and Burks (1995).

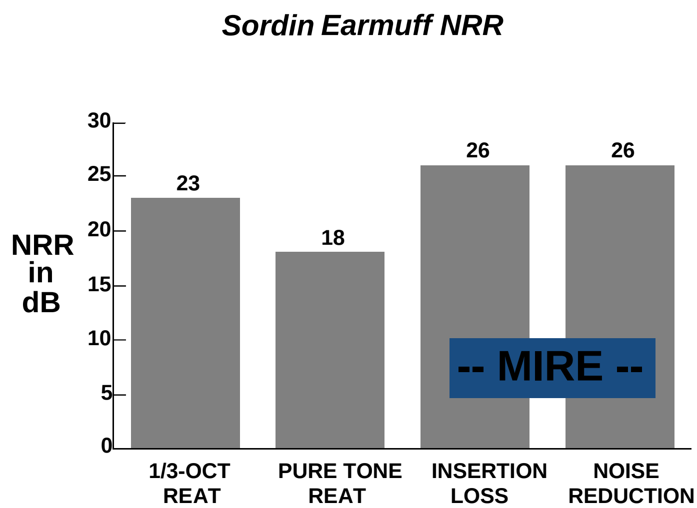


Figure 29. NRRs calculated for the Sordin earmuff tested using REAT, MIRE-IL, and MIRE-NR, from Casali, Mauney, and Burks (1995).

FIRST ACTIONS THAT SHOULD BE TAKEN IN REGARD TO HPD LABELING REQUIREMENTS FOR THE U.S. MARKET

This paper has reviewed all of the different types of augmented HPDs, and pointed out difficulties, pitfalls, and voids in testing the attenuation of individual types. Clearly, the current REAT standards (ANSI S3.19-1974 and ANSI S12.6-1997) do not accommodate all devices, nor do they adequately characterize the performance capabilities of all features of all devices. As such, there is much work to be done toward the development of testing standards and labeling regulations so that augmented HPDs can be properly tested and labeled for their performance capabilities. *These limitations notwithstanding, the most current REAT standard (ANSI S12.6-1997), and more specifically, Method B Subject-Fit of that standard, should now, in the authors' opinions, be adopted by the EPA in a new labeling regulation as the basis for obtaining attenuation data for all conventional passive HPDs as well as for certain aspects of augmented HPDs.* That is, ANSI S12.6-1997, Method B Subject-Fit should be used for obtaining attenuation for the following augmented HPDs, or for their noted specific features, as follows:

- Uniform attenuation HPDs (passive devices)
- Passive attenuation component, in quiet (not in high noise) levels, for:
  - Passive, level-dependent HPDs
  - Active, level-dependent (sound transmission/restoration) HPDs
  - Active Noise Reduction HPDs
- Adjustable attenuation HPDs (passive devices)

The rationale for this recommendation regarding ANSI S12.6-1997 is as follows:

- It is the best testing standard that we have at this time.
- It is based on approximately 9 years of standards committee work with empirical research studies as a foundation.
- Our own laboratory experience since 1983 in conducting both laboratory and field studies support this conclusion, for both validity and reliability reasons.
- Data produced by this standard (compared to S3.19-1974):
  - Reflect the *HPD's performance as a system,* inclusive of instructions and features that impact usability.
  - Are conservative in regard to protecting the end-user.
  - Are likely to yield a stronger liability defense for the manufacturer because the data more closely relate to actual performance realized in the field.

ACKNOWLEDGEMENTS

The various Virginia Tech research studies discussed herein were sponsored by CDC-NIOSH, U.S. Bureau of Mines, U.S. Army Research Lab, and several hearing protection manufacturers.

The authors thank John Franks of the National Institute for Occupational Safety and Health (NIOSH), and Kenneth Feith of the U.S. Environmental Protection Agency (EPA) for requesting this paper for the EPA Docket # OAR-2003-0024.

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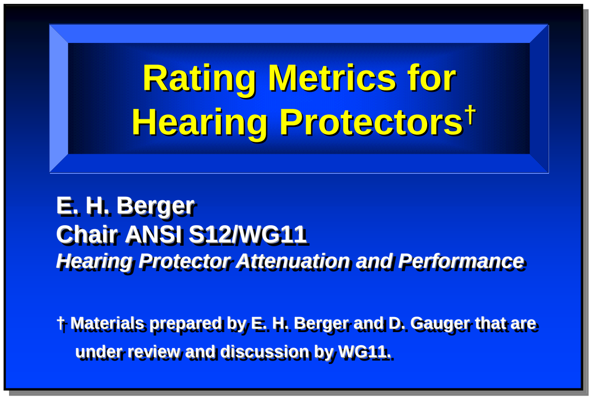
Rating Metrics for Hearing Protectors

E.H. Berger
Chair, ANSI S12/WG11
“Hearing Protector Attenuation and Performance”

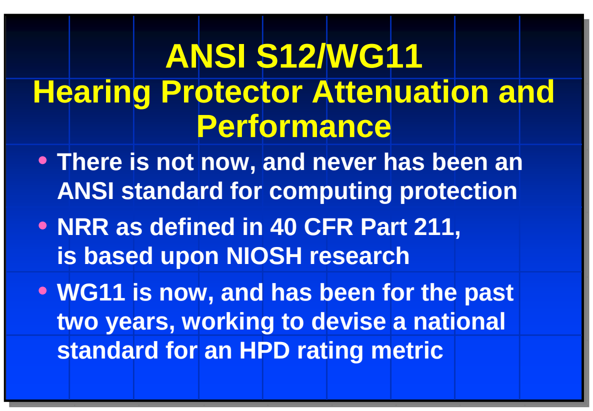
Note: Materials prepared by E.H. Berger and D. Gauger that are under review and discussion by WG11



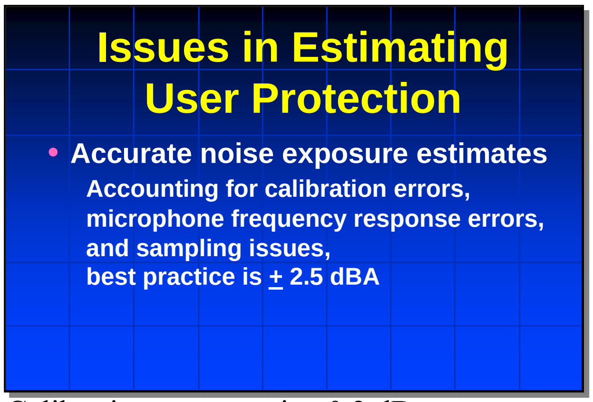
As Chair of ANSI S12/WG11, the national standards committee responsible for many of the US hearing protector standards, I am pleased to join you today to review our recent work. I want to extend my gratitude to Dan Gauger for his collaboration and extensive work in developing computer-based programs to implement the many methods described in this report.

As you know, attenuation has typically been measured in the laboratory using an elderly and withdrawn ANSI standard, S3.19-1974. You have also heard about the new Method-B procedure, which is intended to provide more representative estimates of field performance. Method B addresses part of the prediction and labeling problem, however, the issue of how to work with the new data and what type of number or numbers should appear on the label must also be addressed.

I would like to review various issues in estimating protection and our current thinking on hearing protector ratings. The importance of considering between-subject (or in the real world, between-user) variability will be emphasized.



Let me remind you that the NRR that is so extensively used in this country is based upon an embodiment in the EPA labeling regulation, which, in turn was based on 1970s-vintage NIOSH research and publications. At no time has there ever existed a U. S. national standard defining how to compute a number rating from existing hearing protector attenuation measurements.



An often overlooked issue is the problem of measuring the risk. How much noise are users exposed to and how much protection do they need?

We should keep in mind the following:

Calibration accuracy is ±0.2 dB

Microphone frequency response accuracy is:

(Type 1) ± 1 to ± 1.5 dB

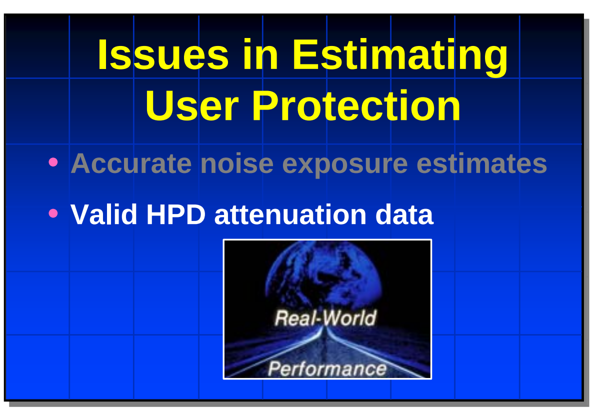
(Type 2) ± 1.5 to ± 3.5 dB

For sampling a worker with an exposure in the top 20% of his group, these are the sample sizes needed for 95% confidence:

N = 12, must sample 8 personnel

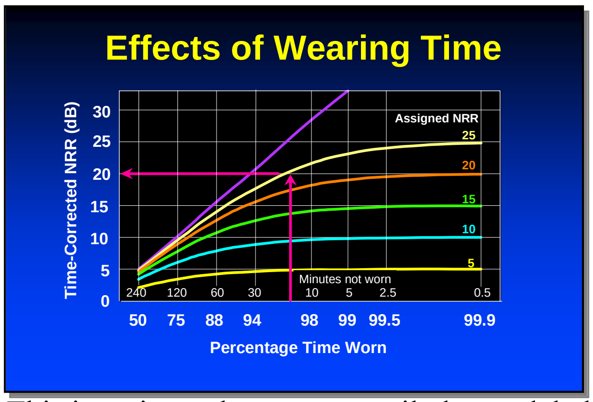
N = 50, must sample 12 personnel

If we can define the exposure of an individual or a group within a range of 5 dBA, we are doing well.



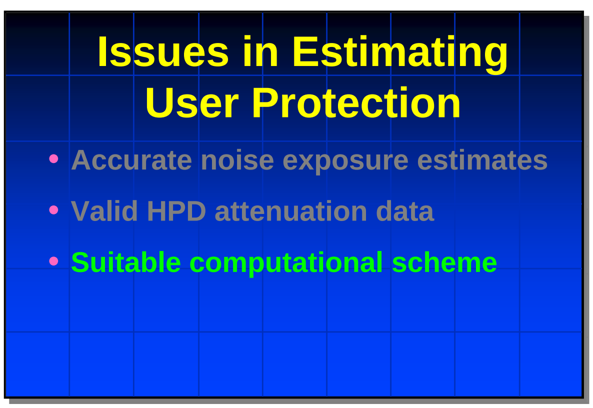
There has already been extensive discussion of the need for improved estimates of real world performance and the problems with the existing 29-yr. old ANSI standard. Suffice it to say that we need an improved test method, and it would appear that the Method-B data serve that purpose.

With respect to the validity of data, keep in mind that the issue is larger than simply specifying suitable *mean* data, as we would ideally like to be able to make predictions for individuals.



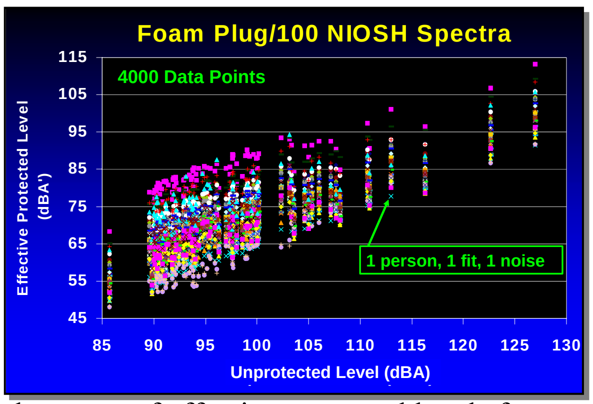
Beyond the issue of specifying attenuation is the equally thorny issue of specifying effective protection, which is as strongly controlled by the percentage-use time as by the inherent attenuation of the device itself.

This is an issue that cannot easily be modeled in our predictions, but one that can affect outcomes dramatically. Effective protection can easily be altered by 5 dB or more.



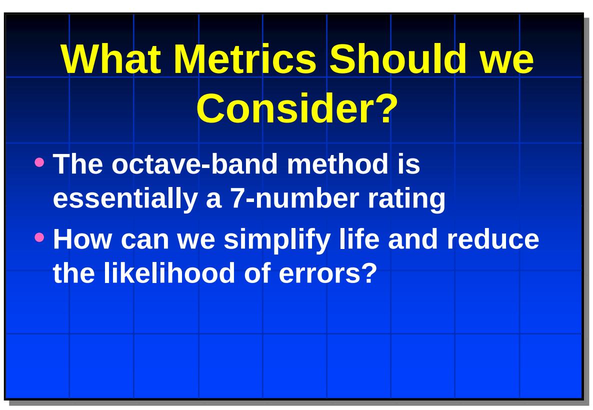
The last of the three issues in estimating protection that I would like to discuss is, in fact, the principal topic of this presentation, namely the development of a suitable computational scheme for the construction of a numeric rating to be put on the hearing protector label.

The octave band (OB) method has been presumed to be a "gold standard" providing "accurate" computations. However, many assumptions are inherent in the use of the OB method, such as presuming the availability of accurate noise and attenuation data, and the fact that the individual user will actually get values that are close to the means reported on the tests. Those assumptions are generally invalid.



Here is one example for 20 subjects fitting a foam plug without supervision (i. e. Method-B data). Each column of 40 symbols represents OB computations in one of the 100 NIOSH noises. Each symbol represents 1 person with 1 fitting of the plug in 1 of the noises. Note that the range of effective protected levels for any one noise is about 30 dB for the lower-level noises (which tend to have more low-frequency content) to about 23 dB for the higher levels noises (which tend to have more high-frequency content).

Note also the wide range in protected levels moving across the chart from left to right. This indicates the variability of the attenuation of the device in different sound spectra.

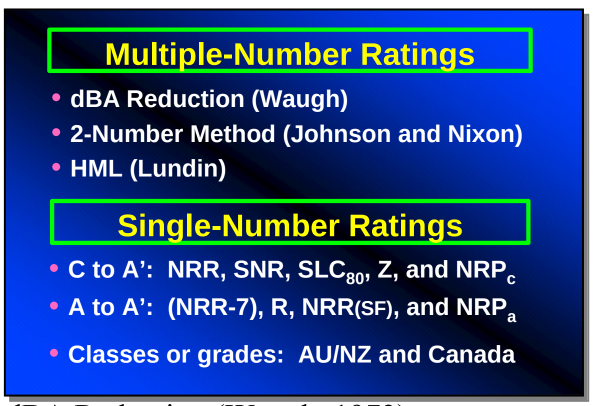


Historically many ratings have been proposed and utilized. We have examined all of the major proposals.

The OB method, which consists of computations at the seven OB center frequencies, is essentially a 7-number method.

So how can we simplify life? One interesting study conducted by John Casali examined the errors that trained users made in applying various single number or multi-number ratings, and, as one might expect, the more complex the rating, the greater the likelihood of error. This should come as no surprise considering the major error made by many users today: application of the NRR to A-weighted sound levels without first subtracting the 7-dB correction that is required in such instances.

In fact that error is in part propagated by the current EPA labeling requirements, which tend to misdirect the user to apply NRRs to A-weighted sound levels.



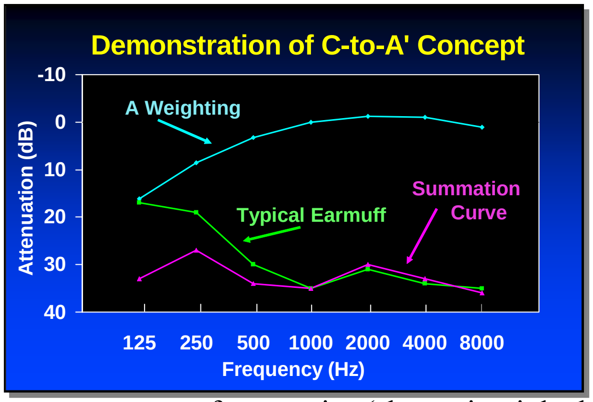
Beyond the OB method we can look at other multiple-number ratings that include ratings requiring the use of two or three numbers:

dBA Reduction (Waugh, 1973)
2-Number Method (Johnson and Nixon, 1974)
HML (Lundin, 1980)

And finally we come to the single-number ratings that require the use of only a single number and either the A- or C-weighted sound levels. The existing NRR falls into this category.

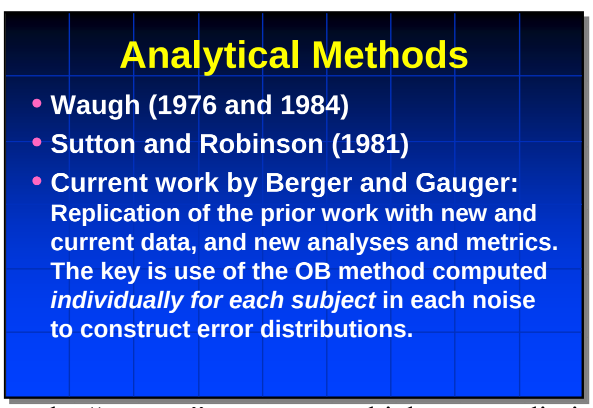
C to A' metrics are of the "Botsford type"
A to A' metrics are of the constant protection type, meaning that regardless of the noise spectrum, they predict the same amount of attenuation.

Class/grade schemes are conceptually the easiest to use but tend to be the least precise.

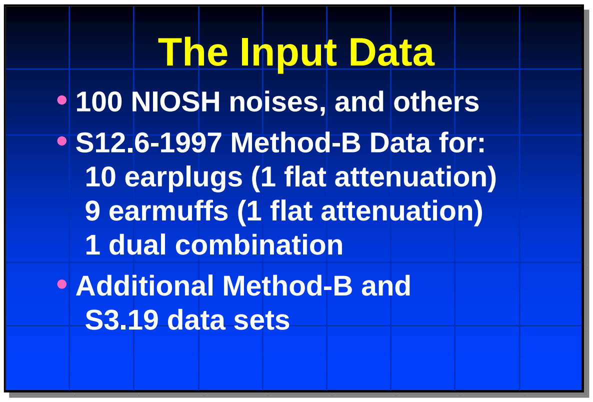


The reason that single-number ratings are subtracted from dBC levels to predict dBA' protected levels tend to work well for many classical HPDs is that the addition of the A-weighting factors to the HPD's attenuation values yields a summation that is approximately a constant across frequencies (shown in pink above). Thus, when this uniform level of noise reduction is applied, we are effectively dealing with a hearing protector with the same attenuation at all frequencies. And of course this is the same type of HPD that would provide the equal attenuation in all noises regardless of a noise's frequency content.

A problem with the C-A type of adjustment is that unique HPDs that might not correspond to this classically shaped attenuation curve, such as flat-attenuation products, will not be well represented by the C-to-A assumptions.



In our current research (Berger and Gauger), we have based our analysis on the seminal work of Waugh and of Sutton and Robinson. Our analyses have been updated and slightly modified. The key is to use the OB method computed *individually for each subject* in each noise as the "correct" answer to which our predictions are compared. That is how the error distributions corresponding to the various rating techniques are computed. (The computational technique will be explained in greater detail later in this presentation.)

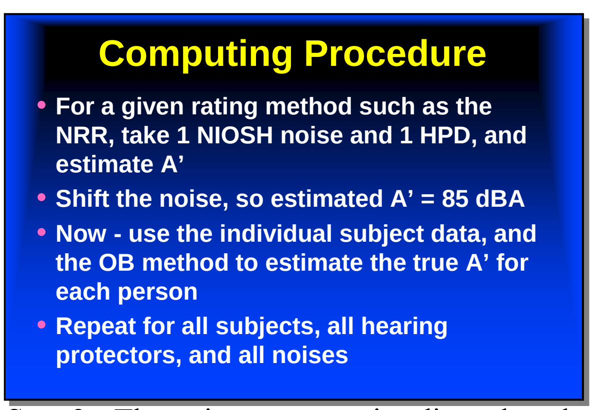


Noises used by Berger and Gauger:

NIOSH 100 based on 579 noises from Karplus and Bonvallet (1953)
South Australian (SA) 615 - from McQueen et al. (1969)
New Zealand (NZ) 230 - Backshall (2000)
Berger/Gauger 300 - synthesized from above 3 data sets
Air Force (AF) 50 - Johnson and Nixon (1974)
General Aviation (GA) 13 - Gauger (1998)

The NIOSH 100 noises are the "gold standard" and have been used by many. We have compared the NIOSH, SA, and NZ noise data bases and found similar distributions and results. The Berger/Gauger data base of 300 noises is a good compilation. The AF and GA noises have many more spectra with extreme low-frequency content and do generate somewhat different results when used to evaluate the various ratings.

The current analyses will also be tested in the future with other sets of HPD attenuation data according to both Method-B and S3.19 procedures.

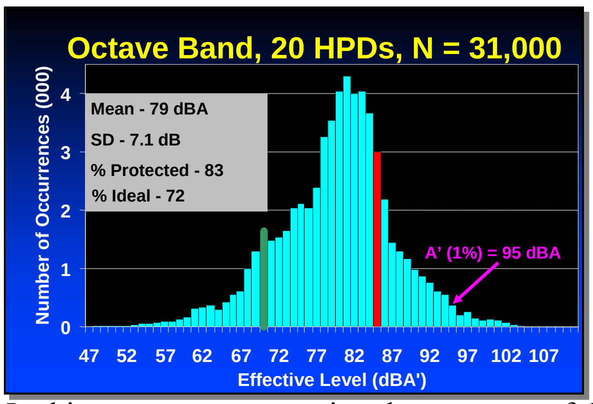


This slide represents the overview of the basic analytical procedure that we employed.

Step 1 - estimate A', the protected level, using the mean data with a specified statistical correction, such as minus 1 SD.
Step 2 - The noise spectrum is adjusted so that A' is exactly at the target of 85 dBA'.

Step 3 - With the adjusted spectrum, the "true" A' values are computed for each individual using their own attenuation values, and the OB method. The OB method is used in this step regardless of which of the ratings is being evaluated.
Step 4 - Repeat step 3 for all subjects, and then repeat the entire procedure for all noises, all HPDs, and all rating methods.

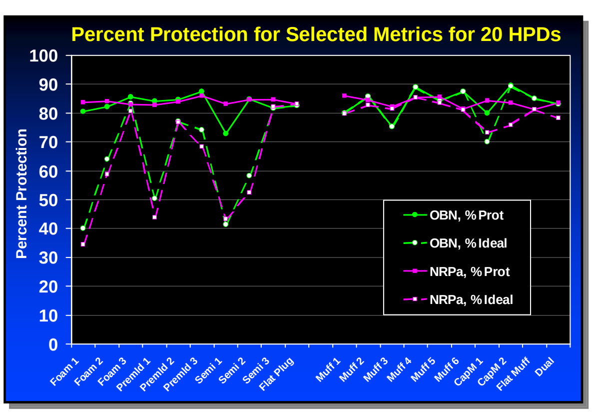
More details can be found in flow chart at the end of this presentation.



This chart, in a histogram format, presents the data from one of our analytical evaluations. The X axis is the effective protected level in dBA, and the Y axis is the number of occurrences of each of those levels.

In this case we are assessing the accuracy of the gold standard itself, i.e. the octave-band method. We use the octave-band method in the classical manner, that is mean attenuation values less 1 SD, and compare it to the octave-band method applied on an individual basis, that is for each of the subjects' attenuation values.

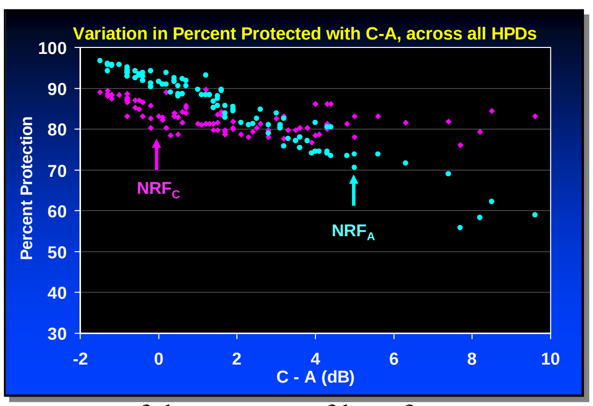
This is a representative distribution of the A' values averaged across all HPDs and noises, a total of 31,000 computations. The goal was to protect everyone to 85 dBA. In fact, on the average the protection was to 79 dBA, but only 83% of the cases did meet the 85-dBA limit. The percentage of cases who were ideally protected, that is, to levels between 70 and 85 dBA, was 72%. The level that was still exceeded by 1% of the subjects is 95 dBA.



We have examined over a dozen different ratings and employed a dozen or so different metrics to compare the accuracy of the ratings and to select the best. I will present here just a brief hint at the extent of our work in this lecture. Dan Gauger and I intend to prepare a full paper for publication and for review by WG11.

Here we look at the "gold standard" rating compared to the one we have chosen to recommend - namely an A-weighted single number rating, in this slide called the NRPa. The data are presented for each of the 20 HPDs, averaged across all 1000+ noises. You will notice how closely the pink and green curves agree, indicating that the percent protection with the NRPa closely approximates that with the OB method.

One rating we examined was the current NRR computed from labeled values based on S3.19, derated by 50%. It was the worst performing rating, with even less accuracy than the grading and class schemes.



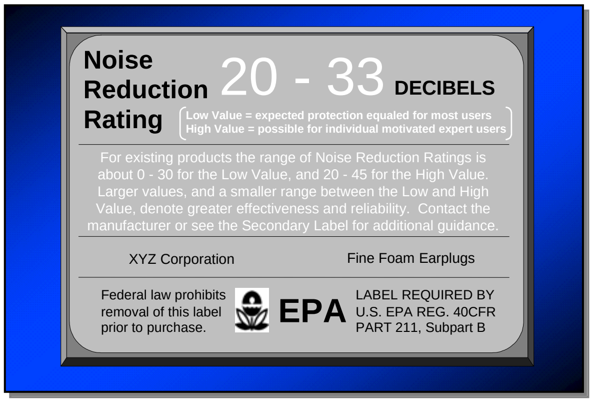
Another way to examine the ratings is to look at them noise-by-noise, averaged across all HPDs. This allows one to find the worst-case conditions, i.e. the noises in which the rating works most poorly.

The X axis is the C-A value of the noise, a measure of the amount of low-frequency energy that is present. Low-frequency dominated noises are to the right. The Y axis is the percent protection.

Here we compare a single number rating suitable for use with dBC (NRF_C) to one that is used with dBA (NRF_A). For high C-A values, representative of very few noises the A-weighted rating is less protective, but for most of the noises the A and C ratings agree closely.

Remember that the current EPA NRR is actually a rating designed for use with C-weighted values, but it is nearly always used with dBA values, with or without the OSHA-required 7-dB correction.

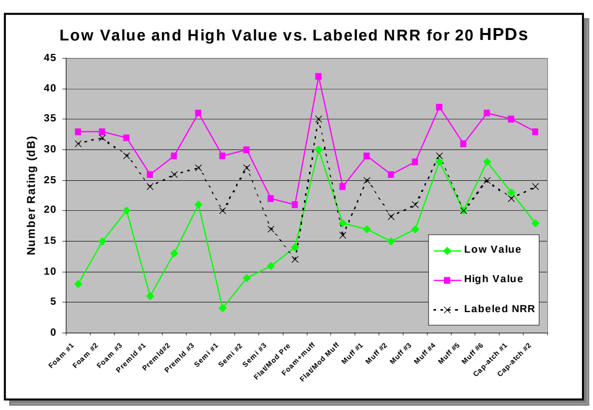
Later in the presentation we propose a “correction” to take care of the errors in the few low-frequency noises where problems occur.



This is our proposal for a revised EPA NRR label based on the findings of our analyses. The EPA has indicated that we must adhere fairly closely to the existing format. The changes from the existing label are indicated in white.

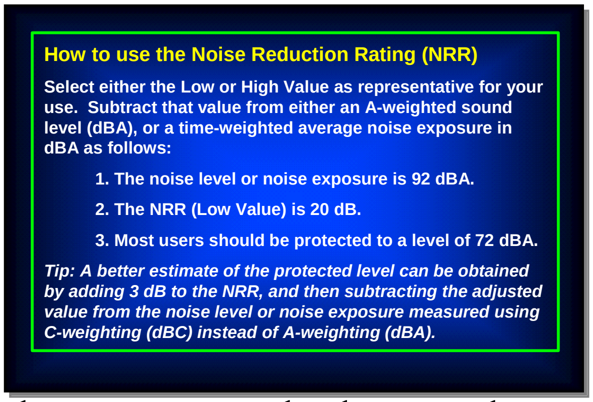
The two-number approach provides several advantages:

1. Like the current EPA fuel-economy ratings it specifies performance for two types of conditions.
2. The user can select the appropriate rating.
3. It makes it harder to accept the numbers blindly since this method does not use one single number.
4. The rating can be simply subtracted from dBA which is what is generally done today anyway (even though that is incorrect with the current rating).



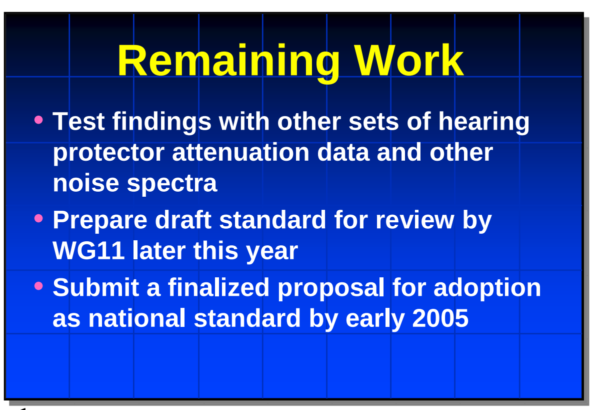
5. Additional information is provided by showing a range of performance so that the reliability of the device can also be assessed.
6. The user is guided to the manufacturer or the secondary label for additional information.

An unexpected benefit of the new 2-value system is that those values span the range of existing labeled NRRs. Note also how the range in values varies across types of devices. Earmuffs and flat-attenuation devices have smaller ranges, which is intuitively correct.



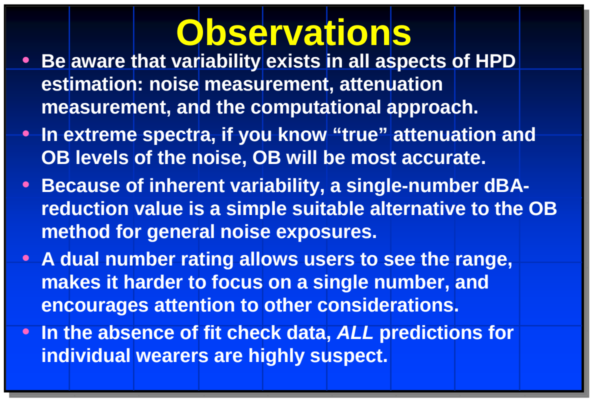
The secondary label, which may be on the master box or the web or accessed in additional ways, should provide very clear guidance on how to use the NRR. This type of information is currently required and this label is based on the current format with enhancements and with changes to correspond to the proposed new numbers.

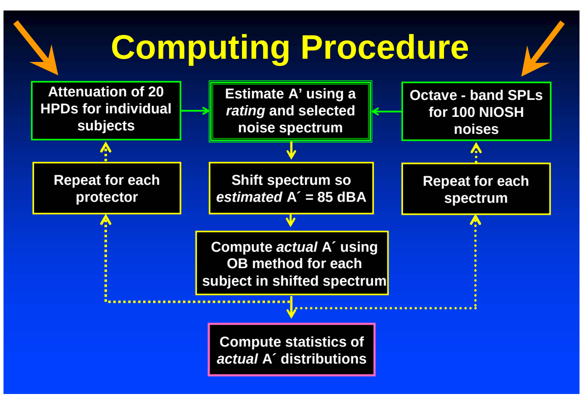
The tip following the example computation is a way of dealing with the problem noted earlier that occurs in noises with excessive low-frequency content. The 3-dB adjustment is based on prior experience with similar ratings, but has not been fully tested. It will be evaluated as we complete our analyses and may change slightly. In Dan Gauger's paper for the afternoon session he provides an alternative graphical technique to deal with this problem.



Before finalizing our recommendations, the analyses described in the paper will be tested with additional sets of hearing protector attenuation data and other noise data bases. Our preliminary analyses with some of those data suggest that the conclusion will be robust and will not change.

Our goal is to prepare a draft standard for review by WG11 later this year and to achieve a national standard in 2005.





Supplementary Materials:

This flow chart provides a more detailed overview of the basic computational procedure utilized in our evaluation of the accuracy of the various rating methods.

EPA Workshop on Hearing Protector Devices
Contributed Presentations
March 27, 2003 –Afternoon Session

1. Jeffrey Birkner, CIH, Vice President of Technical Services, Moldex-Metric, Inc.

2. Mark Hampton, Senior Vice President, Hearing Protection, Bacou-Dalloz Co.

3. John Allan Hall, Human Effectiveness Directorate (Crew System Interface Division), Battlespace Acoustics, U.S. Air Force

4. Patricia O'Hara, Regional Sales Manager, TASCO Corp.

5. Ted K. Madison, M.A., CCC-A, 3M Occupational Health & Environmental Safety Division

6. Brian Myers, E·A·R Product Line Director, E·A·R/Aearo Co.

7. Dan Gauger, Manager, Research & Systems Engineering, Bose, Corp.

8. Janice Bradley, Technical Director, International Safety Equipment Association

9. Alice H. Suter, *Summary of First Day's Presentations*

Jeffrey Birkner, CIH
Vice President of Technical Services
Moldex-Metric, Inc.

My name is Jeff Birkner. I am a Certified Industrial Hygienist and Vice President of Technical Services for Moldex-Metric Inc. Moldex-Metric is a safety product manufacturer of hearing and respiratory protection equipment. We have been in business for more than 20 years. Moldex takes great pride in its commitment to the health and safety of all workers. We welcome this opportunity to provide comments at this meeting today and tomorrow.

As we all know, those portions of the Noise Control Act, 40CFR211, governing Hearing Protection Devices have been in place for more than 20 years. We believe that a revision of the regulation is long overdue. We hope that the agency will consider our comments very carefully.

Let me preface my comments by saying that we are strong proponents of a test method and rating system that is simple yet predictive of the actual protection that will be received by the user.

Currently, 40CFR211 requires testing of HPDs in accordance with ANSI S3.19-1974. This has been superceded by more recent ANSI test protocols, yet the EPA has no means to allow a more current version to be used. The most current test protocols can be found in ANSI S12.6-1997. The EPA regulation should be updated to this standard.

Included in S12.6 are two test methods, Method A Experimenter Fit, and Method B Naive Subject Fit. We are proponents of Method A-Experimenter Fit in conjunction with a single number rating such as the NRR. Hearing protection devices should be measured in such a way as to provide a benchmark to determine what the protector is capable of achieving. In this way, the user of the product will be able to ascertain the amount of attenuation that can be achieved by the device, if it is used properly. The use of Method B in conjunction with the NRR would provide little useful information to the individual user.

It is obtained through the use of subjects that may or may not use the product in accordance with the manufacturer's instructions and therefore is not indicative of the attenuation that the user might achieve if the product were used properly. The use of the Noise Reduction Rating should represent the relative efficacy of the products and should be used by employers in their selection process. Additionally, it is incumbent upon the employer that the device be used by his or her employees properly and that they comply with all elements of OSHA 1910.95. The HPD and its NRR are only one element of a Comprehensive Hearing Conservation Program.

We continue to believe that the single number rating is most useful to the unsophisticated user in determining the appropriate product for their particular worksite. More sophisticated users should have access to the octave-band attenuation data, as they presently do. Great care should be taken in developing the labeling requirements required by any new regulation, as the more information provided on packaging the more confusing it will become for the unsophisticated user.

Finally, the issue of greatest concern to us, other manufacturers, and knowledgeable members of the user community is third party independent testing. One of the problems that arises as a result of the use of the NRR in accordance with the existing EPA regulation is that some major manufacturers do not have their products tested by an impartial and independent laboratory. As a result, the NRR has become a numbers game for some manufacturers to gain commercial advantage, and newer hearing protection devices tested in some manufacturer' own labs, have escalating NRRs. The public must be provided credible numbers for comparison purposes that can only come from objective independent third party testing. There is no other way to provide the confidence that the public needs and deserves to protect their health, safety, and quality of life .

It has been suggested that NVLAP certification serves as one means to ensure the independence of the testing labs including those owned by manufacturers. Nothing could be farther from the truth. NVLAP is a means to ensure the quality assurance of the equipment, record keeping, and calibration of the lab. It provides little oversight in ensuring that the actual testing will be conducted in a manner such that there will be no undue influence. It seems inconceivable that a lab owned by a manufacturer could possibly ensure that there will [be] no influence by the laboratory and/or experimenter on the test subject. This is a clear example of conflict of interest that the public should not have to deal with.

If independent third party testing is not required by your agency then we are certain that any new regulation that you may promulgate will be flawed and will not adequately serve the public. Independent testing must be required by the EPA and the public deserves nothing less!

We thank you for this opportunity to comment on your investigations into an updated regulation and look forward to providing input on any draft proposal promulgated by the agency.

Mark Hampton

Senior Vice President, Hearing Protection

Bacou-Dalloz Company

PROTECTING WORKERS

In the "Real World" over 90% of hearing protection users are industrial and military personnel that wear them 8 hours or more every day. Is this "Real World?" Or is it the "naïve" world implied by method B?

The test method should reflect the real "Real World." Is it a naïve fit or a trained fit? Anything less than proper training is an abdication of responsibility.

User fit is highly dependent on the quality of education and the hearing conservation program. No change in the ratings or stated values can replace them.

There is a concern both for over and for under protection. If the real world is one of trained users, a lower "naïve" NRR potentially can lead to overprotection in a large percentage of the mandated work environments.

METHOD A VS. METHOD B

According to Federal Law, a product rating should predict the performance of the product. Either method (A or B) will still yield uncertainty in the protection afforded for each individual user. The only way to know what protection level each user receives is to verify its performance. Does one testing method have greater validity than another?

(The issues are ascribed to the different rules by which the hearing protector is fit on the subjects).

With ANSI S3.19-1974, the assumption is made that attenuation is achieved by subjects for whom the product is well fit. If the end user does not fit it well, he or she may be under protected.

Method B of ANSI S12.6-2002 assumes that the attenuation estimated represents "true to life" values by virtue of the usage of naïve test subjects and no training in the use of HPDs. It assumes further that all hearing protectors fit all ears. (Even if the product clearly will not fit in a subject's ears, he or she must be retained in the test sample.) Consequently, if the end user fits it well, he or she may be over protected. Does this method encourage apathy with respect to employer provided education regarding proper HPD use?

Method A of ANSI S12.6-2002 assumes that attenuation which is achieved is representative of that received by persons who have been trained in the use of HPDs and perhaps representative of the typical industrial or military situation with a hearing conservation program in place.

THE GOLBAL DIMENSION

Method A may make the best sense, especially since its provisions depart only slightly from the European standard (ISO 4689-1). Adoption could pave the way for a harmonized international standard. NRRs calculated from the same ISO data used to achieve the European SNR values would produce more conservative values and that seems to be the objective of the desired changes. On average, NRR values would come down 20% to 40% from the current 40CFR 211 numbers. This could be implemented without expensive retesting.

Confidence by the consumer is what is at stake with regard to a single number rating and the use of accredited test labs. Are we sending the correct message or looking to cover our proverbial ___ ?

The ultimate solution is to educate people in proper HPD usage and actual verification of performance provided by HPDs in actual noise environments.

The focus should be on doing the right thing, not on an academic debate of who is or is not right on testing protocols.

IMPLEMENTATION

A period of transition is necessary for manufacturers to perform all the testing. There needs to be a period of time in which to make it "fair across entire industry," where no one has a timing edge.

Questions of education need to be resolved. How should users be educated on the new ratings, who is responsible to do it, and how will compliance be enforced?

There is also a question as to the application of the wearer's time-weighted average noise level (TWA). Will a lower NRR result in less time that a worker can be exposed to a noise hazard. We should consider the prospect of lower productivity. Has anyone considered or even been concerned about the impact of this rule in the workplace and for businesses?

There is also the question of industry-wide liability. If the industry has overstated their products for more than 30 years, what are the implications?

Finally, the costs of testing need to be considered. Hundreds of products would require testing within in a certain period of time, with the possible consequence of overloading test labs.

John Allan Hall

Human Effectiveness Directorate
(Crew System Interface Division)
Battlespace Acoustics
U.S. Air Force

The Air Force Research Laboratory (Wright-Patterson AFB) has for many years provided independent assessments of hearing protection devices for the Department of Defense. AFRL data are often cited in scientific literature, and its acoustics team has been a leader in bioacoustics and noise effects for 50 years. Researchers at AFRL have served on numerous national and international standards committees on noise to include the committee responsible for ANSI Standard S12.6-1997 (the latest standard on hearing protection testing). AFRL is a member of the Department of Defense Hearing Conservation Working Group chartered by the Secretary of Defense.

AFRL's position, based on years of study and experience with hearing protection metrics and military hearing conservation programs, is that federal regulatory requirements to use only naïve data for rating hearing protection would have negative consequences for the Department of Defense (DoD). Due to the high levels of noise common throughout the military, proper fit of hearing protection is essential to achieve compliance with the DoD standards on hearing protection (which are stricter than OSHA requirements). Consequently, the DoD requires all se{r}vicemen and women working in hazardous noise to receive annual training in the wear and care of their issued hearing protection devices.

Mandatory use of naïve fit test data would create situations in which military personnel could operate land, air, and sea vehicles for merely minutes prior to overexposure. Furthermore, litigation may be expected to ensue as veterans see hearing protective performance ratings plummet overnight (if a such a regulation were imposed), thus triggering a belief that they were not provided credible protection while on active duty.

Protection should be evaluated in terms of how it may be expected to perform if used properly, not how it is used by the untrained (naïve) user. There is a federal requirement under 29 CFR to provide annual training for individuals on the proper wear of hearing protection. So how would any naïve fit label requirement (if used by itself) be compatible with the current federal law?

Prospective recreational divers should never don SCUBA gear and dive without proper training. Such equipment would not likely be used properly. Likewise, personal protective equipment of any type should never be performance rated (for regulatory purposes) as worn by a naïve user. If there are problems in terms of proper wear and use of equipment, then the target should be to improve user training and compliance. To dumb down the protective value of equipment (with naïve user ratings) is artificial logic and not useful. There is, in fact, an ANSI report that addresses the effectiveness of a hearing conservation program (ANSI S12.13). The metric on how well a device performs if properly worn, however, is a separate issue that should not be distorted.

Naïve fit metrics may indeed be useful to indicate how devices will perform differently due to lack of training, but naïve fit metrics (ANSI S12.6-1997 method B) should never replace metrics based on trained user performance (ANSI S12.6-1997 method A) in terms of regulatory requirements for auditory protection.

We at AFRL agree that the test protocol required by the current EPA label (experimenter fit) requires revision. An experimenter fitting the device for the test takes the user completely out of the loop, and the results of such testing are not practical. Equally impractical is naïve fit (ANSI S12.6-1997 *Method B*), which takes training out of the loop. However, experiment-supervised fit (ANSI S12.6-1997 *Method A*) places the device in the user's hands and the achieved attenuation is based on what is possible under supervision. Such a method holds the greatest promise to hearing conservationists and the people we are trying to protect.

HEARING PROTECTION METRICS

U.S. AIR FORCE PERSPECTIVES

MARCH 2003

John Allan Hall
Crew System Interface Division
Human Effectiveness Directorate
Air Force Research Laboratory

Hearing Protection Metrics
U.S. Air Force Perspectives

- USAF est. 1st national hearing conservation program (1950's)
- USAF est. 1st large scale audiometric database
- USAF research est. basis for EPA & OSHA noise legislation
- USAF research integral to national & internat'l acoustic stds.*
- USAF research drives hearing protection technology (1950's)
- USAF testing hearing protection since 1950's
- EPA requested USAF be national gov't test site for HPD's
- 100's of hearing protection devices tested since 1950's
- Legacy of subject matter experts:

  Dr. Henning Von Girke, Dr. Charles Nixon, Dr. (Col.) Mark Stevenson, Dr. Dan Johnson, Mr. Rich McKinley, Maj. Don Gasaway

*Auditory Protection /Environmental Acoustics /Noise Effects

2

Hearing Protection Metrics
U.S. Air Force Perspectives

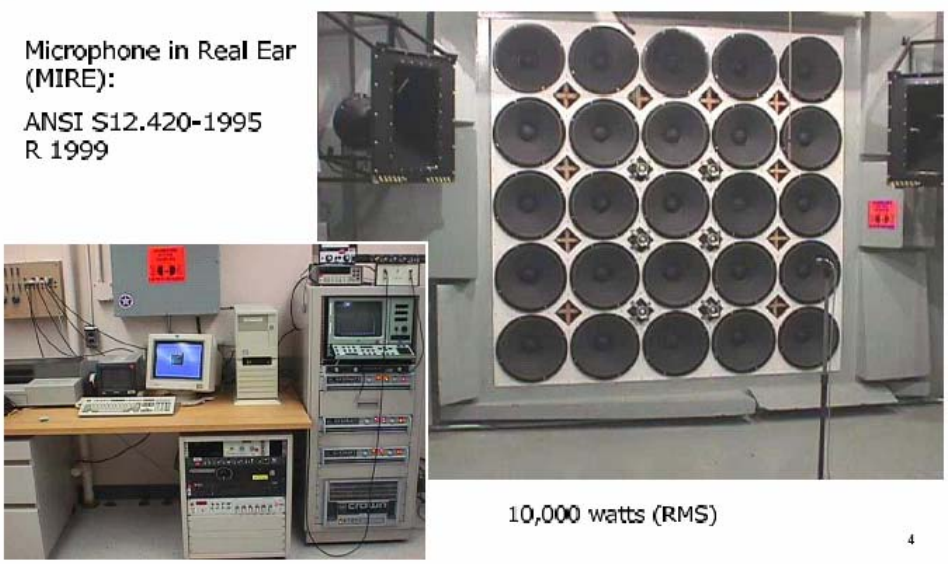
Real Ear Attenuation at Threshold (REAT)

ANSI S12.6-1997

Hearing Protection Metrics
U.S. Air Force Perspectives

Microphone in Real Ear (MIRE):

ANSI S12.420-1995
R 1999



10,000 watts (RMS)

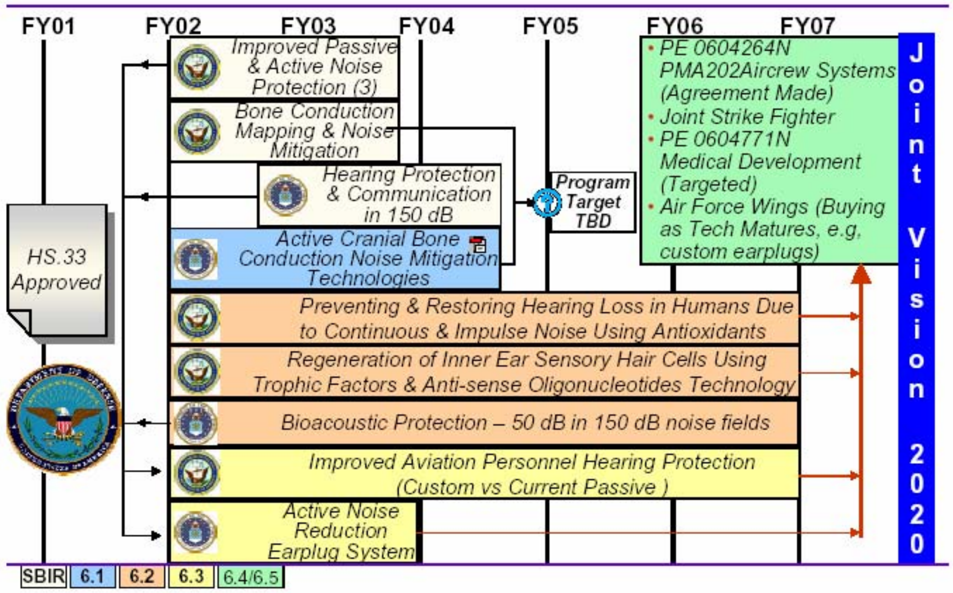
4

Hearing Protection Metrics
U.S. Air Force Perspectives

- Office of Undersecretary of Defense authorized Defense Technology Objective (HS-33: Improved Aviation Personnel Hearing Protection) to counter auditory risk posed by high performance tactical fighter aircraft.
- Exploratory, basic, & applied research portfolio under Air Force Research Laboratory, Air Force Office of Scientific Research, Naval Air Systems Command, & Office of Naval Research

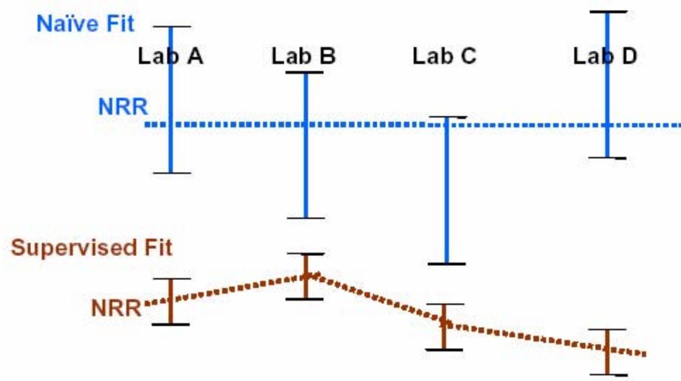
5

DTO Roadmap



Hearing Protection Metrics
U.S. Air Force Perspectives

- In a draft paper submitted for JASA on alternative methods for measuring hearing protector performance there is constant reference to the fact that SD's increase within laboratories as the protocol approaches naïve fit
- And that interfit agreement across labs is improved (?)



7

Hearing Protection Metrics
U.S. Air Force Perspectives

- Measurement error increases with naïve fit testing due to
  - -task inexperience (REAT tracking)
  - -reduced motivation (psychosocial aspects of population)
- Naïve fit testing creates large Standard Deviations (SD's) which often leads to negative NRR's computed with mean – 2SDs*
- The Department of Defense (DODHCWG chartered by OSD) authorized USAF naïve testing of products (ANSI S12.6-1997 method B) and required the naïve data be used (1998-2001)
- USAF, Army & Navy industrial hygienists (CIHs) and environmental engineers widely criticized naïve data and the DODHCWG suspended naïve testing (2002)
- Negative NRRs, inability to achieve adequate protection values, and poor agreement with annual training requirements produced most of the criticism

*The DODHCWG requires mean -2 SDs be applied to attenuation to ensure protection confidence over 98% of the population

8

Hearing Protection Metrics
U.S. Air Force Perspectives

- According to NIOSH most levels in industry are below 95dBA
- However DoD levels can range between 85dBA to 150dBA in the near field (tactical fighter aircraft and support activity)
- The DODHCWG requires mean -2 SDs be applied to attenuation to ensure protection confidence over 98% of the population
- Naïve fit testing with mean -2 SDs produces attenuation results that leave DoD hearing conservationists no ability to protect individuals in many situations
- The DoD has a vigorous inspection process and many organizations within the DoD demonstrated high non-compliance when naïve data was applied
- SHOW EXAMPLE

9

Hearing Protection Metrics
U.S. Air Force Perspectives

- It is argued that naïve test requirements will produce better printed instructions to accompany products to foster better fit
- There is no evidence, despite years of efforts by vendors, that written or schematic instructions produce better fit in the field
- Nor is there any evidence that naïve fit with lower NRR's will reduce the incidence of auditory risk across populations
- The metrics on hearing protection need to move towards error reduction not error expansion
- The use of hearing protection in the field is an application issue that naïve methodology will not satisfy
- ANSI S12.13 is the appropriate standard that address the effectiveness of hearing conservation programs
- If studies identify there is an application issue, then the goal must be to improve application, not increase measurement error within the laboratory to excuse poor application

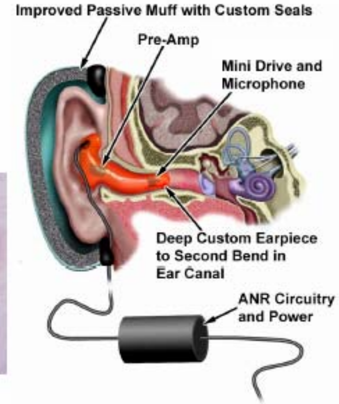
10

Hearing Protection Metrics
U.S. Air Force Perspectives

- 29 CFR legally mandates individuals be trained annually on correct use & fit of the hearing protection devices they wear
- Compliance with this annual training requirement is part of the OSHA inspection process
- Naïve fit methodology therefore proposes use of data which would represent an <u>**illegal**</u> condition according to the law
- Litigation may become a substantial risk to industry, vendors, and the DoD if protection values drastically change due to regulatory labeling requirements for naïve fit
- This is not in the best interest of the DoD or the tax payers if there is no proven public health benefit by use of naïve fit test data

Hearing Protection Metrics
U.S. Air Force Perspectives

- DoD working on hearing protection offering more reliable fit and integration with ANR and communications
- Custom devices/binary fit
- Onboard sensors & electronics to "inform" user it fit is not correct/optimal



Patricia O'Hara
Regional Sales Manager
TASCO Corporation

TASCO Corporation is the last independent, family owned manufacturer of hearing protection products in the United States. We firmly believe, as a matter of public health, that the practice of manufacturers testing their own products must cease and third party testing be specified in any new regulation and/or requirements. This rule should be so specific as not to let any manufacturer test their products in their own facility by both the NVLAP and legal definition of "independent".

Manufacturers with their own test labs have the unfair advantage through the practice of continually testing products until they achieve the specific noise reduction ratings they desire. This practice has forced the industry into a numbers game. Does this practice do anything to protect the end user? No, what it does do is gain these manufacturers a larger share of the market by misleading the consumer into the belief that bigger is better. Unless completely unaffiliated, third party testing is adopted, this practice will continue regardless of what ever test method might be chosen.

The responsibility for correct hearing protection device wearing instruction is that of the hearing conservationists, occupational healthcare workers and all others whose job requires the safety training and education of the employees. Method B testing shifts that responsibility directly onto the manufacturer. Method B will derate the existing NRRs to such a level as to cause manufacturers unjust lawsuits at a potentially backbreaking level.

Companies who have had their products tested independently in the USA, then tested at European laboratories so that they may be sold to the that market, have the most consistently repeatable data without any problem outliers. Test Method B is by no means a reflection of real-world attenuation; it is a reflection of the quality of the test subjects. Furthermore, there is not any information nor statistics to prove that the naïve subject fit test method results in any improvements in reducing hearing loss. Why would anyone consider such a radical change in test methods with out a proven success record?

It seems clear that the only way to achieve less hearing loss is through better hearing conservation programs, providing better training, re-training and regular compliance checks.

In many instances, a graver and immediate danger could arise due to Method B testing. When the naïve subjects' poor test results cause a good performing product to interfere with hearing directions or warning signals, one’s life is placed in harm’s way through overprotection.

Much consideration should be given to the amount of time that will be required for manufacturers to comply with any new EPA labeling changes. There are many issues at hand that will be extremely expensive for the manufacturer.

Packaging is a major component in the cost of manufacturing. Manufacturers must purchase packaging in huge quantities so that it is cost effective. Changing labeling requirements is not a simple conversion. It will require completely new packaging designs for each product. The new changes will also require the added expense of changing manufacturers’ catalogs, web sites, promotional and training materials. Another extremely expensive consideration will be the process of notifying all catalog and private branded customers and changing the artwork for their packaging, catalog pages, websites etc. Depending on the catalog reprinting schedules of the distributors, in some instances, a 3-year window may not be feasible.

This brings into light another advantage for manufacturer owned laboratories. They will have a great advantage in having their products tested to the new requirements in both a financial and more efficient and timely matter, which will afford them a powerful market advantage. In-house labs are also afforded a great financial advantage in the cost of retesting as well as the ability to meet the new requirements in a more expedient manner. This truly is not a matter of the haves and have nots, it comes right down to a matter of ethics and unfair business practices.

We would also like the EPA to reconsider the retesting of products (sunset clause). Manufacturers of other types of Personal Protection Equipment are not required to retest products unless there has been a change to the form, fit or function of the design, and this should also hold true for hearing protectors. A simple re-qualifying test controlled by an organization such as NIOSH should suffice.

TASCO Corporation also believes any product that makes any inference whatsoever to "noise reduction" or similar terminology must also be tested and regulated. More efforts should also be directed toward controlling the illegal imports that are being sold in this country that have not been tested and sold without the mandatory EPA labeling.

The NRR has required decades of user education to achieve its current level of understanding. We feel that to change this rating system will only add more confusion.

[Slides follow]

Method B

Makes the Manufacturer Responsible and Liable

TASCO

Presented by Patricia O'Hara

TASCO Corporation

- Manufacturer of Hearing Protection Products for 29 Years
- 44 Different Styles of Hearing Protectors
- All Products Tested at an Independent 3rd Party Accredited Laboratory

Repeatability of Test Results
Experimenter Fit Testing

Manufacturer	Earmuff Name	Model	NRR	SNR
Bilsom	700 Series	2717	23	27
Bilsom	Comfort	2315	25	27
Bilsom	Warrior	2424	23	27
Bilsom	Nova	2727	27	30
Bilsom	Capmount	2728	25	28
Elvex	Equalizer	HB-2000	26	30
Elvex	Super Sonic	HB-5000	29	33
Elvex	Capmount	HM-80	28	32
Peltor	Peltor	H9A	22	26
Peltor	Peltor	H6A	20	24
Peltor	Peltor	H7A	27	31
Peltor	Capmount	H7P3e	24	30
TASCO	Golden Eagle	2950	29	31
TASCO	Blackhawk	2700	27	30
TASCO	Capmount	2551	24	28

The difference in results is attributed to CE test use of 1 standard deviation. ANSI test use of 2 standard deviations

Method B
Naive Subject Fit Testing

The Problems . . .

CANADIAN STANDARDS ASSOCIATION

File No. S304-26

July 12, 2001

Ms. Pat O'Hara
Tasco Corporation
37 Tripps Lane
Riverside, RI 02915

Dear Pat:

The CSA Hearing Protection TC Executive has now considered your negative ballot comments on the proposal to accept the 7th Draft of the new edition of CSA-Z94.2.

You expressed concern that Clause 6.1 may imply that head and ear canal size variation is being ignored by the requirements for a test method that uses untrained test subjects (ANSI Method B). The Executive found that the Committee had addressed this issue previously. At that time, the Committee had determined by consensus that this implication does not exist. Therefore your objection on this point was ruled as being non-persuasive.

You also expressed concern that the measurement method does not provide a "valid" measure of hearing protection effectiveness. Furthermore you expressed the opinion that hearing protection programs would provide adequate training in order to assure HPD fit. The Executive found that the Committee had addressed this issue previously. At that time, the Committee had determined by consensus that, for a great many Canadian workers, we cannot presume that an effective hearing protection program exists. In addition, the Committee was persuaded by the technical data provided that the ANSI Method B does provide an acceptable measure of hearing protection effectiveness under "real-world" conditions (ie, those typically found in Canadian workplaces). Therefore your objection on this point was ruled as being non-persuasive.

However, I wish to make you aware that two other members raised technical concerns about the use of ANSI Method B in their ballot responses. One of those concerns was ruled as being both technically valid and as not having been previously addressed by the Technical Committee. This issue was over the adequacy of the statistical analysis specified in Method B. The Executive found the issue to be of sufficient technical concern to cause us to propose that the attenuation measurement method fall back to the criteria in the current edition of Z94.2 (ie, acceptance of either Method A or Method B) – at least until the issue can be resolved by the ANSI committee. This proposed change from the accepted criteria will be part of a package of proposals to be sent to members in August. Following that, we will likely convene a special meeting of the TC to vote on the proposed technical changes.

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Telephone: 416.747.4000 1.800.463.6727 Fax: 416.747.4149 www.csa.ca

Thank you for your valuable input on the new edition of the Hearing Protection Device Standard.

Yours sincerely,

David Shanahan
OH&S Project Manager
Tel. (416) 747-2586

TYÖTERVEYSLAITOS
FINNISH INSTITUTE OF OCCUPATIONAL HEALTH (FIOH)
Fysiikan osasto, ilmoitettu laitos nro 0403
Department of Physics, Notified Body No. 0403

March 13, 2003

TASCO Corporation
Ms. Patricia O'Hara
37 Tripps Lane
Riverside, RI 02915 USA

Dear Patricia,

You asked about the ANSI method B (and essentially the same method included into AS/NZS 1270:1999).

We provide these tests and we have some experience on it. Here is our feelings about it.

It is based on naive test subjects. However, according to European Legislation naive subjects should not be allowed in noisy environments at work. There is already a contradiction. Many authors have shown that the protection efficiency depends on motivation of the users. If the user is non-motivated he could in real life act like an naive test subject. But in the other hand among non-motivated subjects we have HPDs in such a bad shape that they do not protect at all in worst case. This seems to be the major problems. Thus there is no way of predicting the protection for naive non-motivated users. On the other hand the result obtained by EN-352 describes the attenuation obtainable with proper use.

According to legislation this proper use should be ensured by proper actions. Thus it is more appropriate to give this value.

ANSI Method B has several difficulties from the point of view of a test lab.

- Testing is more time consuming, because the subjects have to read the instructions alone. Often they ask for the assistance. This puts the test conductors in a difficult position, which they hate.

- Chasing new test subjects is not free. It takes time and as they really do not understand the meaning of all this, they make mistakes.

- The reproducibility of the test is very poor. This is serious problem if the authorities want to make market controls on the products.

- Especially plugs are difficult. They need some courage to put them deep enough. Thus you get almost anything as result of a plug test.

Best regards,

Esko Toppila

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Fax +358-9-47 805

From: Andrew Diamond
Sent: Thursday, March 20, 2003 3:12 AM
To: pat@tascocorp.com
Subject: ANSI S12.6-1997

Dear Pat,

Thank you for your e-mail.

You are correct that that INSPEC are opposed to attenuation testing that requires the use of "naive" subjects, when the test results are the sole mechanism used to determine the attenuation performance of the product.

There is a problem that many users are not able to fit hearing protection properly and therefore do not receive the maximum protection from a product. Critics of results from experimenter-supervised fit panels suggest that they do not give a true indication of the performance of the product in real-life. I would agree that this is potentially true. Also, it is suggested that the tests should be changed to those like Method B, so as to get "real life" results. I cannot agree with that and believe that this is missing the point. The problem is that end users are not receiving enough training so as to be able to fit hearing protection properly, not that the hearing protector is performing any worse than the results of the experimenter-supervised fit panel would suggest.

It is my view that the results from an experimenter-supervised fit panel are a reasonable estimate of the best performance that can be achieved for that product. If we were to test only using naïve subjects, what would these results reflect? I believe that all they would reflect is the "quality" of the test panel!

It is important that the results of an attenuation test are reliable, so that users can make reasonable comparison of products, to select that which is most appropriate to their environment. The use of naive subjects will not provide more useful information, instead the variability will actually degrade the quality of the information.

There is another important aspect to the use of hearing protection that I believe needs to be taken into account, this being that hearing protection should be used to bring noise levels to an appropriate level, not to a minimum level. There are many instances when it is desirable for a user to be able to hear warnings or alarms. By over-protecting the user, it is possible to place them in further danger. By selecting product based upon results obtained using naive subjects, it is quite possible that over-protection will occur.

Experimenter-supervised fit gives reliable results that represent the maximum attenuation performance that can be achieved, but it does not reflect the protection that a user who is wearing a badly fitted product can expect. So what is the answer? I suggest that there are several factors. Testing should be performed under the controlled experimenter-supervised fit conditions, with the experimenter ensuring that users follow exactly the instructions that they are provided with for that product, and not applying any additional techniques that they may have from previous experience or common sense. This will give a set of results that indicate the maximum protection provided by the product.

Statistical adjustment should be made to these figures to give a more realistic indication of the minimum attenuation that end users might expect due to the current state of user understanding.

Improved training of users is essential so that the differences between lab results and real-life results are reduced.

This final factor is the most important. Unless there is improvement so that users are actually able to achieve performance similar to that which can be expected from the lab results, pressure will be applied to go down the road as with respiratory protection, where each user now has to have their own fit test to ensure that the product selected is appropriate. An ideal, but costly, situation.

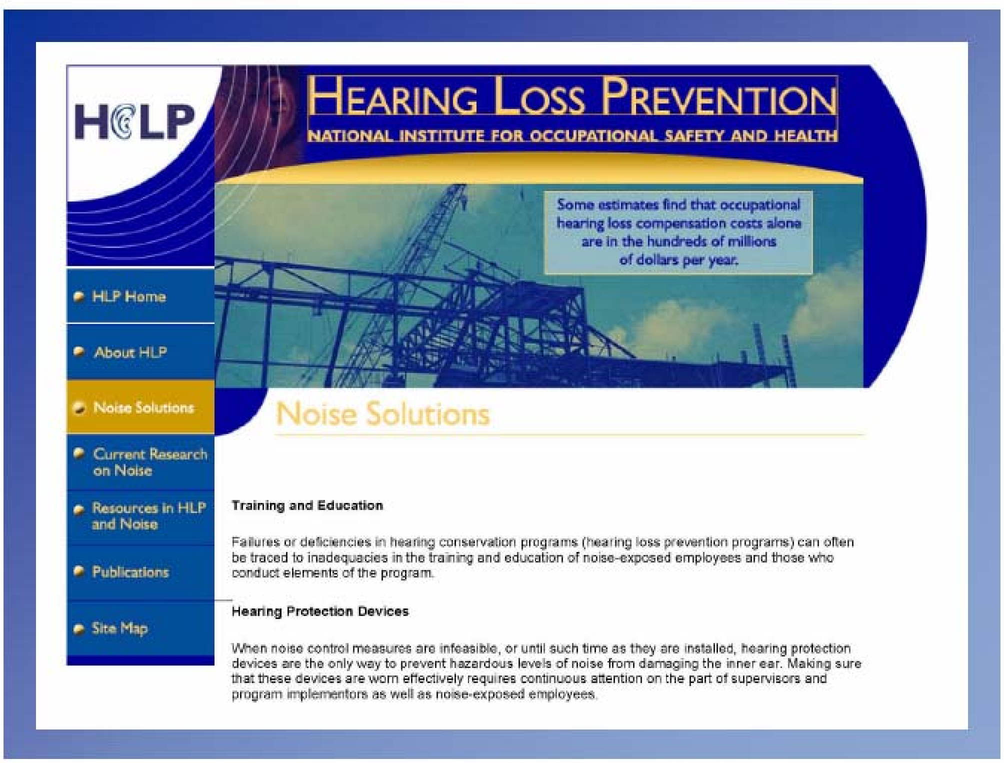
I hope that these comments are useful and would be interested to hear the outcome from the meeting.

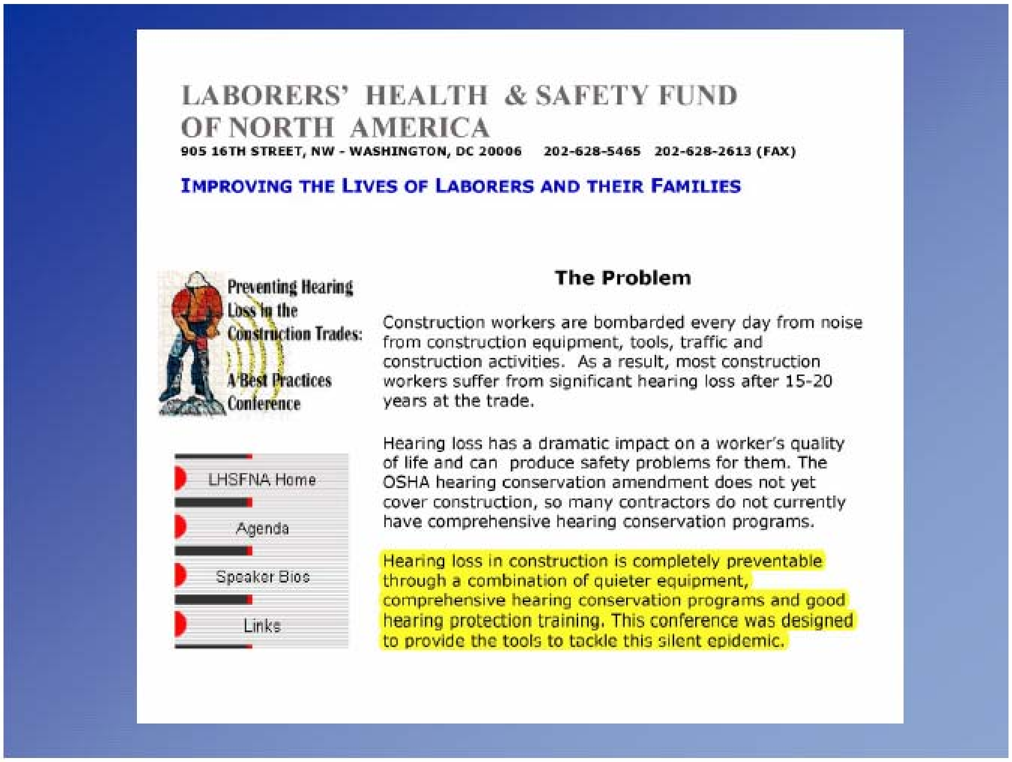
Kind Regards

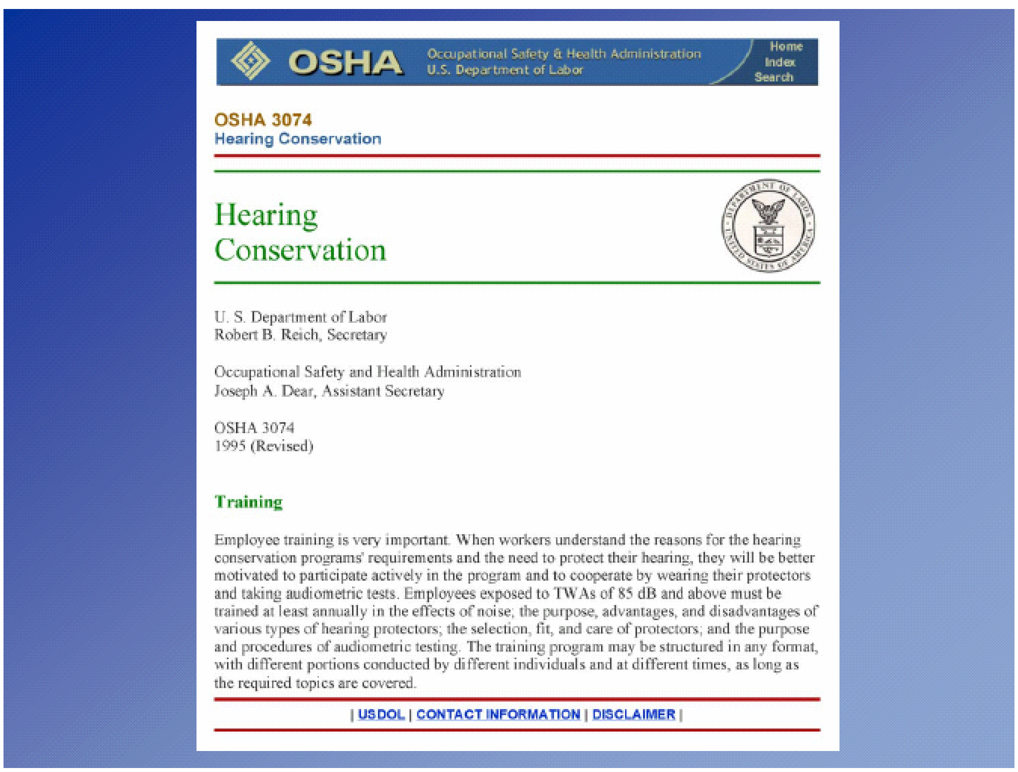
Andrew Diamond
Technical Director
INSPEC International Limited

Lack of Enforcement of Hearing Conservation Programs is the Problem

Not the Test Method




LABORERS' HEALTH & SAFETY FUND OF NORTH AMERICA
905 16TH STREET, NW - WASHINGTON, DC 20006 202-628-5465 202-628-2613 (FAX)
IMPROVING THE LIVES OF LABORERS AND THEIR FAMILIES
Preventing Hearing Loss in the Construction Trades: A Best Practices Conference
LHSFNA Home
Agenda
Speaker Bios
Links
The Problem
Construction workers are bombarded every day from noise from construction equipment, tools, traffic and construction activities. As a result, most construction workers suffer from significant hearing loss after 15-20 years at the trade.
Hearing loss has a dramatic impact on a worker's quality of life and can produce safety problems for them. The OSHA hearing conservation amendment does not yet cover construction, so many contractors do not currently have comprehensive hearing conservation programs.
Hearing loss in construction is completely preventable through a combination of quieter equipment, comprehensive hearing conservation programs and good hearing protection training. This conference was designed to provide the tools to tackle this silent epidemic.


OSHA
Occupational Safety & Health Administration
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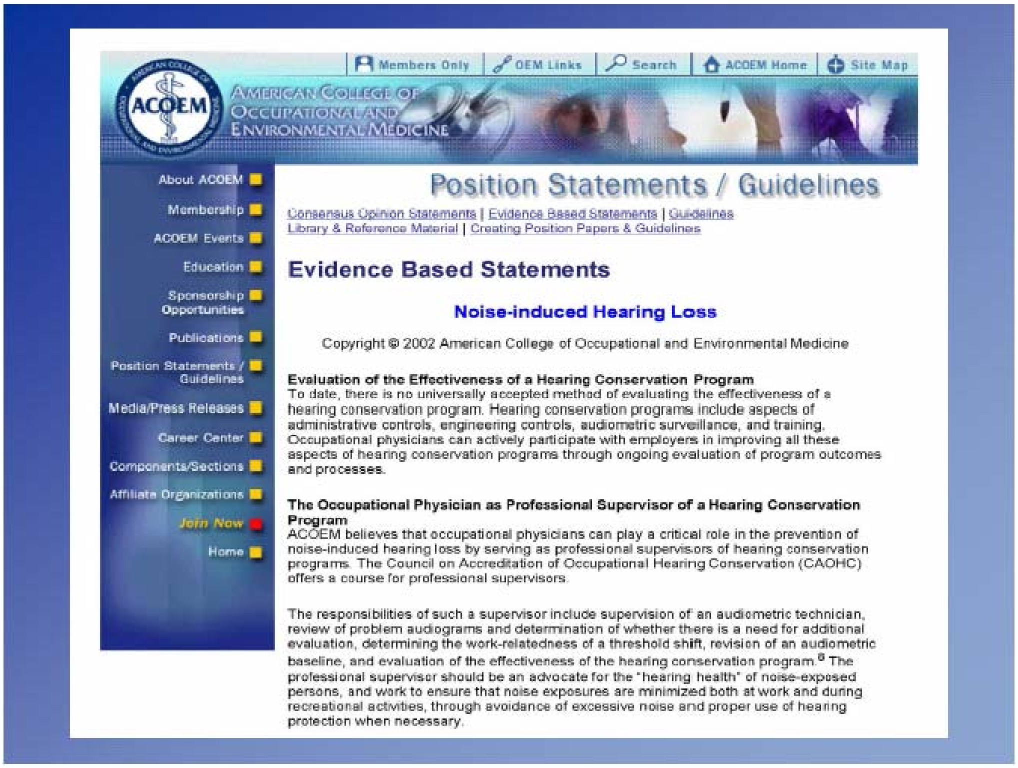
Hearing Conservation
Hearing Conservation
U. S. Department of Labor
Robert B. Reich, Secretary
Occupational Safety and Health Administration
Joseph A. Dear, Assistant Secretary
OSHA 3074
1995 (Revised)
Training
Employee training is very important. When workers understand the reasons for the hearing conservation programs' requirements and the need to protect their hearing, they will be better motivated to participate actively in the program and to cooperate by wearing their protectors and taking audiometric tests. Employees exposed to TWAs of 85 dB and above must be trained at least annually in the effects of noise; the purpose, advantages, and disadvantages of various types of hearing protectors; the selection, fit, and care of protectors; and the purpose and procedures of audiometric testing. The training program may be structured in any format, with different portions conducted by different individuals and at different times, as long as the required topics are covered.
| USDOL | CONTACT INFORMATION | DISCLAIMER |



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Noise-induced Hearing Loss

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Evaluation of the Effectiveness of a Hearing Conservation Program
To date, there is no universally accepted method of evaluating the effectiveness of a hearing conservation program. Hearing conservation programs include aspects of administrative controls, engineering controls, audiometric surveillance, and training. Occupational physicians can actively participate with employers in improving all these aspects of hearing conservation programs through ongoing evaluation of program outcomes and processes.

The Occupational Physician as Professional Supervisor of a Hearing Conservation Program
ACOEM believes that occupational physicians can play a critical role in the prevention of noise-induced hearing loss by serving as professional supervisors of hearing conservation programs. The Council on Accreditation of Occupational Hearing Conservation (CAOHC) offers a course for professional supervisors.

The responsibilities of such a supervisor include supervision of an audiometric technician, review of problem audiograms and determination of whether there is a need for additional evaluation, determining the work-relatedness of a threshold shift, revision of an audiometric baseline, and evaluation of the effectiveness of the hearing conservation program.[6] The professional supervisor should be an advocate for the "hearing health" of noise-exposed persons, and work to ensure that noise exposures are minimized both at work and during recreational activities, through avoidance of excessive noise and proper use of hearing protection when necessary.

Conclusion

- Improving hearing conservation programs is the solution.
- Method B does not accurately measure a hearing protector's performance, but rather the quality of the test subject.
- 3rd party testing of hearing protection is imperative for boosting consumer confidence and offering more reliable and repeatable test results.

Ted K. Madison, M.A., CCC-A
3M Occupational Health & Environmental Safety Division

Today I would like to speak to 3 main points:

1. Based on my observations of and conversations with hearing protector users and hearing conservation program administrators, I am convinced that packages of hearing protectors need to bear labels that communicate more clearly and accurately the product performance characteristics and the use conditions that impact the effectiveness of that product in the workplace or in non-occupational settings.

2. Secondly, there is widespread agreement within the hearing conservation professions that the hearing protector labeling currently required by the United States EPA, under federal regulation 40 part 211, is inadequate and misleading.

3. Thirdly, 3M believes that users of hearing protectors and employers who provide hearing conservation programs for their employees will benefit from improved hearing protector labeling, should the EPA go forward with changes to the rules contained in 40 part 211.

In order to understand the needs of hearing protector users, we need to understand the intended use. In the occupational noise setting, the person who selects the hearing protector needs to know whether or not a particular hearing protection device is capable of reducing the noise exposure of employees to levels below the exposure limit. Typically, the employer has measured or at least estimated employee noise exposure levels relative to exposure limits established by OSHA or company policy. In industries where noise-exposed employees participate in a hearing conservation program, includes annual training and hearing testing, one can assume that the user has some level of understanding of how to properly use hearing protection and the risks of failing to do so.

However, the needs of the non-occupational hearing protector user are quite different. The consumer who purchases a pair of hearing protectors to use while operating a chainsaw, hunting, or attending a NASCAR event often does not know his/her noise exposure level or hearing level. Likewise, these consumers are typically not trained on proper use of hearing protection. Labeling HPDs for these consumers is a more challenging task.

It was apparently this non-occupational hearing protector user that the EPA had in mind in 1979 when the hearing protector labeling rules were implemented. An EPA press release that year stated that the agency intended to put "Primary emphasis on …labels on products used in and around the home". The press release described how the new EPA hearing protector labels would allow the consumer, "…to tell at a glance the relative noise characteristics of a specific brand of product by comparing its…Noise Reduction Rating to those of other brands." I suspect that this emphasis on home use of hearing protectors influenced the EPA to require the use of an ostensibly simple single number rating, the NRR.

The premise behind the Noise Reduction Rating system was, according to the EPA, "The higher the rating, the more effective the product should be" If that were true, few of us would be here today to urge EPA to modify its labeling rules. In fact, we have learned since 1979 that a high NRR is a weak predictor of hearing protector effectiveness. As we heard previously today, research conducted over the last 20 years has shown that effectiveness of a given hearing protector varies widely within the population of HPD users in the real world. Even more concerning is the evidence suggesting that the NRR fails to provide the consumer with an accurate indicator of the effectiveness of a device compared to other devices with higher or lower ratings. Regrettably, we have come to realize that the NRR reveals only the *capability* of the device to attenuate sound under controlled conditions, not it's effectiveness when worn under field conditions. And, yet, it is the effectiveness of the device that is of primary concern to users.

An effective hearing protector is one that helps reduce noise exposure when used according to instructions. Reducing noise exposure involves much more than the capability of the device to attenuate sound. The effectiveness of the hearing protector is influenced by the attributes of the noise itself, a host of user variables, including fit, and, perhaps most importantly, wear time.

3M has concluded that the existing HPD labeling rules set forth by the EPA are inadequate. If you read all of the EPA-required text on a hearing protector package, you may come away with the idea that noise reduction is the most important characteristic of a hearing protector in determining its effectiveness. Few, if any other factors that influence HPD effectiveness are even mentioned in the EPA-mandated text. Given the weight of evidence suggesting that these other factors influence HPD effectiveness as much or more than laboratory attenuation characteristics, it is imperative that changes be made to the labeling rules to provide consumers with better information about hearing protector selection. The omission of valid criteria for selecting hearing protectors in the current EPA labeling rules is compounded by the lack of accurate information concerning how much the performance of a given device varies within a population of users. A single number rating based on average performance, such as the NRR, fails to communicate the tremendous range of attenuation that may be achieved by individual in the field.

3M is also concerned that portions of the EPA-mandated text, which we and other manufacturers must print on packages of hearing protectors, is misleading to consumers. This misleading information has led OSHA to require employers to discount or derate the NRR when evaluating the protection offered by hearing protectors relative to noise controls. Likewise, 3M and other manufacturers, in response to misleading statements on the EPA label, have modified their packages to include cautions and use limitations. The end result is confusion for the consumer. I'd like to show you a couple of examples.

On a box of 3M ear plugs, the consumer may read this statement required by the EPA,

> "The level of noise entering a person's ear… is closely approximated by the difference between the… noise level and the NRR".

However, on the same package, the consumer will read,

> "Research suggests that the NRR may overestimate the protection provided by hearing protectors during typical use. 3M recommends reducing the NRR by 50% for estimating the amount of noise reduction provided."

In another example, the consumer will read these two contradictory statements on the same package:

> "Higher (NRR) numbers denote greater effectiveness"
> "Differences between hearing protector ratings of less than 3 dB are not important. Far more important is the amount of time you wear the hearing protector relative to the amount of time you are exposed to noise."

Clearly, we are sending mixed messages to consumers. By modifying its rulesfor labeling hearing protectors, the EPA can reduce much of this confusion and help consumers make better informed choices about hearing protection. I would like to share with you, now, some specific recommendations for improving hearing protector labeling.

3M supports changing the laboratory test method that manufacturers must use to measure the real-ear attenuation of hearing protectors for labeling purposes to ANSI S12.6, method B. It appears that method B, a subject fit test method, yields a better estimate of real-ear attenuation that is "achievable" by groups of users under field conditions. Because it appears that subject fit data correlate well with the "field attenuation" data measured in numerous studies, using method B to measure hearing protector performance may reduce or eliminate the need to apply safety factors or derate the labeled rating. If the use of subject fit testing yields hearing protector ratings that can be used at face value, the process of estimating the adequacy of hearing protection relative to noise controls would be simplified. Occupational hearing protection users and those who administer hearing conservation programs would directly benefit from such simplification.

3M recommends that the NRR be converted from a single number rating to a two number Noise Reduction *Range*. By providing the user with an NRR at two different performance levels, the EPA can help consumers better understand the range of noise reduction that is achievable depending on use conditions. Such a range of noise reduction provides a clear illustration of the importance of wearing the devices properly and consistently during noise exposure periods. While critics of this approach have argued that a noise reduction range would be too confusing for consumers, 3M believes that a simple explanation of the range can be developed. We support the ANSI S12 working group 11 in its efforts to define the methods for calculating such a noise reduction range and efforts by the EPA to develop a label to communicate a Noise Reduction Range to consumers.

With regard to the so-called secondary label, 3M encourages the EPA to review and incorporate into a revised labeling rule recommendations made by the NHCA Task Force on Hearing Protector Effectiveness on the topics of "Selecting Hearing Protection" and "Estimating Noise Reduction for Individual Users." We agree with the intent of the task force recommendations to de-emphasize the NRR as the primary criterion for selecting hearing protectors.

One statement in the NHCA task force report, shown here, very clearly summarizes the most important information consumers need to know when selecting hearing protectors.

> "The most critical consideration in selecting and dispensing a hearing protector is the ability of the wearer to achieve a comfortable noise blocking seal which can be consistently maintained during all noise exposures."

3M encourages the EPA to require that this statement, or one similar to it, be printed on every hearing protector package sold in the United States.

Should the EPA develop and implement new rules for labeling hearing protection devices, 3M favors a transition period of at least 3 years, during which time manufacturers would be allowed to sell products labeled according to the 1979 rules. This would allow sufficient time for manufacturers to test and label their products in accordance with the new rules. Re-testing of hearing protectors should not be required by EPA unless the manufacturer has modified the product substantially, resulting in a change to the product form, fit, or function. With regard to laboratory testing, 3M and a significant number of other manufacturers encourage the EPA to require, in any new hearing protector labeling rule, that manufacturers of hearing protectors use independent, third-party laboratories for the purpose of measuring the real-ear attenuation values and calculating the performance rating(s) that are to be printed on packages sold in the United States. We believe that this requirement will help boost consumer confidence in the validity of hearing protector performance ratings.

One challenge faced currently by HPD manufacturers is the test-retest variability of real-ear attenuation measurements. In cases where a single product is tested more than once, and the test data yield different ratings, the EPA needs to provide clear rules for determining which NRR is to be printed on the label. Given the “bigger is better” mentality in the industry, with regard to NRR, it is conceivable that HPD manufacturers have, in the past, or may, in the future, attempt to obtain a desired NRR, not by improving the product in a meaningful way, but by retesting a product repeatedly; rolling the dice, if you will, in hope that the variability of test data will eventually yield a higher number. EPA should discourage this practice by including in revised labeling rules specific criteria for when and if a manufacturer must modify its published NRR to reflect newly acquired performance data. By defining these criteria carefully, the EPA can help protect consumers from false claims of “improved product performance” that are based on statistically insignificant variations in test results.

Finally, 3M urges the EPA to seek full funding for the Office of Noise Abatement and Control to assure that hearing protector labeling regulations are kept up-to-date and to enforce those regulations in a meaningful way. If funding for ONAC cannot be obtained, 3M recommends that the EPA consider granting permission to other Federal agencies, such as NIOSH for example, to regulate certain aspects of hearing protector labeling by means of a memorandum of understanding or similar agreements.

Brian Myers
E·A·R Product Line Director
E·A·R/Aearo Company

QUALIFICATIONS

Among the relevant positions I have held are membership on the National Hearing Conservation Association's Board and former Vice-Chair of the International Safety Equipment Association's Hearing Protector Group.

COMMITMENT

Aearo Company markets leading brands of hearing protection in the U.S. and the world under the E·A·R and Peltor labels. We believe that providing consumers, users and other key decision makers with better information regarding realistic hearing protector performance is beneficial to ALL stakeholders in the long run. We are committed to improving hearing conservation efforts. An Aearo professional, Elliott Berger, has chaired the most recent ANSI working group, and our E·A·RCAL^{sm} Lab has participated in the interlaboratory studies used to develop the ANSI standard. We also have several ongoing education and training efforts.

Aearo is one of only two manufacturers to recommend hearing protector derating on every package for more than fifteen years. We have used a NVLAP accredited laboratory for testing our products and we have made significant investments in capital and R&D.

RECOMMENDATIONS

We support ANSI S12.6-1997, the Method B protocol, with one essential modification: We have conducted our own extensive lab-to-lab comparison and we found one case where the product performed as expected across all subjects but one. In this case, the subject had amplification at a key frequency, leading to poor mean attenuation and large standard deviations.

This type of situation would mean that manufacturers could invest significant time, money, and resources in the development of a product, only to be undermined by a "bad" test. We believe that it is unfair to allow a bad test to dictate the failure of a good idea in the marketplace.

What are the solutions? More subjects? But this could mean that an appropriate number of subjects may approach one-hundred, which would be too costly and time-consuming.

A NEW PROPOSAL

A new proposal would be a "full disclosure option," where manufacturers would be allowed to perform multiple tests. They would be required to submit all tests and the reasoning behind their rating selection to the EPA (or other suitable group), the materials would be reviewed, and a decision made within a fixed period of time.

MOVING FORWARD

We believe that Method B provides more meaningful information to consumers leading to better programs. It will increase product innovation, promote a renewed investment in hearing conservation and training materials, and improve product and program performance for users of HPDs.

OTHER ISSUES

Labeling: The “Number” should be de-emphasized, there should be a range of numbers to express performance, and no number should appear on the individual package

A “sunset clause” would be costly and time consuming. If there were such a clause, it should be at least 7 to 10 years

Education and training deserve increased emphasis.

With respect to lab qualification, we favor the National Voluntary Lab Accreditation Program (NVLAP).

We also favor sufficient funding for EPA’s Office of Noise Abatement and Control and for compliance audit testing.

Timing: There should be 3½ to 4 years from adoption of the regulation to the point of consumers. There should also be windows by product style. For example, requirements for the labeling of earmuffs, foam earplugs, and premolded earplugs, etc. should be separated by three-month intervals.

SUMMARY

We support Method B testing with a provision for the “bad” test, and we support the ISEA consensus for increased education, training, and funding. These actions will lead to a change for the better.

Testing & Rating of ANR Headsets

Dan Gauger
Bose Corporation

INTRODUCTION

Active noise reduction (ANR) in headsets or headphones in prototype form dates back to the 1950s (Meeker, 1958). The underlying principle is that, by building a microphone into the earcup of a headset, one can sense and control the sound pressure heard by the wearer. In most cases this has been done by means of a feedback system comprised of the loop from microphone to electronic circuit to speaker, then through the earcup acoustics back to the microphone. This feedback loop regulates the sound pressure in the earcup to a desired signal, either zero (silence) or an audio signal the user wants to hear. From a physical perspective, the circuit "tells" the speaker diaphragm how to move to alternately raise or lower the pressure in the earcup to achieve the desired sound pressure. The constraints of earcup acoustics and feedback loop design dictate that ANR is effective against low-frequency noise ranging from 20 Hz or lower to typically 500 to 1k Hz at the upper end; these values have changed little over the last several decades.

Advances in components in the 1970s began to make ANR headsets practical. Through the late 1970s and 1980s work continued at a few locations with the encouragement of the Bio-Acoustics Lab at Wright-Patterson AFB and the British MoD labs at Farnborough. ANR headsets began to see commercial use with the introduction by Bose of its first generation aviation headset in 1989. Since then various manufacturers have begun to offer ANR communication headsets for general aviation and military applications. ANR headphones for consumer use, particularly frequent airline travelers, have also been on the market for several years and one manufacturer has offered a product for use as an industrial hearing protector.

HAS THE TIME COME TO RATE ANR?

Purchasers of ANR headsets today are not provided with an NRR rating describing the performance of the device. This is because the test method mandated for obtaining the attenuation data, the Real-Ear Attenuation at Threshold method (REAT, ANSI S3.19 now superseded by ANSI S12.6-1997), cannot be applied with reasonable accuracy to ANR devices, as is explained in the next section. The lack of an NRR has not proven to be a real barrier so far to the success of ANR in applications where it offers benefits. The military has been satisfied with evaluating ANR using the Microphone in Real-Ear method (MIRE, ANSI S12.42-1995, originally standardized as MIL-STD-912). General aviation pilots and frequent-flying consumers have largely trusted their own ears, evaluating products by the residual noise they hear when using headsets on their travels. Bose (and presumably other purveyors of ANR headsets) offer customers various ways to “test fly” ANR headsets before paying for the product.

ANR has not succeeded in the market for industrial HPDs but we at Bose Corporation believe this is largely not for lack of an NRR. As will be shown later, ANR offers limited or no hearing protection benefit at present in the majority of industrial noise environments. However, at Bose we believe the real promise of ANR is not simply greater noise reduction (though it can offer that in the right environments) but more comfortable to wear and more natural sounding (i.e., more uniform across frequencies) attenuation than conventional (passive) HPDs can provide. These benefits are desirable in industrial applications as well as general aviation, so it is conceivable that improvements to ANR will make it competitive with conventional HPDs at some point in the future. At that time, the lack of an NRR will be a severe impediment.

The purpose of the NRR and other EPA-mandated HPD labeling should be to inform consumers, either at home, in the industrial workplace, or when flying in aircraft. To do so, the data provided to the consumer should be simple to understand, contain information allowing meaningful comparison of different products, and provide a reasonably accurate portrayal of the performance the consumer can expect to achieve in his or her application of the device. If the NRR rule is to be explicitly extended to encompass ANR devices, it should allow such meaningful comparisons between ANR and conventional devices as well as between ANR devices. If this is achieved, then a redefined NRR can foster innovation, leading over time to HPDs and headsets — both conventional and ANR — that better meet the needs of consumers. If these goals are not achieved (e.g. if a new NRR does not fairly portray the relative performance of ANR to conventional devices in markets where ANR is beneficial) then a redefined NRR can have the opposite effect, with likely severe adverse impact on the ANR industry.

METHOD A OR METHOD B

Many presentations at the EPA Workshop on HPDs addressed improvements to the REAT testing standard embodied in the ANSI S12.6-1997. The debate centers on the choice between method A (experimenter-supervised fit) and method B (subject-fit) in that standard. It is Bose's opinion that any change to the NRR should be built around a subject-fit approach to testing. After all, HPD users fit themselves in actual day-to-day use without careful supervision by highly trained fitting experts. Some criticize method B as not testing the attenuation a device is able to provide but, instead, testing the ergonomics of the device. It is true that device ergonomics is an important factor influencing method B attenuation and this is appropriate; the performance users will achieve in the real world depends both on the attenuation capabilities of the device as well as the ergonomics — how easy it is to fit the device to oneself. Some criticize method B for testing the instructions the HPD manufacturer provides, not the training the user receives in the field. But, as data presented at the Workshop by both Elliott Berger and John Franks showed, method B data correlates well with real-world tests, both as a measure of the level of noise reduction provided as well as the relative performance (rank ordering) among different devices. We also suggest that testing the manufacturer's instructions is appropriate because this will provide an incentive to HPD manufacturers to improve instructions and, as was reported by John Casali at the Workshop, improved instructions have been shown to improve the noise reduction wearers achieve when wearing earplugs. If the NRR is to provide the majority of consumers with meaningful data indicative of their use of the product, then the subject selection and level of experimenter oversight specified by method B is the best means to achieve that goal based on available data[1].

RATINGS FOR METHOD B DATA

At the Workshop, Elliott Berger presented the rating proposed by ANSI S12/WG11; this rating is identified by the name NRP_A (for "noise reduction percentile, A-weighted") in the working group's analysis of rating accuracy. Because the approach to rating ANR devices presented later in this paper builds on the NRP_A approach it is worth reviewing here. NRP_A is motivated by four goals:

1) A single number rating should be of the constant protection type; i.e., intended for subtraction from the A-weighted noise exposure in the workplace (A–A' or noise level dBA minus protected dBA). By contrast, the current NRR is a Botsford-type rating meant to be subtracted from C-weighted levels when properly used (C–A'). A-weighted levels or time-weighted averages are the type of data collected in assessing the need for hearing protection so a constant protection type rating is straightforward to apply. By comparison, a Botsford-type rating, though more accurate with traditional muff-type passive HPDs because of their sloped attenuation response, is burdensome (since it requires both C- and A-weighted data to be collected) or confusing (if adjustments are applied in the absence of C-weighted data, potentially leading to errors in its application)[2].

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[1] ANSI S12.6-1997 method B requires the use of subjects "naïve with respect to the use of hearing protection". It may be appropriate, in the case of a select population working in very high noise levels who receive particularly diligent training in the use of HPDs, to allow an employer to arrange testing of the HPDs offered to that population with a sample of subjects who have been through the training provided. This would test the HPD in conjunction with the training that population receives rather than with the manufacturer's instructions. However, testing with naïve subjects based on the manufacturer's instructions should remain the basis for device labeling for the general population.

[2] In recent years there has been growing interest in "flat attenuation" devices because of the more natural perception of the user's acoustic environment (including speech and warning sounds) they can offer. For a truly flat attenuation device, the situation reverses and constant protection ratings are more accurate than Botsford-type ratings. A constant protection rating does not build in a bias toward a particular attenuation response; it simply gives a figure for the protection the device provides.

2) It is desirable to have a rating convey the range of performance a device may be expected to provide. This can be done by providing two numbers, a lower one that the majority of users will exceed and an upper one that highly experienced and motivated users can achieve. A single number creates a false impression of precision and, in the absence of advice to the contrary, encourages an unwarranted focus in device selection on slight differences in rating values. Upper and lower estimates of HPD performance are also supportive of evolving standards to consider both over-protection as well as under-protection; the lower of the two values would be subtracted from the workplace noise level to make sure that workers are under the level deemed safe (85 or 90 dBA) while the higher of the two values could be used against an over-protection threshold such as 70 dBA. Finally, note that while a device that has a narrow range between the two values is more precise and repeatable in the protection it provides the novice user, a device with a wide range could be considered adaptable to a wide variety of noise levels when used with regular training of workers as to how to achieve the performance they need, preferably including feedback from a system that allows measurement of HPD performance as part of the training.

3) Two sources of uncertainty constrain the accuracy of a rating method for HPDs: the variation in attenuation of the HPD from person to person and the variation in protection provided in different noise spectra caused by the deviation of the HPD from a flat attenuation response[3]. A rating that provides two numbers to convey the range of performance a device offers should be designed so that range is a function of both of these sources of uncertainty. This will motivate innovation by encouraging

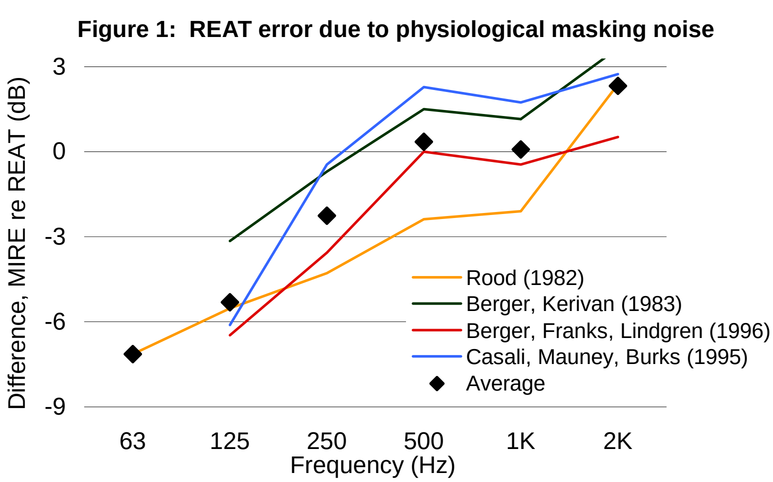
[3] One can characterize the subject-to-subject protection uncertainty by calculating the protection in pink noise (close to the median spectrum for industrial noise) for each subject then computing the standard deviation over the subjects tested. One can then characterize the spectrum-to-spectrum protection uncertainty by calculating the protection in a variety of noise spectra (say, the NIOSH 100 [Johnson and Nixon, 1974]) using the mean attenuation. If one does this with method B data, the subject-fit standard deviation for plugs is always much larger than the spectral standard deviation (typically 8 versus 2 to 3 dB), whereas for muffs the spectral and subject-fit standard deviation are usually close (typically 4 dB for each).

the development of HPDs that offer predictable, natural sounding (flat attenuation) and perhaps adjustable levels of performance.

4) All existing rating systems to date make recourse to normal (Gaussian) statistics to establish a conservative estimate of protection that the majority of users can be expected to exceed. While the assumption of attenuation normality is reasonable when working with experimenter-fit data, attenuation data measured with less experimenter intervention (such as method B) is often quite bi-modal because of the way ease of fitting enters the picture. When working with non-normal data, it is better to establish a conservative estimate by means of percentiles calculated directly from the data rather than assuming that the mean less one standard deviation corresponds to the 84th percentile.

The proposed NRP_A rating addresses all of these considerations in a straightforward way. It provides two values that are computed by taking the attenuation measured on each test subject using method B and the 100 NIOSH noise spectra and computes the protection using the octave-band method in each combination of subject and spectra. This will yield 2000 protection values in the case of a plug (20 subjects) and 1000 in the case of a muff (10 subjects). Upper and lower percentiles are then found on this set of protection values. The 84th and 16th percentiles can be used for comparison with mean less one standard deviation based ratings; this is done in all cases presented in this paper. Preferably, the 80th and 20th percentiles would be used since these are more readily explained and understood (e.g., the 80th percentile is the value exceeded by four out of five individuals).

MEASURING ANR ATTENUATION



In a comprehensive paper written for the EPA Workshop, John Casali and Gary Robinson describe various issues associated with measuring the attenuation of ANR headsets. Several of these issues pose challenges in trying to find a way to encompass ANR devices in a re-defined NRR in way that allows fair comparison between ANR and conventional devices. Two methods of measuring the insertion loss of an HPD are standardized: the REAT and MIRE methods. REAT, though the accepted method for conventional devices, cannot be applied to ANR devices because the self-noise (hiss) from the electronics is loud enough to mask the quiet test signals used and thus raise the occluded thresholds, causing the resulting attenuation values to be inaccurately high. The MIRE test method solves this by using microphones placed in the subject's ear canals to make physical measures of the noise under the earcup, allowing testing at louder noise levels. The problem is that MIRE and REAT for the same circumaural device disagree at low frequencies. The REAT method overstates low-frequency performance because sounds of physiological origin (e.g., the subject's heart beat) are loud enough in the occluded ear to mask the low-frequency bands. Figure 1 shows the difference between REAT and MIRE data for circumaural devices from four different published studies, the average across the studies is shown by the black diamonds: 5 dB at 125 Hz and 2 dB at 250 Hz[4].

To illustrate the importance of this REAT error at low frequencies from a protection perspective, examine Figure 2. This figure (from Gauger, 2002) shows the change in protection that results when octave-band protection calculations (A–A') are done using REAT data for a good quality conventional (passive) muff before and after correction by the averages from Figure 1. Each diamond in the figure represents one spectrum from the set of 50 AF noises (Johnson and Nixon, 1974). The protection values are plotted against the C–A (dBC–dBA) values for the noise spectrum, a measure of the low-frequency content of the noise. The 50 AF noises were used because they are uniformly distributed in C–A value. Figure 2 shows that the REAT error at low frequencies causes a 3 - 4 dB overestimate of protection (i.e., larger than the typical subject-to-subject standard deviation) for C–A values of 4 - 6 dB. While this constitutes only 20% or so of industrial

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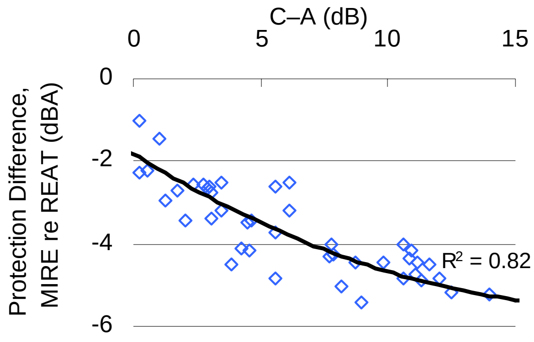
[4] At higher frequencies (2 kHz and above) MIRE data is typically slightly higher (2-3dB) than REAT because it does not include the effects of bone conduction. This is of less consequence than the low frequency REAT error in most situations, however, because the level of attenuation is generally so high at

Figure 2: REAT protection estimate error



noises it comprises almost all environments encountered in general aviation, a key market for ANR devices (Gauger, 2002, Figure 1). Thus, not accounting for this error in defining test methods for rating ANR devices would unfairly disadvantage them compared to conventional devices.

To eliminate this bias in favor of devices tested with REAT and to provide the most accurate data on which to base a rating it would be best to test all devices, conventional and ANR, using the MIRE method. However, testing earplugs using MIRE is impractical because of the need to place a microphone in the ear canal underneath the plug. The practical way to eliminate the low-frequency error is to correct REAT data by the observed REAT–MIRE difference at low frequencies. While this correction is not standardized in ANSI S12.6, the averages presented in Figure 1 could form the basis for this in the case of muffs. There is limited published data upon which to base a correction for plugs, though the existing data indicate the correction should be less (Berger and Kerivan, 1983).

An alternative way to "level the playing field" between conventional and ANR devices would be to require ANR devices to be tested using REAT for their passive performance and MIRE for their active part. The passive performance is measured with ANR turned off, just as if the device were a conventional HPD. The active part is measured, after placing the MIRE microphones in the subject's ears and donning the headset, by taking the difference in the spectra at the microphones with ANR off and with ANR on. The REAT and MIRE tests should be done with the same subject pool; the averages of the passive and active data across trials for each subject can then be added to obtain the total attenuation for each subject to use in rating computation. While this REAT+MIRE approach levels the playing field, it has two disadvantages: (1) it does not eliminate the over-estimate of protection in high C–A noise environments illustrated in Figure 2 and

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these frequencies that the level of the A-weighted spectrum under the HPD is determined primarily by the

(2) it imposes extra cost on ANR manufacturers, requiring two tests on a device, not just one.

Two issues should be addressed in the MIRE standard (ANSI S12.42) to support the adoption of REAT+MIRE testing for ANR devices. First, the MIRE standard includes no method B (subject-fit) protocol, though adapting the approach from ANSI S12.6 is straightforward. Second, some further guidance as to how to mount the test microphones on plugs and seat them in the ear is desirable so as to ensure both accurate and repeatable ANR measurements while ensuring that experimenter coaching of subjects on proper plug+mic fitting for MIRE tests does not disqualify the subjects for method B REAT testing of plugs where the subjects are required to be inexperienced in plug use.
Finally, it is worth mentioning two other ANR testing issues lacking any standardization that would support inclusion in EPA changes to the NRR. First is the issue of "overload." ANR devices must produce an out-of-phase sound of the same level as the noise to be canceled; every ANR device has some maximum noise limit determined by the acoustical and electronic characteristics of the device. When operated in noise above this limit, ANR performance rapidly decreases. This limit is dependent upon both noise spectrum and subject fit; it should be measured with the headset worn on human subjects by some MIRE-like protocol. No standard exists for how to measure this limit and very few labs that measure hearing protector performance have the capability to generate the necessary sound pressure levels at low frequencies. The second issue is the fact that ANR devices that adapt dynamically to the noise environment are starting to appear on the market. For such devices, the ANR performance measured with pink noise (typically used in MIRE tests) can differ substantially from that measured with recordings of the noise for which the device is designed (e.g., general aviation noise, which often has a few strong periodic tones that an adaptive ANR headset can attack). The lack of standards to address either of these issues makes it hard for the EPA to address them in any near-term rule-making in anything but a qualitative, advisory way.

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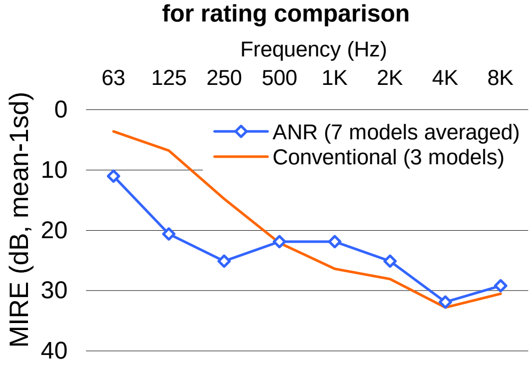
octaves at 1 kHz and below.

ANR FROM THE SINGLE NUMBER RATING PERSPECTIVE

What might typical ratings look like if the EPA were to change the NRR to require MIRE testing for ANR devices and REAT testing for conventional devices, corrected for the REAT low-frequency error as discussed above? What impact would it have on the ANR industry? To examine this, assume that the EPA changes the NRR to the NRP_A rating proposed by ANSI S12/WG11 and described earlier. For attenuation, use an average of MIRE data for conventional and ANR communication headsets sold for general aviation, as shown in Figure 3 (from Gauger, 2002).

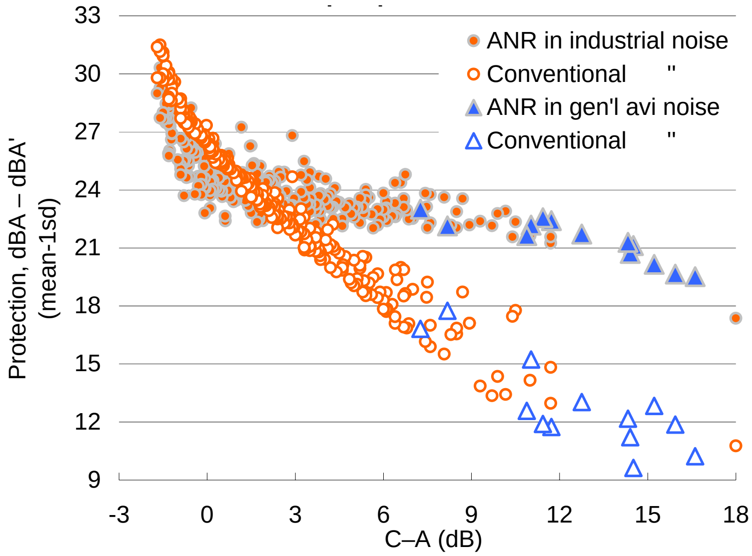
The table at right shows the NRP_A values (84th and 16th percentiles) computed from the MIRE data used to create Figure 3. The table also shows estimates of the NRP_A values that would be obtained if REAT+MIRE data were used, estimated by adding to the MIRE data the average REAT–MIRE difference from Figure 1. Note that the difference in performance between the conventional and ANR headsets is only 1 - 2 dB at the lower value; this is because the NRP_A is computed using the 100 NIOSH noises which are dominated by spectra with low C–A values. It is only in noise with high C–A where ANR offers benefits, as shown in Figure 4. That figure shows that the average difference between the conventional and ANR performance in industrial noise (orange marks[5]) is minimal whereas the difference in general aviation noise (blue marks) is about 10 dB.

Figure 3: ANR & conventional headsets for rating comparison



[5] Compare the apparent mean of the orange open (conventional) or filled (ANR) marks in the figure to the lower values in the MIRE row of the NRP_A table. Note also that the ANR protection varies less with C–A because the attenuation is flatter. This is why the range between the two values in the NRP_A table is smaller for ANR than it is for the conventional headset.

Figure 4: Protection versus C–A for communication



Estimated NRP_A	Conventional	ANR
MIRE	22 – 30	24 – 29
REAT+MIRE	24 – 31	25 – 29

The assumption of industrial-type, low C–A noise in a single number rating is appropriate for a new NRR, given that the industrial workplace is where an improved NRR label is most needed. However, requiring a label with a rating as shown in the table on general aviation headset packaging would misinform consumers. The label would say a conventional headset offers virtually the same performance as an ANR one, whereas in its intended application in general aviation noise, the benefit is substantial as shown in Figure 4. Such a primary label on the box could have a severe financial impact on the ANR industry, impeding future innovation. The best thing to do is to not require simple, single-valued ratings on a primary label for an ANR headset. The numbers on the primary label should be replaced with the text "ANR device — see secondary label for data."

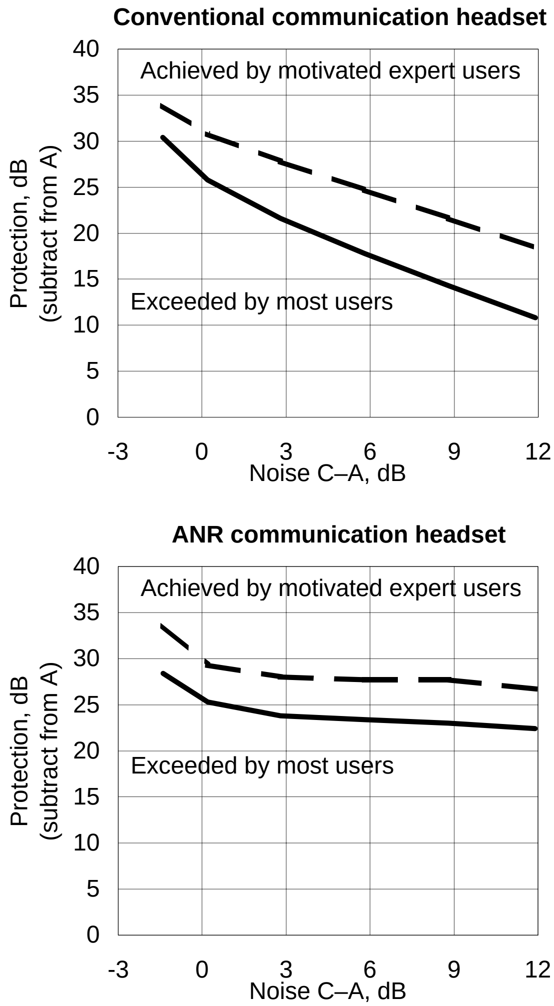
Information on the Secondary Label

To properly convey to consumers the performance of ANR devices compared with conventional ones or to allow comparison of different ANR headsets, some easy-to-use way to communicate performance as a function of noise spectrum is needed. The current secondary label includes a table of octave-band attenuation values, both mean and standard deviation. However, only a small percentage of people understand how to use these data and only a small percentage of users have the means to obtain octave-band noise data in their noise environment(s) of interest.

An alternative is to replace the octave-band attenuation table with data that describes the protection the HPD provides as a function of the noise C–A value; the C–A value for a noise can easily be obtained with many sound level meters. Protection as a function of C–A is the basis of the ISO 4869-2 HML method as well as a multi-number method used by the USAF (R. McKinley correspondence). The approach proposed here is inspired by these methods while, at the same time, extending the proposed NRP_A intended for primary label use. This proposed rating for the secondary label may be called NRP_G where the "G" stands for "graph" since the data are presented graphically rather than in tabular form. The idea is simple: take sets of noise spectra centered on various C–A values and, with each set, compute high and low protection (A-A') percentiles using the subject-by-subject attenuation data in the same manner that the NRP_A is computed using the 100 NIOSH noises. The values can then be plotted as high and low performance bounds on a graph of protection as a function of C–A. Graphical presentation is proposed instead of tabular form (like the HML) since most people can readily read a graph, whereas an approach like the HML requires arithmetic computation to interpolate the table. Figure 5 shows examples of what this graph might look like based on the MIRE attenuation data shown in Figure 3.[6]

[6] A Microsoft® Excel spreadsheet and supporting documentation that computes the NRP_A and NRP_G ratings is being prepared to better explain them and allow interested parties to experiment with them using attenuation data of their choosing. They will be available very shortly. For further information contact the author at Bose Corporation or Elliott Berger at Aearo.

Figure 5: Protection versus C–A graph (NRP_G) for secondary label



From such a graph it is easy to see that an ANR device offers advantages in high C–A noise but not in low C–A ones. The secondary label could include advice that if the noise is from moving vehicles, large air-moving equipment, or has a "humming", "rumbling" or "roaring" sound to it then the C-weighted level of the noise should be measured so that the C–A can be determined and the graph used. Additionally, publications could provide typical C–A values for different types of noise sources and industries. This graphical approach to increasing rating accuracy through the use of C–weighted noise data is preferable to the approach described in Elliott Berger's presentation at the Workshop (wherein a constant correction is added to an A–A' rating such as NRP_A and then this new constant value is subtracted from a C-weighted noise level) since that approach relies on the HPD having the sloped attenuation response characteristic of passive earmuffs. For

flat attenuation devices such as circumaural ANR headsets, that method can overestimate protection in high C–A environments such as general aviation by 10 dB or more.
In addition to the graph showing protection versus C–A in place of the octave-band attenuation statistics table, the secondary label should address several other issues in our opinion at Bose:

1) Consumers should be advised that noise reduction is not the sole, nor in all cases the most important, consideration in choosing a hearing protector. Other factors such as comfort and the ability to communicate or hear important sounds in one's environment must be considered as well. We encourage the EPA to consider the advice of the NHCA Task Force on Hearing Protector Effectiveness in requiring wording to address these issues on a secondary label.

2) In the case of communication headsets or radio-equipped hearing protectors, consumers should be advised to choose a headset that reduces their noise environment to at least 5 dB below the level considered safe (i.e., 80 rather than 85 dBA). This is so that communications can be listened to at a level loud enough above the attenuated noise at the ear to allow good intelligibility without the communication signal posing risk of hearing damage.

3) Should the EPA require passive (ANR off) performance data for ANR headsets on the label? This could, for example, be done by adding one or two additional contours to the graph shown in Figure 5. In our opinion, this should not be required. ANR headsets are designed to be used with ANR operating; they are not used with ANR turned off except for short periods of time (e.g., until a battery can be replaced). Thus the impact on hearing protection of very occasional, short-term use with ANR off is small.

SUMMARY — RECOMMENDATIONS TO THE EPA

In conclusion, Bose Corporation offers the following recommendations to the EPA. These recommendations are motivated by our desire to see a revised HPD labeling standard provide consumers with reasonably accurate, meaningful, and easy-to-use data by which to compare and choose devices appropriate to their needs.

1) The EPA should change the NRR so that it is based on subject-fit data per ANSI S12.6 method B.

2) The rating should be designed for subtraction from A-weighted noise levels and convey to the consumer, by means of two numbers, the range of performance a protector can provide. This range should be computed by some method that factors in both the uncertainty in protection due to variation in subject-fit as well as noise spectrum. The NRP_A rating described by Elliott Berger in his presentation and earlier in this paper accomplishes these goals. We recommend its adoption by the EPA as the basis for a redefined NRR.

3) Our preference at this time would be that the EPA not extend the NRR-defining rules to encompass ANR devices. This is because standards existing at this time do not define how to correct REAT data for the error caused by low-frequency physiological noise masking. Correcting for this error is necessary to enable the computation of reasonably accurate noise reduction ratings in environments with significant low-frequency noise energy (high C–A value). Standards also do not yet exist for the measurement of the maximum safe noise level or overload performance of ANR devices.

4) Alternatively, if the EPA chooses to extend the NRR to encompass ANR at this time it should:

a) Not require an NRR value on the primary label for ANR devices. Words to the effect "ANR device — see secondary label for data" should replace the NRR values.

b) Require that the octave-band table of attenuation statistics be replaced with a graph of high and low protection values versus noise C–A as illustrated in Figure 5 (the NRP_G graph).

c) Require that the attenuation data used to define this graph be measured using MIRE for ANR devices and REAT for passive devices *and* that all REAT data for circumaural and supra-aural devices be adjusted downward by 5 dB at 125 Hz and 2 dB at 250 Hz to correct for physiological noise masking. If such a correction to REAT data is not mandated, then ANR should be tested by means of REAT for passive performance and MIRE for active performance.

d) The secondary label should provide additional advice to consumers regarding the importance of choosing a protector that is comfortable to wear and which allows them to hear important sounds in their environment.

e) Data on passive (ANR off) performance of protectors should not be required.

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Janice Bradley
International Safety Equipment Association

The International Safety Equipment Association (ISEA) is the leading trade organization representing manufacturers and suppliers of personal protective products and equipment, including all types of hearing protection devices. ISEA appreciates the opportunity to provide input to the EPA as it seeks to update its regulation 40 CFR Part 211 regarding the effectiveness rating and labeling of hearing protector devices. As the agency moves toward this goal, ISEA member manufacturers of hearing protectors believe several important issues should be addressed when developing the proposed rule to update the regulation.

GRANDFATHER CLAUSE

While we are aware that the EPA will likely consider several options for revising the current regulation, it is important for the agency to understand that manufacturers will need to be provided adequate time to implement the updated program into its manufacturing processes. As such, ISEA member companies respectfully request that any proposed regulation include a grandfather clause to allow manufacturers a reasonable amount of time to comply with the new regulation. Manufacturers anticipate that there will also be cost implications associated with an updated regulation. ISEA members expect to provide a detailed analysis on the economic impact to their businesses once the EPA publishes a notice of proposed rulemaking.

PRODUCT RETESTING

ISEA member manufacturers would like to state that, depending on the route EPA takes relative to retesting, it could take more than three years to implement the EPA program if manufacturers are forced to retest current products. ISEA recommends that EPA draw a parallel from the NIOSH respirator testing requirement and require that retesting on hearing protection devices must only be conducted if there is a significant changes to the form, fit or function of the device.

FUNDING

We understand the challenge that the agency faces in obtaining the appropriations for the Office of Noise Abatement and Control (ONAC), especially given the fact that the office has gone unfunded for quite some time. ISEA feels strongly that in order for the EPA to effectively implement and enforce any changes to the current regulation, ONAC needs to be adequately funded, and we encourage the EPA to have a plan in place to secure the necessary monies to carry out its program.

EDUCATION

Regardless of what a final rule might look like, manufacturers agree that informing the users of any changes will be critical to the program's success. Many manufacturers and user organizations take great measures to educate users of safety equipment on changes in requirements and regulations; however, we strongly encourage EPA to take the lead in conveying any changes to the users, specifiers and consumers, especially those related to labeling requirements and rating schemes. Manufacturers would certainly be willing to assist EPA or any other agency in providing information to the user community.

OTHER ISSUES

There are other issues that ISEA believes the EPA should consider as it revises its hearing protection regulations, and different views within the industry as to the appropriate solution. These include the following:

• Selection of a preferred test method. Currently 40 CFR Part 211 requires testing of hearing protectors in accordance with ANSI S3.19-1974. This standard has been superseded by ANSI S12.6-1997 (R2002), which includes two test methods. Should EPA require that hearing protectors be tested using method A (experimenter fit) or method B (naïve subject fit)?

• Rating System. Should a hearing protector's rating be expressed as a single number, or a range of numbers? Independent Testing. What criteria should EPA establish for laboratories that will test hearing protection devices? ISEA has urged its member manufacturers to make their positions on these issues known to the EPA, so that the agency will give them full consideration.

Finally, ISEA commends the EPA for moving forward with this proposed rulemaking. We offer the full resources of the association to assist in the process, with the goal of providing users with information that will enable them to select hearing protection that meets their needs.

Summary of First Day's Presentations

Alice H. Suter, Ph.D.

After listening to both the invited and contributed papers today, it is possible to identify several issues that are common to many of the presentations:

1. The NRR overestimates attenuation.

The NRR often leads to significant overestimates of attenuation, when compared to the attenuation achieved in the field. Also, derating schemes, such as that currently used by OSHA and suggested by NIOSH, do not constitute a satisfactory solution. Suter, as well as several other speakers, pointed out that employers and users of hearing protectors tend not to use the NRR correctly, even according to OSHA requirements. They don't understand the NRR and persist in believing that "bigger is better." In response to many of the current problems with the us of the NRR, an NHCA Task Force recommended in 1995 that manufacturers begin to use Method B, but the task force also emphasized many other hearing protector characteristics, most especially comfort, compatibility with other safety equipment, and personal preference.

2. What effectiveness rating metric should appear on the package?

Several speakers brought up the question of what kind of effectiveness rating metric should appear on the hearing protector package that will provide a suitable means for the selection of a specific device relative to the anticipated use environment.
Should it be a single decibel rating (one number), as it is now, multiple decibel ratings that address the best and worse case effectiveness, or some non-numeric form of rating.? A single decibel rating based on Method B might represent the anticipated protection achieved by untrained users or by many workers whose training has been relatively ineffective. A single decibel rating, based on Method A, that results in a high value might

represent the attenuation to be realized by "informed" individual's and expert users. Or perhaps there could be a range of numbers. There was much discussion about the relative advantages and disadvantages of Method A versus Method B, with examples of nations which tend towards each method.

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3. The present instructions should be replaced.

There was general agreement that the current instructions on the hearing protector package need to be replaced, but there were many different ideas on the make-up of the primary and secondary labels. Some even doubted if the instructions make any difference, but others, such as Doug Ohlin of the U.S. Army, affirmed that they indeed do. Participants questioned whether the emphasis should be on the NRR as it is currently or other rating as suggested by Ted Madison of 3M, there should be a simple statement like, "Fit it well, wear it right, and you'll get more protection."

4. **Variability**

The issue of individual variability appears to be a substantial problem. At present, consumers get no indication of the test's precision by looking at the single number. Bill Murphy of NIOSH suggested that one way of achieving a valid rating scheme is to use a pre-determined error value to predict the number of subjects that need to be run for each protector. Brian Myers of Aearo Corp. brought up the problem of what to do about the "bad test," where one or two subjects could skew the results so badly that the resulting number would be artificially low. He suggested "a full disclosure option," where the decision of how to proceed would be left up to EPA.

5. **Augmented hearing protection devices**

As John Casali of Virginia Tech pointed out, special or "augmented" hearing protectors may be slipping through the cracks. These devices have considerable merit, but testing and rating them is more difficult than with conventional devices, and current test methods are unsatisfactory in many cases. He suggested that physical as well as psychoacoustic methods should be considered. The advantage of labeling them would be appreciated by the approximately 20 % of industrial workers who are exposed to low-frequency noise. The disadvantage is that it is hard to label them in a way that will do justice to the product. John Casali, as well as Dan Gauger of the Bose Corp., suggested omitting the NRR from the primary label and putting all rating and other pertinent information on the secondary label. Gauger put forward the idea of passive and ANR graphs as a function of C-A levels to replace the current octave-band data. Despite these suggestions, many questions remain about how to test ANR devices since their electronic and level-dependent features contribute to the complexity of the task.

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6. Transition period and certification

Many presenters requested a transition period in which to allow manufacturers to gear up, test new products, and retest existing products if necessary. There was some disagreement about how laboratories which test hearing protectors should be certified. Some were in favor of laboratory certification by National Voluntary Laboratory Accreditation Program (NVLAP), but several believed that NAVLAP was not a satisfactory answer to test the ability of laboratories to reduce variability between laboratories, test adequately and fairly. Some also questioned the impartiality of manufacturers that test their products in their own laboratories.

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7. EPA role and funding

Many participants expressed the hope that EPA would provide manufacturers with clear rules for testing and retesting products and that the agency would be adequately funded to carry out its mission.

8. Importance of training and education

Regardless of EPA's decision about the characteristics of the label and its timetable in establishing the new rules, everyone agreed about the importance of training and education for management, supervisors, workers, physicians, professionals in occupational health and safety, and consumers in the general environment. This training should be not only in how to interpret the NRR, but in the correct insertion, care, and use of hearing protectors, including their use in communication-sensitive jobs. This recommendation is directed widely, toward NIOSH, OSHA, EPA, manufacturers, and professional organizations.

EPA Workshop on Hearing Protector Devices
March 28, 2003
Break-Out Sessions

On Friday, March 28, 2003, the workshop agenda consisted of break-out sessions to which all participants were invited. Participants signed up for one session in the morning and a different session in the afternoon. That way each person could attend two out of the three sessions offered.

Personnel from NIOSH either facilitated or acted as technical advisors for all three sessions. The technical advisor also served as recorder and gave the summary of his group's discussions at the end of the day on Friday. Session I on the Hearing Protector Label was facilitated by Clayton Doak and the technical advisor was John Franks. Session II on Noise Reduction Rating (NRR) Strategies was facilitated by Barbara McKenzie and the technical advisor was Bill Murphy. Session III, New Hearing Protector Technologies was facilitated by Allison Davis and Rick Davis was the technical advisor.

What follows is a summary of each of the three break-out sessions. The meetings were conducted informally as "brainstorming" sessions and participants were guaranteed anonymity, so there are no attributions to any of the comments.

Break-Out Sessions and Topics

Session I – Hearing Protector Label

John Franks, Recorder and Technical Advisor

Topics:

- Primary Label
- Secondary Label
- Placement of the Label
- Expiration of the Label

Session II – Noise Reduction Rating (NRR) Strategies

William Murphy, Recorder and Technical Advisor

Topics:

- The NRR – What Does It Mean
- How the NRR Should Be Characterized
- The NRR's Derivation
- Label Content and Presentation
- Other Potential Rating Schemes
- Other Topics

Session III – New Hearing Protector Technologies

Rick Davis, Recorder and Technical Advisor

Topics:

- Active Noise Reduction
- Sound Restoration Devices
- Communication Systems and Radios
- Present and Future Test Methods and Metrics to Describe Effectiveness
- Other Topics

Summary of Breakout Sessions

Alice H. Suter, Proceedings Editor

Session I - Hearing Protector Label
John Franks, Recorder and Technical Advisor
Clayton Doak, Facilitator

Primary Label

- There was much discussion about whether the number describing the hearing protector's passive protection should be a single number, similar to what is on present label, and if so, whether that number should be from ANSI S12.6-1997 Method A, experimenter supervised fit, or Method B, subject fit. Those in favor of Method A expressed the view that the label ought to reflect what a trained and motivated user would get. Those in favor of Method B expressed the view that the label ought to reflect what a typical user would realize, whose training consisted of reading the instructions on the packaging. In addition, there were those who felt that people depended on the number too much and that there should be no numeric rating at all.

- As a compromise, it was suggested that there should be two numbers. One number would represent the Method B results (expected to be the lesser) and the other number would reflect Method A results (expected to be the greater). There was discussion as to whether the two numbers would represent two possible outcomes, Method B being "typical" and Method A being "highly motivated," or whether the two numbers would represent a range of possible outcomes. By the end of the working group sessions, the two-number representation seemed to be favored by most, but it remained unresolved as to whether the numbers represented points or lower and upper bounds.

- Another suggestion was that protectors be graded by a class description such as in the Canadian system. For a given noise exposure level, the appropriate protector could be selected from a class, such as A, B, or C, with either A or C describing the most protection, and B, the middle amount. There was some discussion about whether the relative positions of A and C would affect purchasing decisions (i.e. A the least attenuation and C the most, or the other way around), but there was no consensus reached on this issue.

- It was suggested that somehow the primary label should be user friendly and should convey at a glance the information the consumer would need to make the choice. However, there were no ideas presented as to how to do this.

- There was also a suggestion that the primary label provide a range of noises for which the product was suitable, as for example, "This product is suitable for noise levels from xx to yy dB." There was concurrence that such a statement would require agreement on what levels are safe and when overprotection occurs.

- One working group member wanted no label at all for ANR protectors or sound-restoration protectors, but another pointed out that with an ANR device, the passive protection would be the minimum attenuation provided by the device. For the sound restoration protector, the passive protection would be the maximum provided by the device.

- Concern was expressed as to how OSHA and MSHA would use these new labels, and it was pointed out that a "directive" or a change would be needed in the OSHA Technical Manual.

- Most participants agreed strongly with the supposition that no change in the labeling requirement should be made until it was clear that the EPA has the resources and commitment to oversee and enforce whatever regulation was put into place. Since at present, hearing protector labeling issues are left to one person at EPA as an "overtime" task, there was concern that whatever new changes would be made would soon be orphaned by the EPA.

Secondary Label

- There was considerable discussion on the secondary label. The initial response was that it should contain octave-band information, as in the current rule, and instructions for use, along with language that stressed the importance of proper fit.

- It was suggested that the manufacturer's website be clearly listed and that most information about the devices be placed there.

- It was also suggested that the octave band data be replaced by a C-A chart, instructions on how to apply the number(s) on secondary label, fitting instructions, and information on consistency of use. The website should be put on a tertiary label and the web link should include information on calculating the long method.

- The secondary label should also be simple to use, should incorporate pictures as well as words, and ought to be in several different languages. Simplicity is important in that there are two classes of users: Industrial hearing conservationists and casual purchasers. The EPA should allow manufacturers the opportunity to provide instructions without constraints.

- Group members expressed the importance of rewording the statement on impulsive noise to say that the NRR is not related to impulsive noise. It is not that the protector can't be used in impulse noise conditions, but that the tests were not designed specifically for impulsive signals, and the label does not predict how the device will operate at supra-threshold levels.

- A group member suggested that the label require reference to the NHCA Task Force (Royster, 1995), especially with respect to reliability of protection and predicting individual performance. The secondary label should provide a statement that one cannot apply population statistics to an individual, and therefore the number on the label may not be what the user will realize.

Placement of the Label

- There was a recommendation that the primary label need not be on the primary surface of the protector packaging, but that a label on the dispensing box ought to be sufficient. There was also a request that the EPA provide electronically a logo and template that all manufacturers could use.

- Another member recommended that the regulation should specify the exact place on the product where the label should go.

Expiration Dates

The following suggestions were made concerning the issue of expiration dates:

- Third party certification of the product would eliminate the need for an expiration date.

- There should be no need for a test date on the label even though there is a requirement for retesting.

- Retesting should be 7 to 10 years if there is no change in form, fit, or function.

- The name of the laboratory that tested the product should be on the label.

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Session II - Noise Reduction Rating (NRR) Strategies

William Murphy, Recorder and Technical Advisor

Barbara McKenzie, Facilitator

The NRR – What Does it Mean?

- Several participants felt that the NRR's numbers lack meaning. For example, the Navy has dropped the NRR and gives most devices a rating of 20 dB. One person proposed a binary system, giving every device a minimum noise reduction of 10 dB, since typical industrial noises will only need about that much protection. For noises above about 95 dBA, the subjects would need to be individually fit-tested.

- The current NRR is misleading because users don't understand how to use the rating. Changing from C- to A-weighting should help, but it is not clear to the user what the NRR is meant to represent. For example, what percentage of the users will achieve this attenuation? It was suggested that the label offer a percentage to help people gauge the level of protection necessary for a given noise application. Another participant suggested that the use of a fraction is more user-friendly than percentiles. For example, 9 out of 10 or 1 out of 10 will be protected in X noise level.

How the NRR Should Be Characterized

- Many of the group's participants believed that the Noise Reduction Rating (NRR) should include a range of numbers, rather than a single number.

- Also, the NRR should be based in dBA. The current NRR has been criticized for the use of a C-weighted metric in an A-weighted world.

The NRR's Derivation

- The NRR should be derived from percentiles of the attenuation measurements rather than the mean REAT and standard deviations, which can incorrectly estimate the true empirical percentiles. Using Method B, a bimodal distribution often occurs, which is not correctly modeled by the usual normal distribution. The use of percentiles simplifies the analysis and increases the accuracy of the NRR for ill-behaved data and does not degrade the analysis or accuracy for well-behaved REAT data. The solution has been presented by Murphy et al. (2002), where the distribution is either modeled as a mixed gaussian distribution or the empirical percentiles are determined from the cumulative distribution for the particular device being tested.

- Discussion of Methods A and B:
  Some members of the group stated that EPA should adopt ISO 4869-1 or the ANSI S12.6 Method A for measuring REAT. They felt that ANSI S12.6 Method B tests the ergonomics and instructions of the device but not necessarily the noise reduction.

  The argument was presented that Method B's naïve subject fit does not accurately describe the real world performance of well-trained users, and consequently, Method A should be used. However, a study of well-trained users by Berger et al. (1998) failed to bear this out.

  It was suggested that certain devices, such as augmented HPDs, would require special training in order to be tested, but then the subjects would no longer be naïve.

  The use of naïve subjects will increase the variance of the REAT data, (which would not be problematic if appropriate analyses methods are applied). It was pointed out that during the interlaboratory study conducted in 1990-1992, Working Group 11 found that the experimenter-supervised fit (Method A) protocol yielded more variability across laboratories than did the naïve subject fit (Method B) protocol.

Criticism was raised that point percentile estimates of the 84th percentile may have increased error when compared to the mean and standard deviation approach. This is a topic for further research.

- Interlab testing: It was suggested that the interlaboratory variability for both Methods A and B in ANSI S12.6 need to be reexamined. Some participants questioned the finding that the subject fit method has better between-lab repeatability than the experimenter-supervised fit method and also that the within and between subject repeatability for the various methods were comparable.

- Panel selection: Group members agreed that the selection of the subject panel is critical to the HPD test, especially with the naïve subject fit method. ANSI S12.6 does require a balance of male and female subjects, but no guidance is given with respect to literacy, demographics, or native language. Translation of the instructions from English to another language could be a significant factor in test results.

- C-A correction factors: Current C-A correction factors, such as OSHA's 7-dB adjustment and the NHCA Task Force's recommended 5-dB adjustment, assume that the spectra have a particular distribution and that the difference is constant. However, research has shown (Berger, 2003) that there is considerable error if one assumes a spectrum that is anything other than flat. These adjustments are not useful for other types of noise spectra like military and aircraft noise. If, however, a plot such as the one recommended by Gauger (2003) is included on the label, then it is simply a matter of finding the C- and A-weighted noise levels on the plot to estimate the rating correctly.

- Testing special HPDs: Participants agreed that physical as well as REAT testing must be used for certain devices in order to get a rating. REAT testing is inappropriate for some devices, but MIRE testing may be unethical in certain circumstances because it could necessitate exposing subjects to very high levels of noise. Consequently, the acoustic test fixture (ATF) may be the most practical method for testing these devices.

- Achieving statistical certainty may increase the cost: If a device has poor repeatability, then the solution may be to increase the number of test subjects until a desired level of certainty has been achieved. However, more subjects equates to a higher cost for the test.

- The continuum of fitting: Participants pointed out that naïve subject fit, experimenter-supervised fit, and experimenter fit reflect different places along the continuum of the subject fitting problem. Experimenter fit data tend to represent the extreme of high attenuation and the subject-fit data lie more on the other end, correlating with the way the protection is typically worn.

- Refitting the protector: The question arose as to what happens when someone refits the protector during a testing situation. The results of the REAT test would change. This lead to speculation about how a worker's noise exposure could be affected if the device is refit while on the job.

The Label's Content and Presentation

Much of this session centered around a discussion of the content of the label that should be provided with the hearing protection device as well as a critique of the ANSI standard method for measurement of real ear attenuation at threshold (REAT), ANSI S12.6-1997.

- Several participants favored a range of appropriate noises on the label, which would be somewhat similar to the classification scheme used in Canada, Australia, and New Zealand. Some suggested that the exchange rate be built into the rating, which, because of differences in regulations between agencies, would only be appropriate if the various authorities agreed on an exchange rate. Also, because the spectral content of the noise affects the NRR, the range of A-weighted noises would not necessarily reflect the types of spectra one might encounter.

- The presentation of the label must be understandable. The information to be included on the label needs to be carefully developed so that it is effective for communicating the information to the users. One proposal was to include a graph of the C-A difference on the label. Other comments noted that certain types of industrial noises and aircraft noises could be shown on the graph if the noises could be characterized by a C-A difference. A possibly useful comparison was the fitting chart for panty hose, in which both height and weight are considered in a graph to facilitate selection of the appropriate size.

- Two-label system: There was a suggestion that there should be two labels on the package, one for the average consumer and another for the knowledgeable professional, such as the industrial hygienist. The label could be ideographic for the consumer and numeric for the professional.

- Range of expected outcomes: One participant suggested that EPA examine the FDA's requirements for labeling ENT devices, such as cochlear implants and hearing aids. The HPD's label could provide a range of expected outcomes for subjects. Just as the medical community recognizes that prostheses and certain types of devices can only provide limited restoration of function, hearing protection devices can have a limited potential and the results depend to a large extent upon how well it is fit.

Other Potential Rating Schemes

- The NRR lacks sufficient information to protect in different noise spectra, as it is calculated for only one noise spectrum. Recent research has shown that the SNR[1] method tends to describe the results better for C-A values less than 4 dB, although the NRR tends to do better than other descriptors for C-A values greater than 4 dB.

- The HML method, which is already adopted as an international standard, could be an effective compromise between the NRR and SNR methods. [2] The HML method lists three ratings that must be used to estimate noise reduction for different noise spectra. Using the C-A plot discussed above, pre-calculations would be made and the results presented in a graph. Various types of noises could be depicted on the plot along with the curve.

- Recommendation for a class-based system: The suggestion was made for the U.S. to adopt a class-based system, which is the basis for the Canadian and New Zealand/Australian standards. One problem with class-based systems is that a protector gets pegged into a single class rather than being applicable across more than one class.

Other Topics

- Role of individual fit testing: Checking the fit of individual HPDs in the field was seen as very important for high noise environments, where it is particularly risky to apply population data to an individual. Even with dual protection, the spectral characteristics of the noise and of the attenuation of both protectors must be known in order to estimate the level beneath the protectors. Without this information, the use of fit testing would allow the hearing conservationist to know the attenuation characteristics for a particular worker more precisely. There could be a limit above which fit testing would be mandatory.

  Assessing attenuation by means of individual fit-testing may also be indicated for certain devices, such as a custom-molded protector or an ANR device.

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[1] SNR = single number rating.
[2] HML = high, middle, and low rating.

- Preventing overprotection: Increasing concern has been applied to the issue of overprotection. The NRR provides no guidance to the user about overprotection. A range of protection with special attention to overprotection should be considered.

  It was suggested that ideally a person's protected exposure level should not be greater than 85 dBA or lower than 70 dBA. The EPA might consider and possibly adopt a pamphlet such as EN-458, which provides a set of recommendations on the selection, use, and appropriate care of hearing protectors.

- Recommendation for sticking with NRR and recertifying existing products: One participant proposed that there is nothing wrong with the current NRR and that we ought to require recertification of the existing universe of products and publish those data.[3].

- Global testing and rating: The benefits of harmonizing international standards on protectors and labeling were discussed. EPA should give consideration to incorporating other international standards for hearing protection to reduce the burden on industries and manufacturers in the application of consistent noise and hearing conservation policies worldwide. It makes sense that HPD manufacturers should need to test a product once and the results can be useful for all international labeling of that device. Many of the scientists who have an interest in the revision of the EPA regulation also have input to the ISO standards committee TC43 working group 17.

[3] This allows the possibility of recertifying existing products with the current NRR measurement method but also with a Method B measurement. Then a hearing conservation program could be required (by OSHA, for example) to demonstrate that its users are achieving a certain level of competency before the higher rating may be applied. Otherwise, the subject fit numbers would be used.

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Session III – New Hearing Protector Technologies

Rick Davis, Recorder and Technical Advisor

Allison Davis, Facilitator

Active Noise Reduction

- Manufacturers' opinions differ on whether there are industrial uses for active noise reduction technology. For example, Bose does not sell its aviation headset with an NRR. In the 1980s Bose did sell a series of ANR headsets for industrial use but soon withdrew them. It appears that a number of manufacturers are interested in selling ANR devices to the industrial market.

- ANR for the military, and aviation: There is clearly a market for unconventional hearing protectors in the general aviation community because ANR is very good at low- frequency noise attenuation, where conventional protectors are weak. Rumor has it that the new Joint Strike Fighter will make extensive use of ANR. Although ANR can be expensive, military personnel are trained in the use of these devices.

- It would be a shame to exclude the estimated 10-20% of workers in general industry who would benefit from access to ANR technology. As hardware and software become faster, limits in the useful frequency range for ANR are going to shift upwards.

- The passive performance of ANR devices is important. Manufacturers often compromise the passive performance of the muff in order to gain ANR performance under the assumption that the wearer has other headsets or batteries available. Manufactures have an obligation to users to protect them adequately even in the event of a power failure, but there is an assumption on the user's part that the passive muff will provide adequate protection until batteries can be obtained–perhaps even the next day. Manufacturers may face litigation from users if this assumption is not met.

- ANR has to be designed into a hearing protector, not just added to a passive muff.

- ANR hearing protectors can be affected by the electromagnetic environment, for example by arc welders or furnaces, radios, high voltage electrical lines, and transformers, etc.

- If ANR devices are to be used in the industrial setting, there needs to be an unbiased rating system. Consequently, questions arose as to how to test ANR hearing protectors. Group members suggested the use of REAT for passive muffs and MIRE for active muffs. They agreed that conventional tests can be biased against ANR, but there is a problem as to how to correct MIRE for physiological noise to be consistent with REAT (or correct REAT to be consistent with MIRE). Another question would be whether ANR headsets should be tested in the same manner as ANR earplugs.

- With respect to the way ANR devices should be labeled, suggestions ranged from no primary NRR label to labeling for passive attenuation only. One member suggested a C-A weighting label and another suggested labeling with whatever technique was used to test the device.

Sound Restoration Devices

- Sound restoration devices, also known as level-dependent, amplitude-sensitive, or sound-transmission devices, include non-linear plugs and muffs that rely on acoustical networks, mechanical valves, or electronics. The purpose of these devices is to allow sounds of low or moderate intensity to pass through without attenuation (or even amplified), but to increase their attenuation as ambient noise levels increase.

- The non-linear, level-dependent behavior provides a challenge for testing in that it is very difficult to capture in a single number. Moreover, it is possible to expose a subject to dangerous levels of noise in order to test the high-level portion of the protector. Evidently ISO and ANSI committees are working on testing methods. It was suggested that ANSI S12.6 be used only to assess performance in quiet. MIRE measurements may have to be used when exposing protectors to levels greater than 120 dB in transition ranges.

- Passive attenuation is particularly important for "shooters" muffs, where protection is needed for high-level impulses.

- A group member suggested that there should be a separate label for the level-dependent portion of the protector's function and that both passive and active performance should be labeled.

- It is also important to measure the attack and decay times of electronic circuits.

Communication Systems and Radios

- There was some discussion of Method A in ANSI S12.6. Representatives of the manufacturers of military headsets pointed out that many of these devices are custom-fit to the user, as with helmet headsets, and training is often a part of the product's sale and distribution. Consequently these subjects are not naive users so Method A should apply. Also, small companies can save money by using employees as subjects under Method A rather than having to obtain a panel of naive subjects.

- One problem with communication systems is that the microphone can inadvertently transmit noise to the listener under the muff.

- Also, it was suggested that there should be a warning to keep the level of speech through headphones below 80 dBA. However, a problem occurs when users have a hearing loss and need to turn up the gain to understand speech. This may be a reason not limit the output of the headphones. The actual amount of time that communication is taking place is unknown. It may be a very small percentage of the time that the device is being used and therefore make an insignificant contribution to the noise dose.

- The quality of the transmitter and receiver is important, so the question arose as to whether these systems should be tested for speech intelligibility.

Present and Future Test Methods and Metrics to Describe Effectiveness

- There was a discussion of field attenuation checking methods. We now have the capability to derive personal attenuation ratings in the field through methods such as "Fitcheck." Several questions came up around this topic: How do these methods correlate with the NRR? Would such a method be acceptable in place of the NRR? Can we allow for a personal attenuation rating in our hearing conservation programs? Can we use this as a predictor of risk? ANSI Working group 11 is currently working on field monitoring systems.

- One group member suggested that the concept of "protected dose" is related to noise-induced hearing loss (NIHL) rather than either to attenuation or the NRR, and asked what the regulatory outlook would be on a "life measure" rather than a "statistical measure." Personal attenuation methods should try to reduce the noise to 75-80 dB, not over protect.

- Manufacturers appear to be happy with ANSI S12.6 Method A and Mil 912 ANR for the rating of passive and active performance respectively. It was suggested that we keep the options open, allowing for MIRE when appropriate and the use of Acoustic Test Fixtures (ATFs) for high-noise situations. The need was expressed for a transfer function from the ATF to the human ear.

- Group members reported that ISO 4869 working group 39 is concerned with level-dependent hearing protectors. We need be informed about the activities of the various working groups and standards committees in this area

- With respect to adjustable hearing protection, the only current option is to adjust attenuation, but in the future the user will be able to adjust frequency as well.

Other Topics

- The opinion was expressed that new rules should not penalize new technology. New technology might be handled as a "new investigational device" (as with FDA regulations) for a limited time-period of 5-10 years until its efficacy can be proven, as long as it is shown not to be dangerous to the hearing of the user.

- Comfort and wearability are very important dimensions of both old and new technology. Laboratory comfort measures are not predictive of field comfort levels. Information about comfort could be placed on a secondary label. Topics could include guidelines, subjective measures, and information on materials, heat and humidity, headband compression force, and cushion pressure. Helmets should also be subject to comfort testing.

- Currently, there are ISO guidelines for muff design but not for comfort. It would be useful to determine what has been developed on the subject of comfort.

- Manufacturers' representatives requested flexibility in the testing of new technologies.

Summary of Breakout Sessions

Alice H. Suter, Proceedings Editor

This section is an attempt by the Proceedings Editor, after reviewing all of the break-out session summaries, to identify the major issues emerging from these sessions, categorize them, and divide them into "issues to be revolved" and "points of consensus." This summary reflects the observations of the Proceedings Editor and does not represent the positions of either the EPA or NIOSH.

ISSUES TO BE RESOLVED

Primary Label

- Single number vs. more than one: The major issue regarding the primary label was whether there should be a single number rating or more than one, and if there is only one number, whether it should be derived from the most recent ANSI S12.6-1997 standard's Method A or Method B. Method A data would represent the trained and motivated user and Method B data would represent the naive user as reflected by the field studies of hearing protector attenuation.

- If two numbers: Many participants favored the concept of a two number rating scheme on the label, one derived from Method A and the second from Method B. The question remained as to whether the numbers represented discrete points or upper and lower bounds of a range, with the latter being the more probable condition.

- <u>Other alternatives to the NRR</u>: Several other viable alternatives were discussed.

  - ✓ A class system, such as the A, B, and C classes used in Canada.
  - ✓ A range of noise levels on the primary label with a statement that this product is suitable for noise levels of xx to yy dB. This is somewhat similar to the classification scheme used in Canada, Australia, and New Zealand.
  - ✓ SNR (single number rating), in which the rating is subtracted from the user's C-weighted noise levels.
  - ✓ HML (high, middle, and low) rating scheme, which requires knowledge of both dBA and dBC noise levels in the user's environment.
  - ✓ HML could be used with a C minus A plot, either on the primary or secondary label.

  Both SNR and HML are calculated in accordance with ISO 4869 and are used in the European standard EN352. The SNR is slightly more accurate than the current NRR for noise with energy mainly in the middle and high frequencies and slightly less accurate than the NRR in predominantly low-frequency noise. The HML method could represent a compromise between the SNR and NRR by attempting to compensate for spectral variations in the noise environment.

Secondary Label

There was some question as to whether to keep the octave-band information, as in the present regulation, but many favored replacing it with a C-A chart, which would include instructions on how to apply the rating of the specific protector to the user's noise environment . Certain types of noises, characterized by their C-A differences, could be shown on the graph. Using a C-A chart would obviate the need for adjustments for spectral uncertainty, such as the 7-dB correction required by OSHA and the 5-dB adjustment recommended by the NHCA Task Force.

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Making the Labels User-Friendly

Most agreed that the labels should be as user-friendly and instructive as possible. There were at least two suggestions about how to do this:

1. Offer information on the percentage of people that will achieve a given attenuation with this HPD.
2. Give the fraction of people that will be protected, for example, 9 out of 10 will be protected in certain noise levels.

Derivation of the NRR

Much of the discussion of the NRR's derivation focussed on the relative advantages and disadvantages of using either Method A or Method B.

- <u>Favoring Method A</u>:

  - ✓ Those in favor of Method A cited the fact that a nearly identical method has been incorporated into ISO 4869 and is used in Europe. This way American manufacturers would only need to test to one method.
  - ✓ Method A reflects the attenuation realized by trained users and training is required by the OSHA noise standard and in military hearing conservation programs.
  - ✓ Method B tests ergonomics and instructions of the device but not necessarily its noise reduction capabilities.
  - ✓ The use of naïve subjects will increase the variance of the data.

- <u>Favoring Method B</u>:

  - ✓ Those favoring Method B maintained that it best predicts the attenuation received by users in the real world as opposed to the laboratory.

- ✓ Data from most field studies show slightly lower real-world attenuation than the laboratory data using Method B.
- ✓ Studies of well-trained users (as opposed to test subjects) showed results similar to Method B data.
- ✓ The interlaboratory study from 1990-1992 found more variability across labs using Method A than with Method B.

- Percentiles: The question arose as to whether the NRR should be derived from percentiles of the attenuation rather than the mean and S.D. because the data will not always be normally distributed.

- Cost: The need to achieve adequate reliability may add to the cost of the test. If a device has poor test-retest reliability, the number of subjects would need to be increased and therefore so would the cost.

Special or Augmented HPDs

- Should special HPDs be required to be labeled at all? There are many practical problems with labeling special protectors, but it would be a shame to exclude the many workers who would benefit from them. For example, 10-20 % of the workers in general industry who could benefit from active noise reduction (ANR) devices because of their low-frequency noise exposures.

- Physical methods: Should physical as well as real-ear-at-threshold (REAT) testing methods be allowed (or required)?

  Problems:

  - ✓ In some cases microphone-in-real-ear (MIRE) testing may be unethical for supra-threshold testing because of the necessity of exposing subjects to high noise levels. The use of acoustical test fixtures (ATFs) may be the answer in these situations.

- ✓ How do we adjust the MIRE data to be consistent with REAT data (or vice versa)?

- Passive protection: Should ANR devices be labeled for passive protection only? This would hardly be fair since they are designed to protect at supra-threshold levels and often by active rather than passive means.

  How important is passive protection in ANR devices? Do manufacturers have an obligation to protect users even if there is a power failure?

- Separate ratings: Should there be separate ratings (or even separate labels) for the passive and active (or level-dependent) components of an augmented HPD?

- Limiters: Should EPA require limiters to the level of speech or noise transmitted through the headphones of communication systems?

POINTS OF CONSENSUS

Despite the many issues needing resolution, there were many points of general consensus. They are summarized below:

- The present regulation is unsatisfactory and needs revision because people don't understand the NRR, they don't know how to use it, and it overestimates the attenuation users actually receive.

- The presentation of the label must be understandable to those who use the product as well as to those who purchase it. It should be clear, concise, and easy to use.

- Participants want to be assured that the EPA has sufficient resources to oversee and enforce the regulation.

- Any rating scheme should be usable with A-weighted noise levels. This would obviate the need for OSHA's 7-dB correction, which is confusing and sometimes erroneous.

- The current statement on impulse noise should be reworded so as not to discourage the HPD's use in impulsive noise environments.

- Fit-testing (or fit-checking) in the field is useful, especially in high-noise environments and for certain special devices, such as augmented HPDs.

- In addition to under-protection, over-protection is also a problem that should be avoided and addressed.

- Comfort and wearability are important dimensions for both conventional and new technology when it comes to HPD selection.

- Augmented HPDs: Non-linear, level-dependent, and other special HPDs provide a challenge for testing and rating with a single number.

- It is important that new rules should not penalize the development of augmented HPD technology.