

BEYOND THE LABEL

SELECTING AND VALIDATING HEARING PROTECTION DEVICES

Deanna K. Meinke, Ph.D.

When we buy products such as food, pharmaceuticals and even car seats for our children, we rely on the accuracy of government-required labeling information. We would never dream of using labels based upon decades-old data and inaccurate measurement methods to decide what is safe for our personal consumption or use. Yet that is what we do when we select hearing protection devices (HPDs) based on the 34-year-old Environmental Protection Agency's (EPA) Noise Reduction Rating (NRR) label. Unfortunately, professionals and the public continue to be misinformed by these labels, highlighting the need for more informed guidance and improved methods to determine the effectiveness of HPDs. Fortunately, recent technological advances afford new opportunities to provide evidence-based hearing protection selection, fitting and verification.

What went wrong?

The current NRR label describes the sound level reduction (attenuation) achieved under highly controlled and standardized experimental conditions in a laboratory test environment.

The NRR value on the current labels, for example 29dB, is based upon statistical analysis of octave band sound attenuation data obtained by testing 10 individuals in a highly controlled laboratory setting in accordance with procedures described in a rescinded ANSI S3.19-1974 (Experimenter Fit Method) standard (Figure 1). ANSI S3.19-1974 testing was conducted by having the laboratory experimenter fit the hearing protector to the wearer (as opposed to having the wearer insert his or her HPDs). The NRR label was originally crafted to provide a simple, single number rating that would provide an estimate of noise reduction for the 98th percentile of protection obtained by users when properly fit (EPA, 1978). Unfortunately, earplugs are often not properly fit by the wearer. The EPA has no requirement for retesting the product once it is labeled. Furthermore, the NRR was designed to be applied to C-weighted noise levels. Occupational noise exposure standards utilize A-weighted measurement protocols. This measurement-weighting discrepancy between the two standards creates the need to apply a -7dB reduction to the NRR when evaluating an HPD's suitability for use in a specific work environment.

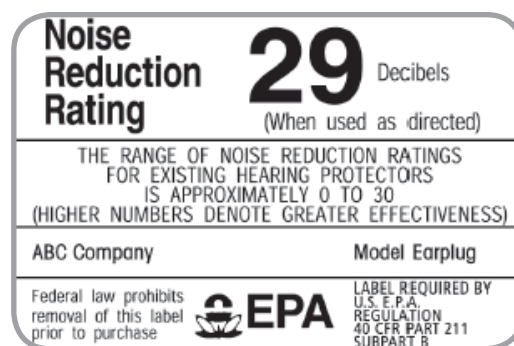


Figure 1: An example of a current NRR label.

Once the EPA labeling system was implemented, manufacturers competitively marketed their products on the basis of the NRR. Understandably, health and safety managers began choosing products with the highest NRR for their employees. Higher numbers became synonymous with “better” protection. The EPA’s original 1979 press release even stated that “The higher the rating the more effective the product should be” (EPA, 1979). We now know that for most ears, the NRR overestimates the actual protection afforded by a particular earplug or earmuff (Berger, Franks & Lindgren, 1996). Consequently, NRR “derating” methods have been proposed by the National Institute for Occupational Safety and Health (NIOSH) to approximate real-world performance until the labeling system is changed or fit testing is required (NIOSH, 1998). Derating is accomplished by multiplying the NRR by a specified value depending on the type of HPD: 75 percent for earmuffs, 50 percent for foam earplugs and custom plugs, and 30 percent for all other earplugs (e.g., $\text{NRR} \times 0.75$ for muffs, $\text{NRR} \times 0.5$ for foam plugs and custom plugs, and $\text{NRR} \times 0.3$ for other plugs). The Occupational Health and Safety Administration (OSHA) recognizes hearing protection as the last resort for noise control (after engineering and administrative noise control). Hearing protection devices used in the workplace are required to sufficiently attenuate the occupational noise at the employees’ ears to the levels specified in Table G-15 of 29 CFR 1910.95 (90dB(A) time-weighted average (TWA) permissible exposure levels) (OSHA, 1983). If an employee has had a standard threshold shift (STS), noise reduction must be sufficient to reduce noise exposure to 85dB(A) TWA. Because the NRR overestimates protection, OSHA formally requires a safety factor of 50 percent be applied to the NRR when evaluating the adequacy of the protector for a particular employee. An example of applying the derating method to an NRR for OSHA regulatory compliance is provided in Figure 2. It is important to remember that these considerations only apply to passive (nonelectronic) hearing protection devices and the current NRR labeling requirements do not address the attenuation performance for impulse/impact noise.

Simpler Solution: Just Update the Label

More recently an updated ANSI standard, S12.6-2008, was created that incorporates both a Method-A, designated as a “Trained-Subject Fit” (rather than “Experimenter Fit”), and a Method-B, designated as an “Inexperienced-Subject Fit” test protocol. The Method-A testing is comparable to ISO 4869-1:1990, Acoustics — Hearing protectors — Part 1: Subjective method for the measurement of sound attenuation, and is designed to approximate optimum fitting by an informed and intensively trained subject. Method-B testing is comparable to ISO/TS 4869-5:2006, Acoustics — Hearing protectors — Part 5: Method for estimation of noise reduction using fitting by inexperienced test subjects. Method-B was developed to test sound attenuation under more realistic wearing conditions and is intended to approximate achievable results for workers in hearing conservation programs. Subjects utilized for Method-B testing must be inexperienced HPD users, and instruction on fitting the earplug is provided by reading and interpreting the HPD package instructions. Method-B attenuation values are typically lower than Method-A values. These test methods were validated by inter-laboratory research studies and serve as the basis for current efforts to change the EPA HPD NRR labeling.

RECONCILING THE NRR WITH EMPLOYEE NOISE EXPOSURE:

Eight-hour TWA noise exposure:	95dB(A)
NRR of the hearing protector:	28dB
Spectral correction for C to A weighting*:	-7 (28dB - 7dB = 21dB)
Derate by 50%:	21 / 2 = 10.5dB
Subtract 10.5 from eight-hour TWA:	95 - 10.5 = 85.5dB(A)

Decide if 85.5dB(A) protected exposure level is below the 90dB(A) permissible exposure (PEL) for an employee without an STS (YES) OR below the 85dB(A) action level (AL) for an employee with an STS (NO). If “no,” then a protector with a greater amount of attenuation must be provided.

*Omit this step if noise exposure is measured with C-weighted filtering.

Figure 2: An example of reconciling the employee noise exposure with the NRR for OSHA regulatory compliance.

In the U.S., the EPA historically coordinated all federal noise control activities through its Office of Noise Abatement and Control. In 1981, the Reagan Administration defunded the office, and by 1982, federal noise control policies became the primary responsibility of state and local government without any centralized technical support or coordination. Today, essentially one person at the EPA has been assigned primary responsibility to advocate, coordinate and update hearing protector labeling requirements. These duties are currently managed through the EPA Office of Air and Radiation, Office of Policy Analysis and Review. In fact, the Office of Noise Abatement and Control has been unfunded for so long that noise issues are absent from most current EPA environmental and community agendas planning for the healthy living environments of the future.

Despite this situation, the EPA published a proposed new labeling rule in April 2009, solicited public comment until November 2009, and held stakeholder meetings in early 2010 (EPA, 2009). The agency proposed a new set of three labels to describe the attenuation performance of conventional HPDs, advanced electronic devices (noise cancellation) and active level-dependent hearing protectors, with special consideration for performance in impulse noise (Figure 3). The new labels are comprised of two numbers rather than a single number in order to describe the range of attenuation values achieved by 20 percent to 80 percent of the population. Active noise reduction (ANR) devices are tested with a “microphone-in-real-ear” or MIRE method with the electronics in the

“on” condition and again in the “off,” or battery-dead, condition. Earmuffs are also tested using MIRE methods. Earplug testing is conducted on an acoustic test fixture unless designed for deep canal insertion and then the testing is conducted with human subject ears. Level-dependent HPDs will be tested with three levels of impulse noise (~130, 150 and 170dB peak SPL). The new labels are also advantageous in that they are designed to be used directly with A-weighted noise exposure measurements and do not require spectral correction from C to A filtering.

At this time, it appears that the proposed labeling changes are pending administrative clearance at the EPA. After the revised labeling rule clears the agency, it will be reviewed by the Office of Management and Budget (OMB), a process that requires a review and response within 90 days or less. If a final rule is ultimately promulgated, manufacturers will likely have two and one half years to implement the new labeling requirements. In the meantime, some manufacturers have voluntarily tested some products according to ANSI S12.6, 2008, and they either publish the outcomes or make it available upon request.

Beyond the Label

The newly proposed labels were developed to approximate the real-world attenuation achieved, on average, by most groups of users enrolled in occupational hearing conservation programs. It is not possible to use these values to select and

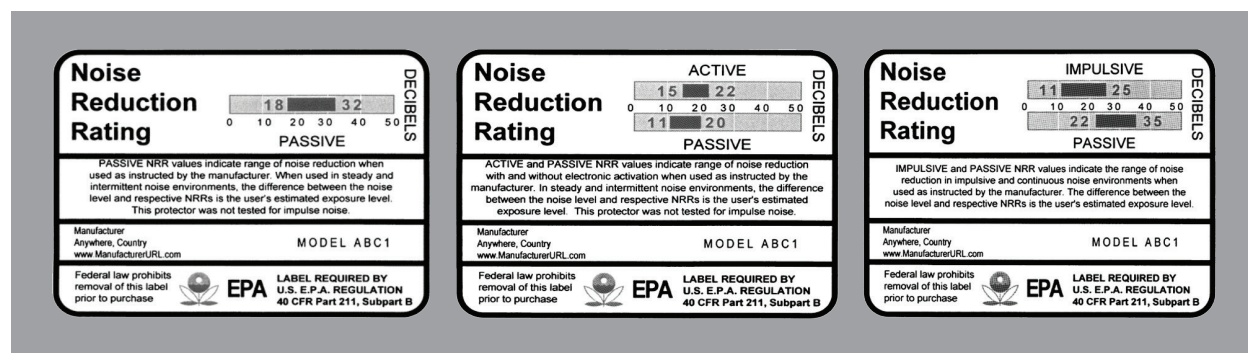


Figure 3: Proposed EPA NRR labeling for conventional passive HPD (left), active noise reduction (ANR) devices (center) and impulsive noise HPD (right).

predict the level of protection for a given individual in a specific sound environment. It is possible to get different attenuation values for each ear, even when wearing the same style of protector. The only means to reliably ascertain the actual level of attenuation provided by a particular HPD is to perform fit validations on each ear.

Hearing protector fit testing is the process by which an earplug or earmuff is fit to an individual ear and attenuation performance is measured in the workplace, clinic or mobile van. The methods include real-ear attenuation at threshold (REAT), loudness balance and field microphone-in-real-ear (F-MIRE). The most common method is REAT, which essentially is a hearing test conducted with and without the HPD worn. The attenuation is the difference in hearing threshold levels between the ears with and without the HPD in place. Unlike conventional audiometry, the stimuli used for the REAT method are typically one-third octave bands of noise rather than pure tones delivered through earphones capable of sufficient output to measure protected thresholds in impaired ears. Earphones also need to have sufficient space to accommodate earplugs that protrude from the ear canal (e.g., large volume circumaural-style headphones), since physical contact with the earphone should be avoided. Commercially available REAT systems have been developed.

Loudness balance testing is a series of loudness matching volume adjustments conducted binaurally under three conditions: both ears unoccluded, one ear occluded with an earplug and one ear open, and both ears occluded with earplugs. The F-MIRE approach typically uses multiple microphones to simultaneously measure sound pressure level (SPL) in decibels external to the HPD and underneath the HPD in the ear canal.

Audiologists are familiar with real-ear measurement systems for hearing aid verification and the same instrumentation can be used with earplugs; however, the microphone tubing will create a slit-leak between the earplug and the ear canal wall and will likely affect the magnitude of attenuation. One commercial system uses an external speaker on a stand and an external microphone hanging in front of the concha,

and this system avoids slit-leaks from the internal microphone tubing by using specialized probed earplugs whose acoustical properties are factored into the attenuation calculations.

All of the commercial fit-test systems report attenuation as a single number metric called the Personal Attenuation Rating (PAR). There is no consensus standard regarding the number of frequency bands tested or the calculation of PAR. Differences in the precision and accuracy of the PAR measurements exist between systems. One advantage of the PAR on most systems is that it is designed to be used with A-weighted noise exposure measurements. For example, if a worker's noise exposure is 95dB(A) and they have a PAR of 20dB, the protected exposure would simply be 75dB(A). Individual HPD fit testing has proven beneficial in other ways: it improves the training experience and provides immediate feedback to the wearer regarding proper earplug placement, creates worker confidence in the appropriateness of the HPD selection, identifies fit adequacy for each ear independently, is time efficient (~10–15 minutes), and satisfies regulatory requirements for assuring adequate protection following an STS. Currently, OSHA does not incorporate HPD fit testing into the formal hearing conservation regulation but has jointly issued a best practices document with the National Hearing Conservation Association (NHCA) and NIOSH regarding fit-testing in the occupational setting (NHCA, 2008). Presently, NIOSH is engaged in discussions with regulatory agencies regarding the need to incorporate fit-testing into hearing loss prevention programs.

Taking HPD Fitting to the Next Level

Today's HPD fittings should not rely upon guesswork regarding noise exposure levels and attenuation performance. If noise exposure data is not known, consumer-priced noise dosimeters and smartphone sound level and noise dosimetry apps are available for the public to informally quantify the noise levels in the environment and subsequently gauge the approximate amount of attenuation needed for a particular noise exposure. Audiologists are advised to use calibrated sound level meters and noise dosimeters for formal noise

exposure assessments as app performance varies. We are moving into the era where an individual may need to be fit with more than one style of hearing protector depending upon the various hazardous sound exposures encountered in his or her work and recreational environments. We have access to multiple styles of shoes that are best for specific activities, such as running, walking, and hiking. In terms of HPDs, a patient may need a passive conventional earplug for work, electronic “shooters” earplugs for hunting, and flat-attenuation, filtered earplugs for concert attendance. Each device should be fit, verified and reconciled with noise exposure levels prior to dispensing. We have the technology, the devices and the expertise to prevent noise-induced hearing loss without relying on outdated labels.

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Global Headquarters
6700 Washington Ave S
Eden Prairie, MN 55344