Hearing protectors "real world" performance and the European Directive 2003/10/EC

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This is a summary of a workshop held at the Institut National de Recherche et de Sécurité (INRS) in Paris, France on July 4, 2008.—Ed.

Presentation of the Issue

The problem of hearing protection devices (HPDs) "real-world" attenuation has been topical and increasingly critical in the European Union (EU) since the implementation of the 2003/10/EC Noise Directive (EU, 2003), which requires to "... *take account of the attenuation provided by the individual hearing protector worn by the worker...*" to compare noise exposure to the allowable limit values. The rules proposed to assess the "real world" noise attenuation (as opposed to the declared values) vary among the European states, and include homogeneous derating of declared values, derating per HPD type, relative individual derating, and use of statistical manipulation (including multiple standard deviations from the mean) to calculate the assumed protected value (APV). This situation, where multiple and highly variable approaches are applied to attempt to address a single requirement in the same Directive, is not satisfactory. Additionally, this question has been under consideration by various North American researchers and regulators for some time. American National (ANSI) standards dealing with this issue have been published recently or are being revised. This significant experience would be useful to consider. Lessons learned in North America regarding HPD derating and attenuation management approaches could be of great value in implementation of the EU Directive.

The Meeting

International congresses in 2007 have provided the opportunity to discuss these issues between North American and European experts. The discussions underlined the differences of point of views, of contexts and of experiences between the two continents. The Canadian ETS (École de Technologie Supérieure, Technology High School, Montreal) and the French INRS (Institut National de Recherche et de Sécurité, National Institute of Health and Safety Research) decided to organize an international meeting on this issue. The target was to initiate a reasoned scientific exchange between individual experts with interest in the field to avoid known pitfalls, learn from each others' experience, and find a common science-based position on this important issue.

"Real World" HPD attenuation is important.

The meeting took place at INRS in Paris, on 2008 July 04. 44 people from 17 countries attended the meeting, and 11 additional people asked to be informed of the outcome. Attendees were researchers, Occupational Safety and Health (OSH) and standardization experts, Notified Bodies, and manufacturers representatives who are specialists in the HPD field. The meeting began with three presentations: background and context of the issue, the European situation, and recent American work in the field. Three parallel discussion groups were organized to debate on the main points highlighted in these presentations. A synthesis of the discussion groups was presented to the whole audience.

In this report, we give a short summary of this meeting—to underscore the main points that were discussed, and on which some agreement was reached among all participants. A comprehensive "source book," containing all the presented material is available (Source, link)

Stake and Context of the Issue

Speakers: Pierre Canetto Noise Assistance and Consulting Expert, Occupational Noise Reduction Laboratory, Institut National de Recherche et de Sécurité (National Health and Safety Research Institute), France; Jérémie Voix, P.Eng., Ph.D., Vice-President of Scientific Research and Chief Technology Officer Sonomax Hearing Healthcare Inc; Research associate, Ecole de Technologie Supérieure, Canada.

In the European Union (EU), HPDs have to achieve requirements from two different sources of regulation: one deals with the EU market (the HPD being a product

moving inside and into the EU), the other deals with occupational safety and health (OSH) matters (the HPD being a protection device). As products, HPD performance is assessed by testing implemented by Notified Bodies according to European standards which ensure a presumption of conformity to the European regulation ("harmonized standards"). As far as OSH is concerned, the HPD is an "*individual protective measure.*" As a consequence, an essential principle of prevention states that its use is a last resort solution to protect workers, and collective solutions such as noise reduction have priority. The 2003/10/EC "Noise Directive" introduces the notion of "limit values." These thresholds are in "competition" with the classical "action values." They take into account the HPD attenuation when assessing the workers' noise exposure.

HPD performance standards are evolving.

In the United States of America, the use of HPDs is the main solution used in Hearing Loss Prevention Programs, though nominally noise control is accorded the highest priority. The standards used to assess HPD performance and label the devices for performance have evolved over the last 30 years. The U.S. Environmental Protection Agency (EPA) labelling regulation still requires use of ANSI S3.19-1974. This situation will probably change soon.

The "real world" attenuation of HPDs is on average much lower than the attenuation measured in the laboratory. This difference comes from many parameters which may be linked a poor use of a HPD by the worker, variability of product performance and the difference between acoustical conditions of laboratory tests and the industrial situation, and is compounded by the time HPDs are not worn.

In Europe, this problem is taken into account in some countries by derating laboratory measured values. The derating method may vary from one country to another. Three main methods are used. Absolute derating asks to decrease the laboratory value by a fixed number of dB, which may differ according to the type of HPD. Relative derating gives a percentage of the lab value. "Statistical enlargement" consists in subtracting more than one standard deviation from the mean of the test results. In the United States, relative derating has been proposed in the past. A new standard proposes to use untrained subjects for laboratory tests ("Subject-Fit" or "B" Method). Field Attenuation Measurement Systems (FAMS) have also been developed based on either objective or subjective methods. Objective methods implement measurement systems in the HPD. Subjective methods use human hearing threshold or noise loudness balance between the two ears.
A solution for this issue needs to address both a short-term action asked by the EU regulation enforcement and a long term action which could deal more deeply with the root of the problem.

The European Situation: Standards, Regulation, Certification. The European Experience

Speaker:Martin Liedtke, Head of the Ergonomics - Physical Environmental Factors Division, BGIA - Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung (Institute for Occupational Safety and Health), Germany. Chairman of CEN TC 159 "Hearing Protection", Convenor of ISO/ TC 43 "Acoustics"/WG 6 "Determination of noise immissions from sound sources placed close to the ears," Chairman of the European "Horizontal Committee of Notified Bodies – PPE," Chairman of the national accreditation body's co-ordination and co-operation group of Notified Bodies PPE in Germany.

The mechanism of hearing must be considered when dealing with HPD concerns. Acoustic perception is guided by the transfer function of the ear, the frequency-dependent hearing threshold, and the noise masking effect. The use of HPDs must not impede the perception of auditory signals. Depending on the choice of HPD, signal audibility may be worsened or, on the contrary, improved. EN 458 standard recommends the use of HPDs showing a flat frequency characteristic in order to ensure a good signal audibility. The Berufsgenossenschaftliches Institut für Arbeitsschutz (BGIA) has developed a new method which uses the gradient of the mean value of attenuation for 125 Hz up to 4000 Hz.

The European Union (EU) regulation gives requirements about health and safety at the workplace, which are linked to the use of HPDs. A major principle is the priority to collective solution in regard to personal solutions. Thus, the HPD should be used only when the risk cannot be avoided by other means. Information and training must be given regarding the use of protective equipment, including HPDs.

HPDs are manufactured products moving into and inside the EU. Thus, they must fulfill requirements checked by the "market surveillance." The goal of these

requirements is to ensure that all EU citizens will have the same protection by using one product. Manufacturers must follow the design requirements to ensure their safety performance.
Other EU legal requirements are given for the selection and the use of PPE (and HPDs). Their enforcement is the responsibility of employers. The selection takes into account the results of the risk assessment. The use takes into account the workplace environment, the worker's situation and ergonomic considerations.

HPD performance is controlled by Notified Bodies. The tests include the assessment of the HPD noise attenuation, the result being the "declared" values. The "CE" marking on the product ensures that it fulfils the legal requirements. Notified Bodies are independent. They are involved in technical exchanges with all European Notified Bodies active in the field of hearing protection, with national authorities, and in standadization activities. The technical procedures to ensure that the legal requirements are achieved are described in European "hamonized" standards. The origin could be an ISO standard and Recommendation-for-use sheets of the European Horizontal Committee of Notified Bodies-PPE.

Manufacturers must follow design requirements.

The difference between laboratory and real-world attenuations was evaluated by a BGIA study in the late 1980s. The study gave average values of the difference between declared and real world attenuations for each type of HPD. A recent study confirmed these results. They were used to propose absolute derating of declared values.

The laboratory-measured values of HPD noise attenuation cover a statistical range of workers protection. Derating these values allows the range of protected persons to be extended. This derating can be omitted in case of workers with appropriate training. However, HPD non-wearing time remains a major factor in the decrease of HPD 8-hour average performance.

Methods to take into account the real world HPD attenuation are needed. The employer is responsible in assessing the efficiency of the HPD in the workplace. When using a method to deal with real world situation, a specific care must be taken in the situations of very high noise exposure level and when there are risks of accident (e.g. tracklayers, vehicle drivers).

Octave band values may be important.

The EU context requires the use of a test which allows comparison of results between laboratories. According to this requirement, the European standardization bodies decided to use the ISO 4869-1 method with an experienced test subject. It was recommended to provide assistance to employers to derate these values within the EN 458 standard. A comparison with the situation of respiratory equipment shows that in this case, various derating methods are used among the EU member states.

The development of another test method would raise further questions. The EU authorities should support additional standardization work and additional product testing. The use of various attenuation data ("old" and "new" method) could be confusing for employers and users. The choice of the statistical range of the population to be protected should be decided. In other regards, asking for additional efforts in HPD training could be difficult in the case of SMEs. Finally, the non-usage of HPDs when exposed to noise should be considered.

Observations on Labeling and Rating Hearing Protectors, the American Experience.

Speaker: Elliott H. Berger, M.S. Senior Scientist, E-A-R / Aearo Technologies, Chair of ANSI S12/WG11 on hearing protectors, US representative on ISO/TC 43/SC 1/WG 17.

The fact that real-world attenuation of HPDs is much lower than the one obtained in laboratories has been studied in the United States of America for a long time. Individual attenuations measured in different industrial plants show that the attenuation of the same earplug may vary significantly among workers. Several issues should be considered when estimating the HPD user protection. The noise exposure is assessed with an uncertainty which may vary from 3 to 13 dB. The susceptibility of subjects to the same exposure may vary. Valid attenuation of HPDs must be taken into account, as well as the effect of non-wearing time. A suitable computational scheme must be use to derate the laboratory-measured values.

When applying the "gold standard" (octave band calculation) to subject-fit attenuation values, we find that for the same noise, according to the plug fit, the noise level calculated as effective when the HPD is worn (L'A) may vary by 30 to 35 dB from person to person. In other respects, the overall L'A value for a same octave band (OB) HPD attenuation depends a great deal on the frequency distribution of the noise exposure.The use of number-rating methods is easier and is a valid alternative, but in extreme noises (high exposures over about 105 dB or steeply sloping spectra), the OB method should be considered because of its potential increased accuracy.

The relevance of the OB method has been studied through statistical calculations

using a database from the National Institute for Occupational Safety and Health (NIOSH) of 100 noise spectra and the HPD attenuations measured in a laboratory for an individual subject (i.e., single and not average values). 20 HPDs were evaluated (earplugs and earmuffs). The results show that when choosing a HPD which would ensure an exposure of 85 dB(A), 17% of the situations would lead to an unacceptable exposure, even with this most accurate "gold standard" method.

A new rating called NRSA has been developed and is proposed in standard ANSI S12.68-2007. It has also been proposed for consideration by the ISO and will likely be part of the forthcoming updated US EPA labelling regulation. The first idea is to get a single number rating which will allow calculation of L'A by subtracting its value directly from individual worker ambient exposure LA. The other feature is to take into account the variety of the noise situations (frequency distributions) and the inter-subject variability in laboratory test results. This number is given with two figures: NRSA80 corresponds to a "statistical protection" of 80 % of the workers, when NRSA20 corresponds to a "statistical protection" of 20 % of the workers. Having these two values allows the user to be aware of a range of possible values, and to consider the risks of under- or over-protection. It underlines the influence of training on HPD fit and worker's motivation. An alternative graphic method takes into account more precisely the frequency distribution of the noise exposure.

An updated version of ANSI 12.6 was published in 2008. It will reflect Method A (experienced-fit subject) and Method B (inexperienced subject-fit). Method B gives results closer to the real-world attenuation than method A. The idea of workers in the real world getting regular one-to-one training in order to ensure protection approaching Method A values is very optimistic.

Studies have been undertaken to evaluate the interlaboratory variability of Method A and Method B attenuation values. When looking at absolute differences (number of dB), Method A performs less well. When looking at differences in percentage, Method B looks worse. Variability within subjects is similar for the two methods. Variability between subjects is better for the Method A, and cost of testing is lower for Method A. However, variability is present at the various steps of the "real world" exposure assessment. The use of NRSA method aims to deal with this problem.

NRSA is a new rating method, and is in a standard.

Considering the derating methods (absolute and relative derating, statistical enlargement, reducing the limit value), it is not clear that any is best. What is worse is however quite clear, and that would be for individual European countries to each devise their own deratings. Deratings can only provide approximate guidance, none is the "best" and by requiring different ones country by country will simply lead to confusion. These methods as well the use of laboratory Method B do not account for individual variability. Individual field-fit testing is then the best approach and a standard on their performance criteria and measurement uncertainty is currently under development in ANSI WG11.

Synthesis of the Main Points Raised During the Debates

Moderator: Jean Jacques, Head of the Standardization Unit, Former Noise Consultant for the European Commission, Institut National de Recherche et de Sécurité, France
Workshops convenors: E.H. Berger, J. Jacques, M. Liedtke

Noise Exposure and Risk Assessment. Worker protection remains the objective. Consideration of limit value should not evade the fact that in case that action values are exceeded, noise control engineering should be implemented. This should be the first priority. Pressure should be put on government and companies to set up effective Hearing Conservation Programs, even by using penalties.

The problem of HPD real world *attenuation* should not be separated from the target which is the real world worker's *exposure*. The sole problem of noise exposure assessment itself is not well known in companies. The problem of taking into account the HPD protection should then not complicate the issue too much. From a technical point of view, the limit values are defined for an "ambient noise." SPL in an occluded ear canal should then be adjusted for a diffuse field condition.

Influence of HPD Use. Discussions of HPD real world performance must not hide the problem of HPD non-wearing time. This point is a major parameter in the HPD global performance. Its influence may be more important than the decrease of HPD attenuation in the "real world." From this point of view, HPD comfort is an important matter and HPD manufacturers should work on improving it.

Wearing HPDs properly is another major parameter to ensure optimum performance. Worker training is the way to increase their motivation in HPD wearing and ensure a proper HPD fitting. Training is a key issue. Information on the influence of training should be clearly given. A minimum training program should be defined. The HPD performance may decrease with time. Criteria should be given for HPD which allows protection to be guaranteed over time, taking into account their use.

Methods to Approach "Real World" Attenuation

Given the regulatory context in the European Union, fast action is required by employers. A common position should be looked for in the EU: the best choice for derating is not clear, but the worst choice (i.e., as it is done now with different countries doing it differently) is clear. Short-term activity needs to use the current label values. A method to approach the HPD real world attenuation should take into account the specific behavior of the various kinds of HPDs—and especially custom-moulded earplugs—as well as the difference between ear muffs and helmet-mounted ear muffs. Derating is not satisfactory in the long term. According to one's point of view, derating can be considered as too small (in regard with the decrease of the labelled attenuation) or too high (for the users to have an opinion on the HPD performance). Statistical enlargement method has the effect of allowing individual HPD derating. Method A (experimenter fit) and B (subject fit) have both their supporters. In the longer term, the American method of NRSA is interesting and seems to answer many of the problems.

Whichever method is chosen, care must be taken in order to implement a solution which will not address workers overprotection. When choosing this method, we should take into account its possible influence on the development of future devices. The particular point of impulse noise should be taken into account, as well in risk assessment as in HPD attenuation labelling.

Individual HPD Testing

Individual fit testing is a next step in assessing the "real world" HPD attenuation. It is however not obvious that all companies will be able to implement this kind of measurement on all their employees. Individual testing methods should be made available for all companies by using methods which are not owned by a manufacturer. When comparing individual testing with laboratory measurements, the accuracy and the uncertainty of individual testing results should be considered.

References

EU, 2003. Directive 2003/10/EC of the European Parliament and of the Council of February 6, 2003 on the minimum health and safety requirements regarding exposure of workers to the risks arising from physical agents (noise). http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:042:0038:0044:EN:PDF

Source, link. http://www.etsmtl.ca/zone2/recherche/labo/erest/Paris_HPD_Meeting_Source_Book_V2.pdf.

NEW

American National Standard

Readers of *NNI* with an interest in the above article should see the announcement on page 139 of a new American National Standard, S12.6-2008, *American National Standard Methods for Measuring the Real-Ear Attenuation of Hearing Protectors*.