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Hearing Protectors "Real-World" Performance and the European Directive 2003/10/EC

Workshop held at the Institut National de Recherche et de Sécurité (INRS), Paris, France, July 4, 2008

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1. PRESENTATION OF THE ISSUE

The problem of the real-world attenuation of hearing protection devices (HPDs) has been topical and increasingly critical in the European Union (EU) since the implementation of Directive 2003/10/EC, which requires taking "account of the attenuation provided by the individual hearing protectors worn by the worker" (p. 40) [1] to compare noise exposure to the allowable limit values. The rules proposed to assess real-world noise attenuation (as opposed to declared values) vary among the European states, and include homogeneous derating of declared values, derating per HPD type, relative individual derating, and the use of statistical manipulation (including multiple standard deviations from mean) to calculate the assumed protected value. 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 considered by various North American researchers and regulators for some time. American National Standards Institute (ANSI) standards dealing with this issue have been published recently or are being revised. It would be useful to consider this significant experience. Lessons learned in North America regarding HPD derating and attenuation management approaches could be of great value in implementing Directive 2003/10/EC.

2. THE MEETING

International congresses in 2007 provided an opportunity for North American and European experts to discuss these issues. The discussions underlined the different points of view, contexts and experiences of the two continents. The Canadian ETS (École de Technologie Supérieure, Montréal) and the French INRS (Institut National de Recherche et de Sécurité) decided to organize an international meeting on this issue. The aim was to initiate a reasoned scientific exchange between individual experts with interest in the field to avoid known pitfalls, learn from one another's experience, and find a common science-based position on this important issue.

The meeting took place at INRS in Paris, on July 4, 2008. Forty-four people from 17 countries attended it and 11 more asked to be informed of the outcome. These people were researchers, occupational safety and health (OSH) and standardization experts, and 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.

These minutes are a short abstract of this meeting, to underscore the main points that were

discussed, and on which some agreement was reached among all present participants[1].

2.1. 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, 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 EU, HPDs have to meet requirements set out in two sources of regulations: one related to the EU market (an HPD being a product moving into and inside the EU), the other related to OSH matters (an HPD being a protection device). The performance of HPDs, as products, is assessed by testing implemented by notified bodies according to European standards which ensure a presumption of conformity to European regulations (harmonized standards). As far as OSH is concerned, an 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. Directive 2003/10/EC introduces the notion of limit values [1]. These thresholds are in "competition" with classic action values. They take into account the HPD attenuation when assessing workers' noise exposure.

In the USA, the use of HPDs is the main solution 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 the use of ANSI S3.19-1974 [2]. 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 to a bad use of an 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 HPD nonwearing time.

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 requires decreasing the laboratory value by a fixed number of decibels, which may differ according to the type of HPD. Relative derating gives a percentage of the laboratory value. Statistical enlargement consists in subtracting more than one standard deviation from the mean of the test results. In the USA, 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 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 to this issue requires both a short-term action asked by EU regulation enforcement and a long-term one which could deal more deeply with the root of the problem.

2.2. 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*

[1] A comprehensive source book, containing all the presented material, can be downloaded from: http://www.etsmtl.ca/zone2/recherche/labo/erest/Paris_HPD_Meeting_Source_Book_V2.pdf or you can get a copy from the authors.

Gesetzlichen Unfallversicherung), 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. According to the choice of HPD, signal audibility may be worsened or, on the contrary, improved. The EN 458:2004 standard recommends the use of HPDs showing a flat frequency characteristic to ensure good signal audibility [3]. BGIA has developed a new method which uses the gradient of the mean value of attenuation for 125 Hz up to 4000 Hz.

The 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 of collective solutions with respect to personal solutions. In this scope, the HPD should be used only when the risk cannot be avoided with 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. From this point of view, they must fulfil requirements checked by the market surveillance. These requirements aim to ensure that all EU citizens will have the same protection when 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 personal protective equipment (PPE; and HPDs). Their enforcement is the responsibility of employers. The selection takes into account the results of risk assessment. The use takes into account the workplace environment, the worker's situation and ergonomic considerations.

The 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 (Conformité Européenne) 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 standardization activities.

The technical procedure to control if the legal requirements are achieved is described in European harmonized standards, which can originate from an International Organization for Standardization (ISO) standard, and Recommendation-for-Use sheets of the European Horizontal Committee of Notified Bodies, PPE.

The difference between laboratory and real-world attenuations was evaluated in a BGIA study in the late 1980s. The study gave average values of the difference between declared and real-world attenuations for each kind 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 worker protection. Derating these values makes it possible to extend the range of protected people. This derating can be omitted if workers are trained appropriately. However, HPD nonwearing time remains a major factor in the decrease of HPD 8-h average performance.

Methods that take into account the real-world HPD attenuation are needed. The employer is responsible for assessing the efficiency of HPDs at the workplace. When using a method of dealing with a real-world situation, special care must be taken in situations of very high level of noise exposure and where there is accident risk (e.g., tracklayers, vehicle drivers).

The EU context requires the use of a test to compare results between laboratories. That is why, the European standardization bodies decided to use the ISO 4869-1:1990 method with

experienced test subjects [4]. It was recommended to provide assistance to employers to derate these values within the EN 458:2004 standard [3].

A comparison with the situation of respiratory equipment shows that in this case, various derating methods are used among EU member states.

The development of another test method would raise further questions. EU authorities should support additional standardization work and additional product testing. The use of various attenuation data (old and new methods) could be confusing for employers and users. The choice of a 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, nonusage of HPDs when workers are exposed to noise should be considered.

2.3. 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 USA for a long time. Individual attenuations measured in different industrial plants show that the attenuation of the same earplug may vary significantly according to the workers.

Several issues should be considered when estimating the HPD user protection. The noise exposure is assessed with an uncertainty which may go from 3 to 13 dB. The susceptibility of subjects to the same exposure may vary. Valid attenuation of HPD must be taken into account, as well as the effect of nonwearing time. A suitable computational scheme must be used to derate the laboratory-measured values.

When applying the golden standard (octave-band, OB, 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 from 30 to 35 dB from person to person. In other respects, the overall L'_A value for the same 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 noise (high exposures over ~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 NIOSH database of 100 noise spectra and the HPD attenuations measured in a laboratory for individual subjects (i.e., single and not average values). Twenty 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 golden-standard method.

A new rating called NRS_A has been developed and is proposed in Standard No. ANSI S12.68-2007 [5]. It has also been proposed for consideration at ISO and will likely be part of the forthcoming updated U.S. EPA labeling 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 L_A. 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: NRS_{A80} corresponds to a "statistical protection" of 80% of the workers, when NRS_{A20} corresponds to a statistical protection of 20% of the workers. Getting 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 workers' motivation. An alternative graphic method takes into account more precisely the frequency distribution of the noise exposure.

An updated version of ANSI 12.6 is likely to be published in 2008 [6]. It will reflect Method A (experienced subject-fit) 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 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 decibels), 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 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 the NRS_A method aims to deal with this problem.

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 devise their own deratings. Deratings can only provide approximate guidance, none is the best and by requiring different ones country by country would 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.

3. 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: ***Elliott H. Berger**, **Jean Jacques** and **Martin Liedtke***

3.1. Noise Exposure and Risk Assessment

Worker protection remains the objective. Consideration of limit values should not evade the fact that if action values are exceeded, noise control engineering should be implemented. This should be the first priority. Pressure should be put on governments 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 aim which is establishing workers' real-world exposure. The problem of assessing noise exposure is not well known in companies. The problem of taking into account HPD protection should then not complicate the issue too much.

From a technical point of view, the limit values are defined for ambient noise. The sound pressure level in an occluded ear canal should then be adjusted for a diffused field condition.

3.2. Influence of HPD Use

Discussions on HPD real-world performance must not hide the problem of HPD nonwearing time. This point is a major parameter in HPD global performance. Its influence may be more important than a decrease in 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 HPDs to guarantee protection over time taking into account their use.

3.3. Methods to Approach Real-World Attenuation

Given the regulatory context in the EU, 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. Current label values need to be used in the short term. A method of approaching the HPD real-world attenuation should take into account the specific behaviour of the various kinds of HPDs, especially custom-moulded earplugs, and 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 (with regard to the decrease in the labelled attenuation) or too high (for the users to have an opinion on the HPD performance). The statistical enlargement method has the effect of making individual HPD derating possible. Methods A (experimenter fit) and B (subject fit) both have their supporters. In the longer term, the American method of NRS_A is interesting and seems to solve many problems.

Whichever method is chosen, care must be taken to implement a solution which would 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, both in risk assessment and in HPD attenuation labelling.

3.4. 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 for all their employees. Individual testing methods should be made available for all companies by using methods which are not owned by a manufacturer. When individual testing is compared with laboratory measurements, the accuracy and the uncertainty of individual testing results should be considered.

REFERENCES

1. Directive 2003/10/EC of the European Parliament and of the Council of 6 February 2003 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (noise). OJ. 2003;L42:38–44.
2. American National Standards Institute (ANSI). Standard for the measurement of real-ear hearing protector attenuation and physical attenuation of earmuffs (Standard No. ANSI S3.19-1974). New York, NY, USA: ANSI; 1974.
3. European Committee for Standardization (CEN). Hearing protectors—recommendations for selection, use, care and maintenance—guidance document (Standard No. EN 458:2004). Brussels, Belgium: CEN; 2004.
4. International Organization for Standardization (ISO). Acoustics—hearing protectors—part 1: subjective method for the measurement of sound attenuation (Standard No. ISO 4869-1:1990). Geneva, Switzerland: ISO; 1990.
5. American National Standards Institute (ANSI). Methods of estimating effective A-weighted sound pressure levels when hearing protectors are worn (Standard No. ANSI/ASA S12.68-2007). Washington, DC, USA; ANSI; 2007.
6. American National Standards Institute (ANSI). Methods for measuring the real-ear attenuation of hearing protectors (Standard No. ANSI S12.6-2008). New York, NY, USA: ANSI; 2008.