

## Hearing Protectors “real world” performance and the European directive 2003/10/EC.

Workshop held at INRS Paris  
July 4<sup>th</sup>, 2008

### Source Book

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Source Book prepared by J. Voix from original material presented on July 4<sup>th</sup> and from presentation handouts received from their authors since that date.

## **MEETING MINUTES**

Written by P.Canetto, J. Voix. Reviewed by Elliott Berger, Jean Jacques, Martin Liedtke.

### **Presentation of the issue**

The problem of hearing protection devices (HPD) “real-world” attenuation has been topical and increasingly critical in the European Union (EU) since the implementation of the 2003/10/EC Noise Directive, 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 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 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.

The meeting took place at INRS in Paris, on 4<sup>th</sup> of July 2008. 44 people attended the meeting, and 11 additional people asked to be informed of the outcome (the attendance list is given in appendix). These people are researchers, Occupational Safety and Health (OSH) and standardization experts, notified bodies and manufacturers representatives who are specialists in the HPD field (see list in appendix). They were from 17 different countries.

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.

We give in these minutes 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.

## **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), HPD 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 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, 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.

In the United States of America (US), the use of HPD 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 US 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 HPD is on average much lower than the attenuation measured in the laboratory. This difference comes from many parameters which may be linked a bad use of 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 non wearing 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 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 US, 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 HPD must not impede the perception of auditory signals. According to the choice of HPD, signal audibility may be worsened or on the contrary improved. EN 458 standard recommends the use of HPD showing a flat frequency characteristic in order to ensure a good signal audibility. 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 HPD. A major principle is the priority to collective solution in regard with personal solutions. In this scope, 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 HPD.

HPD are manufactured products circulating 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 citizen 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 HPD). 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.

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” 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 are described in European “harmonized” standards, which origin could be an ISO standard, and Recommendation-for-use sheets of the European Horizontal Committee of Notified Bodies-PPE.

The difference between laboratory and real-world attenuations has been evaluated by a BGIA study in the late 1980’s. The study gave average values of 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 workers protection. Derating these values allows to extend the range of protected people. This derating can be omitted in case of workers appropriate training. However, HPD non wearing time remains a major factor in the decrease of HPD 8-hours 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 at 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).

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 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 (“ancient” 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 HPD 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 HPD is much lower than the one obtained in laboratories has been studied in the United States of America (US) 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 a same exposure may vary. Valid attenuation of HPD must be taken into account, as well as the effect of non-wearing time. A suitable computational scheme must be used to derate the laboratory-measured values.

When applying the “gold standard” (octave band calculation) to subject-fit attenuation values, we find that for a same noise, according to the plug fit, the noise level calculated as effective when the HPD is worn ( $L'_A$ ) may vary 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 NIOSH database of 100 noise spectra and the HPD attenuations measured in laboratory for individual subject (i.e. single and not average values). 20 HPD 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  $NRS_A$  has been developed and is proposed in standard ANSI S12.68-2007. It has also been proposed for consideration at 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  $L_A$ . 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 worker’s motivation. An alternative graphic method takes into account more precisely the frequency distribution of the noise exposure.

An updated version ANSI 12.6 is likely to be 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  $NRS_A$  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 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 (National Health and Safety Research Institute), 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 the HPD use

Discussions on 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 HPD 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 allow to guarantee protection 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 behaviour of the various kinds of HPD and 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 (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  $NRS_A$  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 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, 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.

**APPENDIX A : ORIGINAL AGENDA****The agenda**

<b>Time</b>	<b>Who</b>	<b>What</b>
8:30 - 9:15	Welcome coffee	
9:15 - 9:30	INRS	Presentation of INRS
9:30 - 10:15	J. Voix P. Canetto	Why this meeting. What is the problem; the stake, the context
10:15 -11:00	M. Liedtke	The European situation : standards, regulation, certification. The European experience.
11:00 -11:45	E.H. Berger	The US situation : standards, regulation, certification. The American experience.
11:45 -12:00	J. Jacques	Short debriefing– Organization of 3 sub-committees (same topics discussed)
12:00 -13:30	Complimentary buffet provided by INRS	
13:30 -15:30	Debate in the 3 sub-committees	
15:30 -16:00	Sub committees convenors	Debates debriefing
16:00 -17:00	E.H. Berger – P. Canetto – J. Jacques – M. Liedtke - J. Voix	Synthesis of the main points

**Note : no fee** is asked for this workshop. It is not necessary to be registered to Acoustics'08 meeting to attend the workshop. Simply bring your Acoustics'08 **name-tag**, if you have one, please.

**The speakers (alphabetical order):**

Elliott H. Berger		Chair of ANSI S12/WG11 on hearing protectors US representative on ISO/TC 43/SC 1/WG 17. Senior Scientist, E-A-R / Aearo Technologies (US)
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
Jean Jacques		Head of the Standardization Unit Former Noise Consultant for the European Commission Institut National de Recherche et de Sécurité (National Health and Safety Research Institute), France
Martin Liedtke		Head of the Ergonomics - Physical Environmental Factors Division BGIA - Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung (National Institute for Occupational Safety and Health), Germany Chairman of CEN TC 159 Hearing “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
Jérémie Voix		Vice-President of Scientific Research and Chief Technology Officer at Sonomax Hearing Healthcare Inc Research associate, École de Technologie Supérieure, Canada

**How to get to INRS?**

INRS headquarters are located in Paris « intra-muros » at 30 rue Olivier Noyer (Arrondissement XIV). To reach the INRS, from the and Palais des Congrès, it is a nice 32 min. journey in the -safe and famous- « Metro de Paris ».

A bilingual guide will be leaving from the Concorde Lafayette Hotel lobby hall at 7:30 on Friday July 4<sup>th</sup>. He can also be reached on a cellphone: +33 6 79 15 53 56.

Other wise the detailed itinerary is available online at:

<http://www7.ratp.info/Pivi/piviweb.php?>

exec=piviweb&cmd=Itinaire&Profil=RATP\_UK&nom\_dep=Palais+des+Congres+PARIS-17EM  
E&type\_dep=LIEU&x\_dep=596093&y\_dep=2431143&nom\_arr=30+Rue+Olivier+Noyer+PARIS  
-14EME&type\_arr=RUE&x\_arr=598842&y\_arr=2425901&mode=TOUS\_MODE&critere=PLUS\_  
RAPIDE&jour=4&mois=7&annee=2008&heure=7&minute=30&typeDate=DATE\_DEPART

**APPENDIX B : ATTENDANCE LIST**

<b>Name, first name</b>	<b>Organization</b>	<b>Country</b>	<b>e-mail</b>
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### Interested people who could not come

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Malchaire Jacques	UCL	Belgium	<a href="mailto:jacques.malchaire@uclouvain.be">jacques.malchaire@uclouvain.be</a>
Pääkkönen Rauno	FIOSH	Finland	<a href="mailto:Rauno.paakkonen@ttl.fi">Rauno.paakkonen@ttl.fi</a>
Renard Christian	Laboratoire Renard	France	<a href="mailto:c.renard@laborenard.fr">c.renard@laborenard.fr</a>
Williams Warwick	National Acoustic Laboratories	Australia	<a href="mailto:Warwick.Williams@nal.gov.au">Warwick.Williams@nal.gov.au</a>
Zera Jan	CIOP	Poland	<a href="mailto:jazer@ciop.pl">jazer@ciop.pl</a>

And many others that more recently heard about that past event...

**.APPENDIX C : SOME -LIMITED- VISUAL MEMORIES**



Photos credits: Olav Kvaløy <Olav.Kvaloy@sintef.no>.

**APPENDIX D : PRESENTATION HANDOUTS**

**APPENDIX D-1: J. Voix and P. Canetto's Presentation**



**Hearing Protectors "Real world" performance**

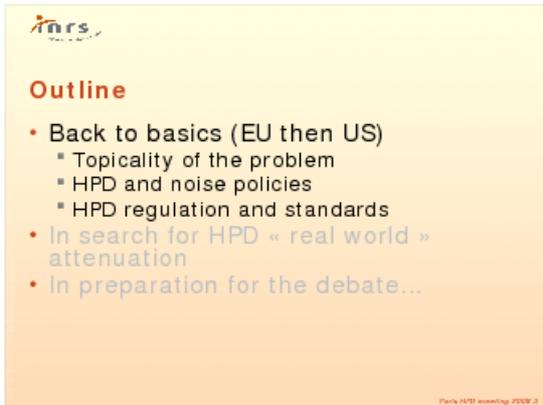
Pierre Canetto, INRS  
Jérémie Voix, ETS

International Workshop, INRS Paris  
July 4<sup>th</sup> 2008



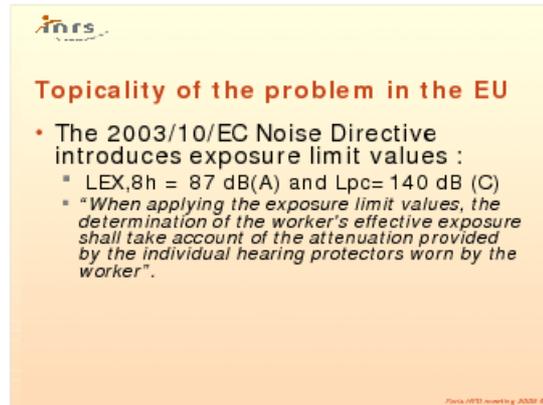
**Outline**

- Back to basics (EU then US)
  - Topicality of the problem
  - HPD and noise policies
  - HPD regulation and standards
- In search for HPD « real world » attenuation
- In preparation for the debate...



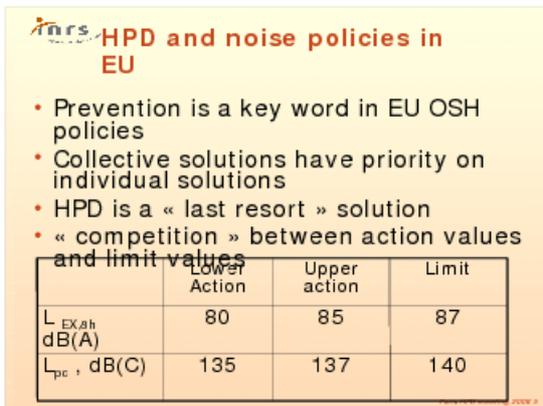
**Outline**

- Back to basics (EU then US)
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**Topicality of the problem in the EU**

- The 2003/10/EC Noise Directive introduces exposure limit values :
  - $L_{EX,8h} = 87 \text{ dB(A)}$  and  $L_{pc} = 140 \text{ dB (C)}$
  - "When applying the exposure limit values, the determination of the worker's effective exposure shall take account of the attenuation provided by the individual hearing protectors worn by the worker".



**HPD and noise policies in EU**

- Prevention is a key word in EU OSH policies
- Collective solutions have priority on individual solutions
- HPD is a « last resort » solution
- « competition » between action values and limit values

	Lower Action	Upper action	Limit
$L_{EX,8h} \text{ dB(A)}$	80	85	87
$L_{pc} \text{ dB(C)}$	135	137	140



**HPD regulation in EU**

- HPD being **products**
  - Directive 89/656/EEC « use of PPE »
  - Directive 89/686/EEC « design of PPE »
- CE exams and labelling
  - Health & Safety requirements
  - Certification tests
  - Notified bodies
- HPD being **OSH devices**
  - 2003/10/EC « Noise » Directive
  - 89/391/EEC « Frame » OSH Directive

**inrs** **HPD standards in EU**

- ISO standards
  - EN 24869-1 (or ISO 4869-1) ; EN-ISO 4869-2
- EN standards :
  - EN 458 : 2004 Hearing protectors – Recommendation for selection, use, care and maintenance – Guide document
  - EN 352 series (Part 1 to 8) : Hearing protectors - Safety requirements and testing
  - EN 13819 : HPD test methods

« harmonized » standards :  
the presumption of legal conformity

Paris HPD meeting 2009 7

**inrs** **Topicality of the problem in US**

- EPA is still referencing ANSI S3.19 (originally written in 1974)...
  - But it will soon change
  - EPA will refer to:
    - ANSI S12.68-2007 : Effective SPL when Hearing Protectors are Worn
    - ANSI S12.6-2008 (?) (rev. of ANSI S12.6-1997) : Methods for Measuring the Real-Ear Attenuation of Hearing Protectors
      - Last miles

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**inrs** **HPD and noise policies in North-America**

- HPD is the main solution taken into account in Hearing Prevention Programs
- « noise control » solutions are evoked

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**inrs** **HPD regulation and standards in N-A (1/2)**

- Currently relies on ANSI S3.19-1974:
  - Experimenter fit only.
- ANSI S12.6-2008(?) "HPD Attenuation Measurement"
  - Includes "subject-fit" since 1997;
  - Will include "trained subject-fit" and "inexperienced subject-fit".
- ANSI S12.68-2007 "Protected Level"
  - Provide NRSa, dual number value;
  - Provide NRSg, graphical as of C-A exposure.

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**inrs** **HPD regulation and standards in N-A (2/2)**

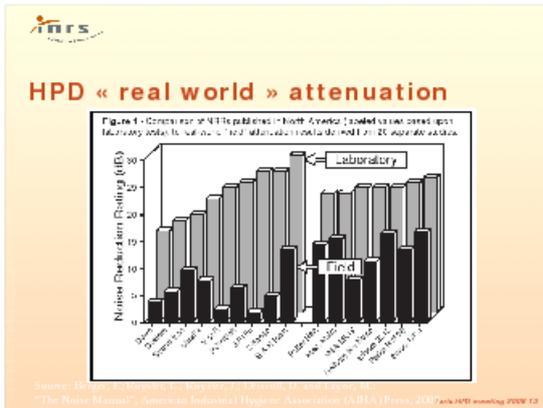
- Standards currently updated:
  - ANSI S12.42-20xx: MIRE and ATF for HPD
- New standard in preparation:
  - ANSI S12.71-20xx: Performance and Uncertainty for Field Attenuation Measurement Systems (FAMS)

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**inrs** **Outline**

- Back to basics (EU then US)
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- In preparation for the debate...

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### The discrepancy parameters

Family	Parameters
Working constraints	Gestures (retention), jaws movements, HPD adaptation, HPD care, Motivation...
Human factors	Bad wearing, HPD adaptation, HPD care, Motivation...
Product quality	Manufacturing variability, ageing, human ear fitting...
Laboratory tests	Noise levels, frequency range, subjective character...

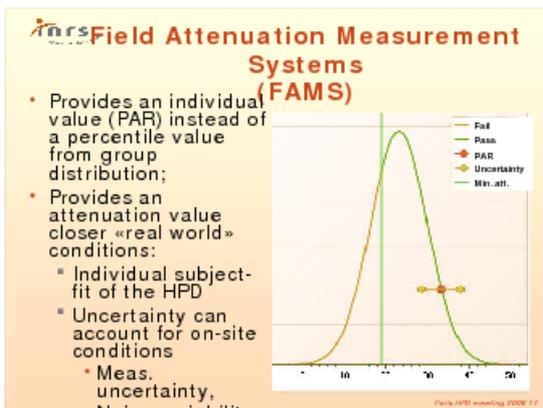
- ### Decreasing lab. attenuation values
- Absolute derating: decrease the declared attenuation from a global amount
    - The amount can be different according to the HPD kind
  - Proportional derating: the declared attenuation is decreased from a percentage
    - The amount of the % can be different according to the HPD kind
  - Statistical enlargement
    - The HPD attenuation can be calculated by subtracting more or less standard deviations to the mean

### « Subject Fit » tests

- In ISO / EN harmonized standards, subjects used for HPD tests are trained and the HPD good fitting is checked
- New ANSI standards propose to use untrained subject who will fit themselves the HPD without an expert

**Noise Reduction Rating 25 DECIBELS**

**1280**



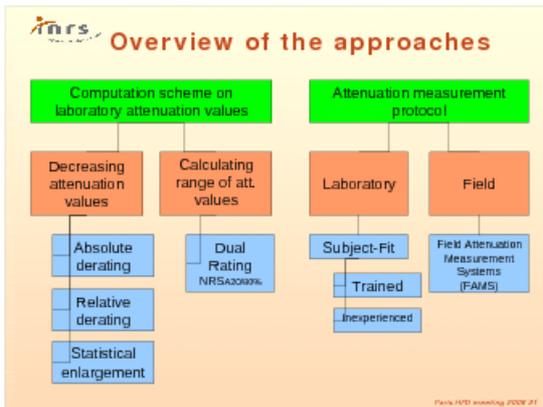
- ### Field Attenuation Measurement Devices
- Subjective (Psycho-physical)
- FitCheck – Michael and Associates
  - VeriPRO – Howard Leig
  - ?

**Field Attenuation Measurement Devices**  
*Objective (Physical)*

- SonoPass - Sonom
- Acoustic Analyzer - Hearing Co
- FlashTest - Custom Protect Ear
- Phonak Attenuation Control System - Phonak
- E-A-Rfit - E-A-R/AEARO Technologies
- ?

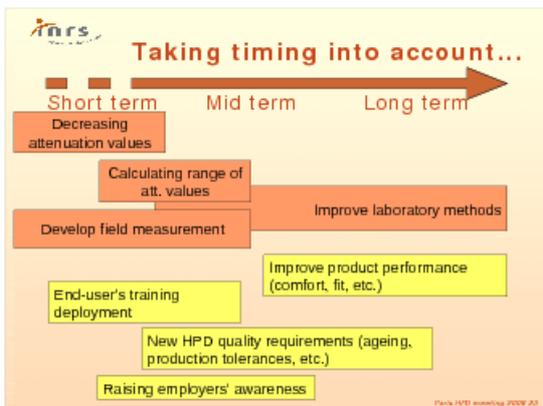
**Outline**

- Back to basics (EU then US)
  - Topicality of the problem
  - HPD and noise policies
  - HPD regulation and standards
- In search for HPD « real world » attenuation
- In preparation for the debate...



**Pending issues... to debate**

- Applicability of the solutions
  - re. industrial reality;
  - re. regulation context.
- Relevance according to prevention principles
  - Training, motivation, selection, use& care.
- Ability to test the product on its own
  - to distinguish between the product itself and its use;
  - to distinguish between the lab conditions and real-world conditions (excluding human behavior);
  - to differentiate HPD models of the same kind.



**APPENDIX D-2: M. Liedtke's Presentation**

HPD real world performance and 2003/10/EC workshop 2006-07-04, Paris, France

**BGIA** Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung

**The European situation: standards, regulations, certification. The European experience.**

**Dr. Martin Liedtke**

Institut für Arbeitsschutz - BGIA  
der Deutschen Gesetzlichen Unfallversicherung

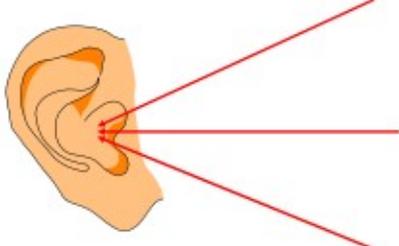
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HPD real world performance and 2003/10/EC workshop 2006-07-04, Paris, France

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**Hearing - Acoustic Perception**

**„above and below listening“ by diffraction at the pinna**



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**Content**

- > Hearing
- > Real world and laboratory attenuation in Europe/Germany
- > EU-Directives: PPE product, PPE user, Noise
- > Selection of hearing protectors
- > Implications of real world attenuation



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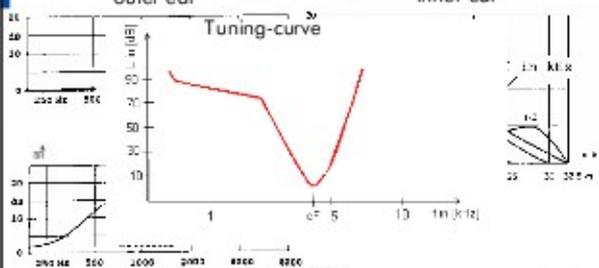
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**Hearing - Acoustic Perception**

**transfer functions of the ear**

outer ear      inner ear

**Tuning-curve**



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**Hearing - Acoustic Perception**

- Acoustic perception is much more important than people are aware:
  - eyes observe only the area in front of the head
  - ears recognise sound even when it comes from behind  
for example: a fork lift truck's acoustic warning signal from behind

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**Hearing - Acoustic Perception**

**threshold of hearing**



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### Hearing - Acoustic Perception

hearing filters and technical filters

100  
90  
80  
70  
60  
50

0,1 1 10

frequency [kHz]

tuning curves of acoustic nerve fibres  
from Evans, E.F. (1983) "Hearing science and hearing disorders (pp.60-80)"

One-third octave band filter

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### Hearing - Acoustic Perception

Methods for estimation of signal audibility of German tracklayers' warning signal

- Methodes of ISO 7731 „Danger Signals for workplaces – Auditory Danger Signals“(1984)“ according to
- Wittmann, H., and H. Meißner: Simple methode for assessment of the signal audibility of tracklayers' warning signal when hearing protectors are used – Hearing protection study 2nd report No. 10.391/1. Müller-BBM GmbH, Planegg (Munich) [in German] (1986)
- not suitable

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### Hearing - Acoustic Perception

masking

100  
80  
60  
40  
20  
0

0,02 0,05 0,1 0,2 0,5 1 2 5kHz 10 20

Narrow band noise

sine tone

$L_r = 100 \text{ dB}$

$f_c$

Threshold of a pure sine tone masked by narrow band noise

Source: Zwicker, E. and R. Finkhler: Das Ohr als Nachrichtenempfänger. S. Hans Verlag, Stuttgart, (1947)

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### Hearing - Acoustic Perception

signal: private car horn

14  
12  
10  
8  
6  
4  
2  
0

10 20 30 40 50 60 70 80 90 100 110 120

1,4 1,6 1,8 2,0 2,2 2,4 2,6 2,8 3,0 3,2 3,4 3,6 3,8 4,0 4,2 4,4 4,6 4,8 5,0 5,2 5,4 5,6 5,8 6,0 6,2 6,4 6,6 6,8 7,0 7,2 7,4 7,6 7,8 8,0 8,2 8,4 8,6 8,8 9,0 9,2 9,4 9,6 9,8 10,0

signal

$W_A = \text{area} / \text{area} = 0,012$

Zwicker diagram taken from ISO R 352, Part B

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### Hearing - Acoustic Perception

masking

80  
60  
40  
20  
0

0,02 0,05 0,1 0,2 0,5 1 2 5kHz 10 20

$f_{1/2} = 0,25$

$f_1$

$f_2$

$f_3$

$\Delta L_r = 100 \text{ dB}$

Threshold of a pure sine tone masked by narrow band noise at several frequencies

Source: Zwicker, E. and R. Finkhler: Das Ohr als Nachrichtenempfänger. S. Hans Verlag, Stuttgart, (1947)

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### Hearing - Acoustic Perception

Noise of car crane, lifting loads (87,4 dB(A)); signal: private car horn

14  
12  
10  
8  
6  
4  
2  
0

10 20 30 40 50 60 70 80 90 100 110 120

1,4 1,6 1,8 2,0 2,2 2,4 2,6 2,8 3,0 3,2 3,4 3,6 3,8 4,0 4,2 4,4 4,6 4,8 5,0 5,2 5,4 5,6 5,8 6,0 6,2 6,4 6,6 6,8 7,0 7,2 7,4 7,6 7,8 8,0 8,2 8,4 8,6 8,8 9,0 9,2 9,4 9,6 9,8 10,0

working noise

signal

$W_A = \text{area} / \text{area} = 0,012$

$W_A$  selective perception

Zwicker diagram taken from ISO R 352, Part B

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### Acoustic performance requirements for HPD

- suitable protection level – a comparison
  - sun glasses:
    - as much protection as possible?
    - as much efficiency/investment as possible?
  - Welding goggles while steering a car on a sunny day
- For safety reasons very often a certain amount of acoustic information on the working environment is necessary

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### Recent BGIA-project

#### Real world and laboratory attenuation in Europe/Germany

**"Audiomobil"**

**Vehicle for hearing conservation programme**

Technical changes at BGIA: additional loudspeakers, signal generators, computer, etc. same test protocol as in the lab (ISO 4869-1)



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### Recent BGIA-project

#### Real world and laboratory attenuation in Europe/Germany

- **Motivation and goal of the recent BGIA-project**
  - Different investigations worldwide:
    - Real world attenuation is considerably smaller than lab values.
  - **First study by BGIA concerning this topic in 1989**
  - **This study: Check of first study's values.**
  - **New: Also custom moulded plugs are investigated.**
  - **Involved institutions:**  
BGIA and different German accident insurance authorities

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### Recent BGIA-project

#### Real world and laboratory attenuation in Europe/Germany

#### Measurements

**From September 2005 till July 2007**  
Organisation of measurements by the accident insurance authorities  
Partly pre-selection of appropriate hearing protectors

**Measurements directly in the companies**  
**Use of hearing protectors under real conditions**

**Principle:**  
Determination of hearing level with and without hearing protector  
Five octave bands between 250 Hz and 4 kHz  
Difference is the sound attenuation.

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### Recent BGIA-project

#### Real world and laboratory attenuation in Europe/Germany

#### Types of hearing protectors

- Formable ear plugs
- Pre-formed ear plugs
- Banded ear plugs
- Ear muffs
- Custom moulded ear plugs



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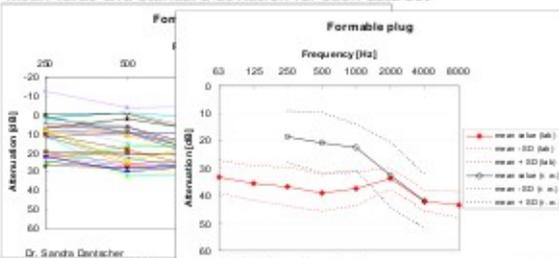
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### Recent BGIA-project

#### Real world and laboratory attenuation in Europe/Germany

#### Results – Raw data

Check for extreme values of attenuation (not plausible)  
Sound field correction (lab vs. test vehicle)  
Mean value and standard deviation for each data set



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**Real world and laboratory attenuation in Europe/Germany**

**Results - Summary**

For every product:  
Difference between (mean of) attenuation in the lab and real-world  
Mean value of five measured frequencies

For every type of hearing protector:  
Weighted mean of different products

Type	Products	Data sets	Difference of mean values [dB]	Derating [dB]
Formable plugs	5	262	7,8	9
Pre-formed plugs	2	85	5,0	5
Banded plugs	2	63	4,5	5
Ear muffs	1	33	3,0	5
Custom moulded	3	139	6,1	6 resp. 3

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**Overprotection**

**decrease of protection versus non-usage duration**

In relation to an 8 h-shift

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**Overprotection**

**Signal audibility and hearing protection**

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**Unexpected high risk due to short term removal of hearing protectors in noise**

$L'_{Ex,8h}$  versus exposure duration

Usage rate: 97 %  
100 %

With HPD:  $L'_{Ex,8h} = 80$  dB, without HPD:  $L'_{Ex,8h} = 105$  dB, each 1/2 hour 1 minute without HPD

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**Overprotection**

**decrease of protection versus non-usage duration**

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**Signal audibility**

Noise of car crane, lifting loads (87.4 dB(A)); signal: private car horn

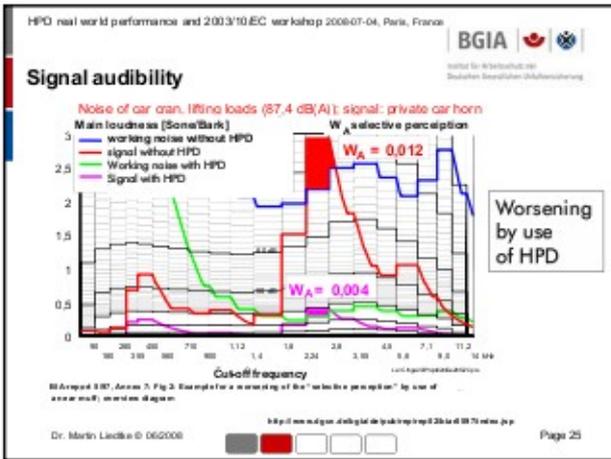
Main loudness [Sones/Bark]

Zwicker diagram taken from ISO R 352, Part B

© Manpower & Assoc. 7, Fig. 2 Example for a working of the "hearing perception" system of an ear muffs wearing diagram

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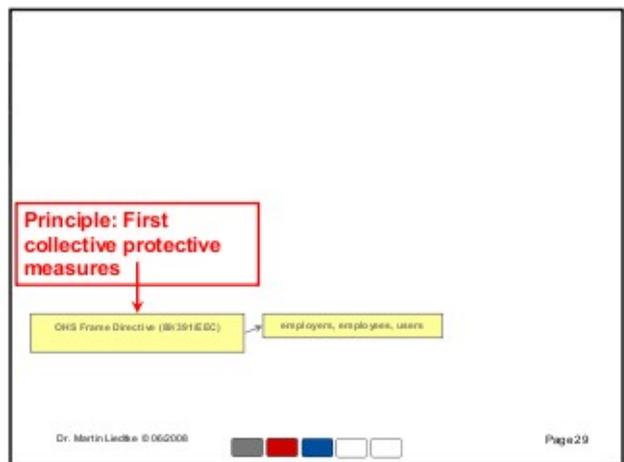
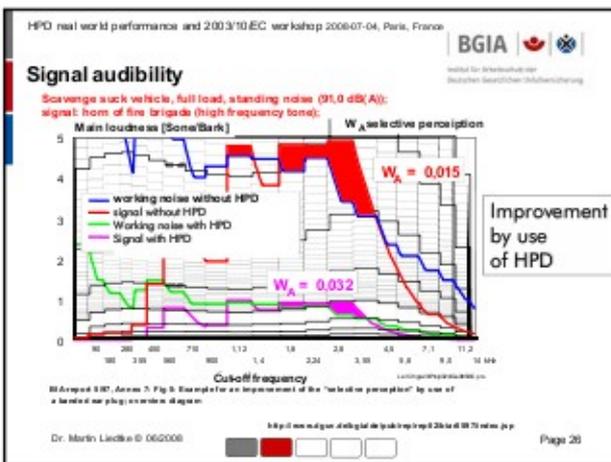
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### Health and safety at work (European Council Directive 89/391/EEC)

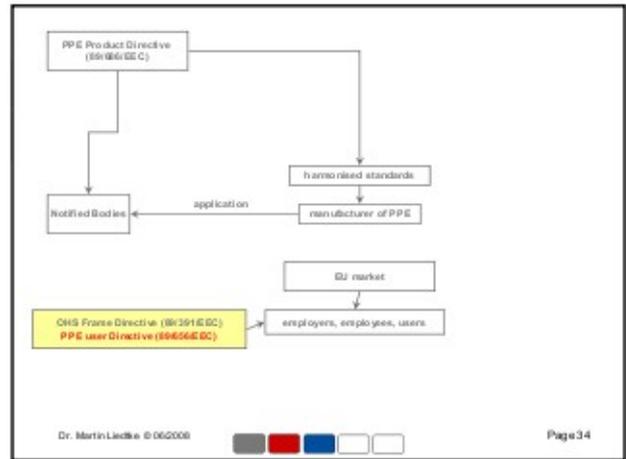
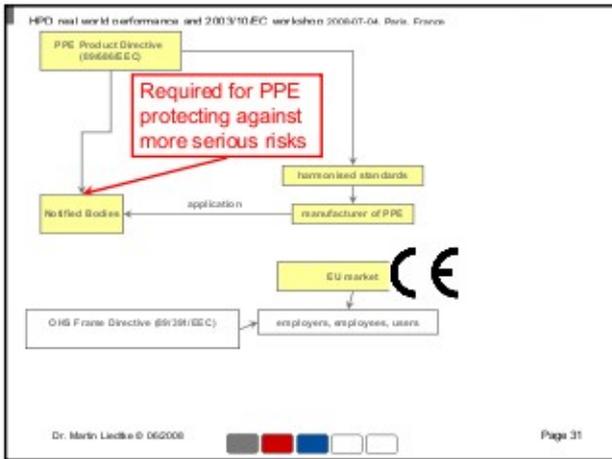
- Employer has to ensure safety and health of workers by e.g.
  - Prevention of occupational risks
  - Provision of information and training
  - Provision of the necessary organization and means
- Principle: Collective protective measures is given priority
- Personal protective equipment (PPE) used only when risks cannot be avoided by other means
- Workers have to make correct use of PPE and, after use, return it to its proper place

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- BGIA Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung
- ### European regulations - Content
- Introduction
    - Health and safety at the workplace
    - PPE manufacturing
    - Selection and use of PPE
  - Measures to ensure safe use of PPE in Europe
    - Manufacture of PPE and placing on the EU market
      - Special role of standardisation bodies
      - Notified Bodies' responsibilities
      - Manufacturers' responsibilities
    - Market Surveillance
    - Selection and use of PPE
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- ### PPE manufacturing (European Council Directive 89/686/EEC)
- CE marking signals: Legal obligations ensure that PPE on the European market give the highest level of protection
  - Manufacturers or their authorised representatives in EU can comply with the technical requirements directly, or by means of European Harmonised Standards
  - European Harmonised Standards provide presumption of conformity to the essential health and safety requirements (EHSRs)
  - Directive 89/686/EEC details EHSRs and conformity assessment procedures
  - Intervention of Notified Bodies required for PPE products protecting against more serious risks
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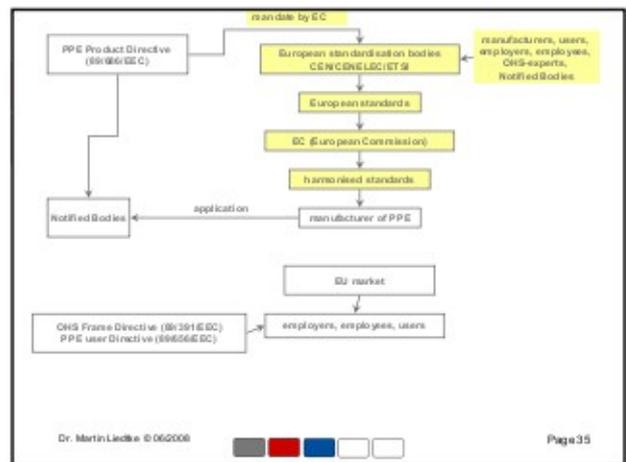
**Selection and use of PPE**  
(European Council Directive 89/656/EEC)

BGIA  
Institut für Arbeitsschutz der  
Bundesanstalt für Arbeitsschutz und  
Arbeitsmedizin

- Employers' obligation: All PPE must
  - be appropriate for the risks involved, without itself leading to any increased risk;
  - correspond to existing conditions at the workplace;
  - take account of ergonomic requirements and the worker's state of health;
  - fit the wearer correctly after any necessary adjustment.
- Simultaneous use of PPE: PPE must be compatible and effective
- Before choosing PPE employer has to assess whether items above are satisfied

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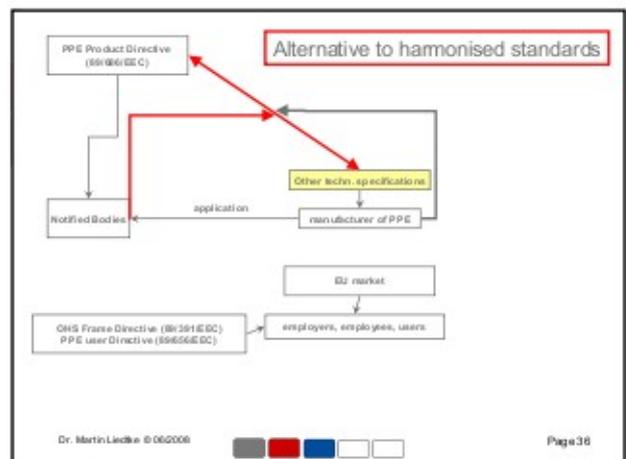
**Selection and use of PPE**  
(European Council Directive 89/656/EEC)

BGIA  
Institut für Arbeitsschutz der  
Bundesanstalt für Arbeitsschutz und  
Arbeitsmedizin

- This assessment shall involve
  - Analysis and assessment of risks which cannot be avoided by other means
  - Definition of the characteristics which PPE must have in order to be effective, taking into account any risks which this equipment itself may create
  - Comparison of the characteristics of the PPE available with the characteristics referred to above
- Assessment shall be reviewed if any changes are made to any of its elements

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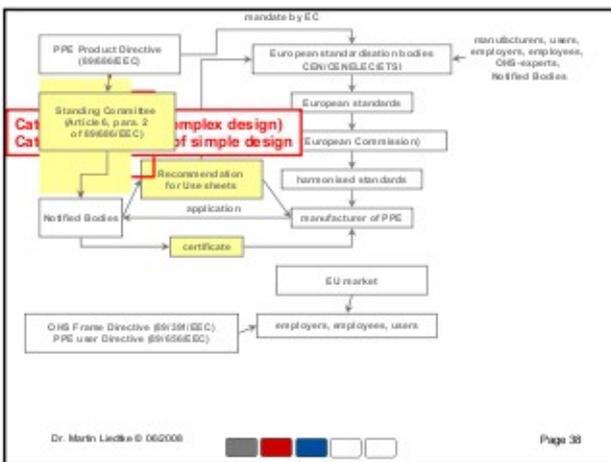
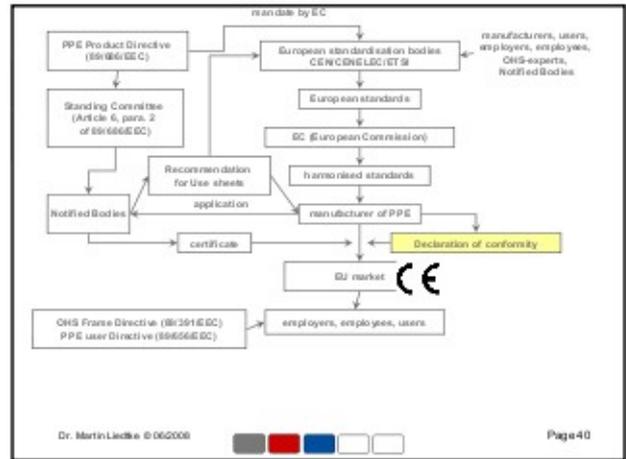
**Notified Bodies' responsibilities**

**Notified Bodies shall**

- provide relevant information to their notifying authority, the market surveillance authorities and other notified bodies
- operate in a competent, non-discriminatory, transparent, neutral, independent and impartial manner
- employ the necessary personnel
- make adequate arrangements to ensure confidentiality
- be adequately insured to cover their professional activities
- participate in coordination activities and standardisation – or in addition represented in European standardisation, or otherwise ensure that they know the situation of relevant standards

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**Market surveillance**

**Is an essential tool**

- It has to ensure that provisions are complied with
- Citizens are entitled to an equivalent level of protection throughout EC
- To eliminate unfair competition
- Needs to have necessary resources and powers
- Ensure technical competence and professional integrity
- Act in an independent and non-discriminatory way
- Notified Bodies should be excluded from responsibility of market surveillance activities

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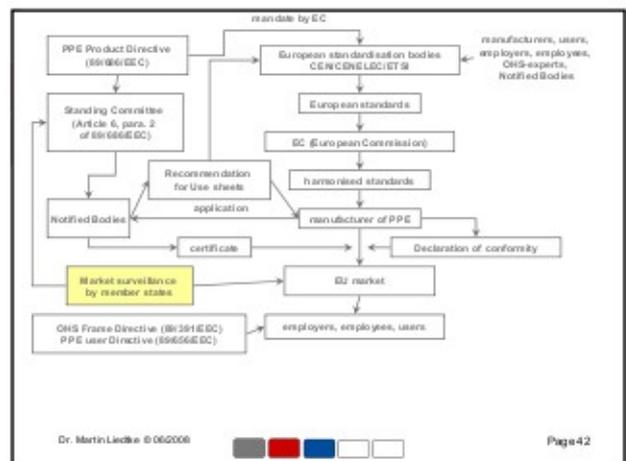
**Manufacturers' responsibilities**

**Manufacturer**

- Is responsible for designing, manufacturing a product with a view to placing it on the EC market on his own behalf
- Has obligation to ensure product is designed, manufactured, and its conformity assessed to essential requirements of relevant product directive
- Uses harmonised standards and Recommendation for Use sheets
- May use list of Notified Bodies published by European Commission
- Declaration of conformity, EC-Type examination certificate, CE marking

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**Selection and use of PPE**

- Only safe PPE should be available in Europe. How to get safe use of PPE?
- PPE only corresponds to risk or level of risks in case
  - Proper selection
  - Proper worker information and training
- Additional risks may be introduced by use of PPE
- European and national guidelines

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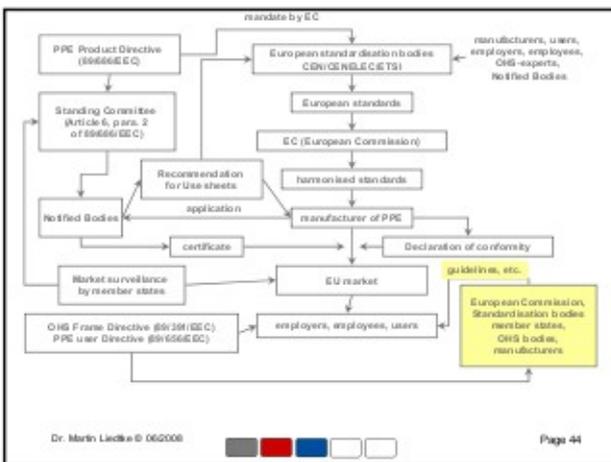
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**Requirements: HPDs showing a flat frequency characteristic**

- In cases, in which the perception of
  - informative working sounds
  - warning signals
  - communication
 may be impaired, EN 458 recommends use of „HPDs showing a flat frequency characteristic“

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**result of a BGIA study**

- The criterium specified by the technical committee „PPE“ for „warning signals general“, communication necessary“ and „informative working sounds“:
  - The gradient of the linear regression of mean values of attenuation (obtained according to ISO 4869-1:1990) for 125 Hz up to 4000 Hz is smaller than 3.60 dB per octave

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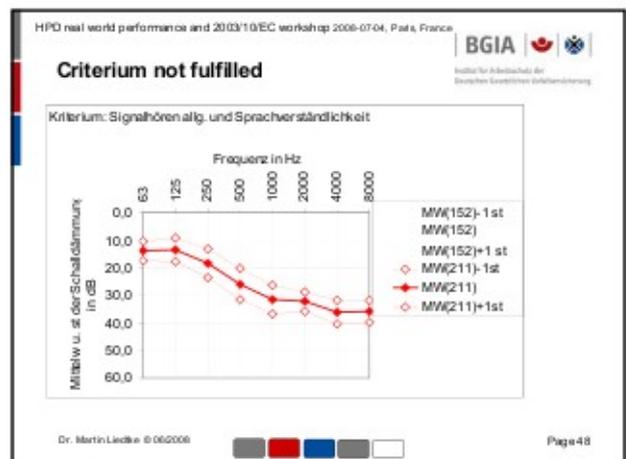
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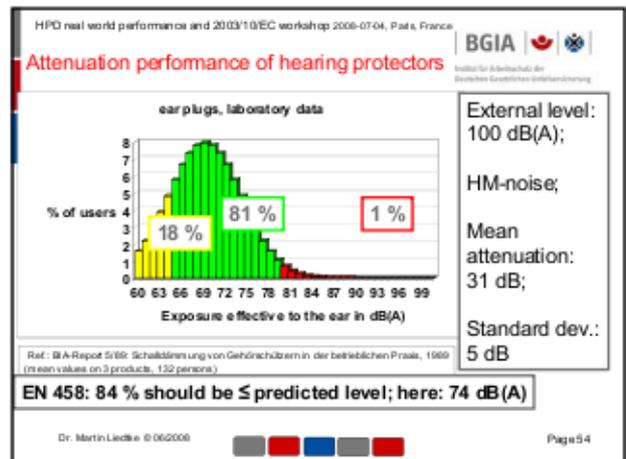
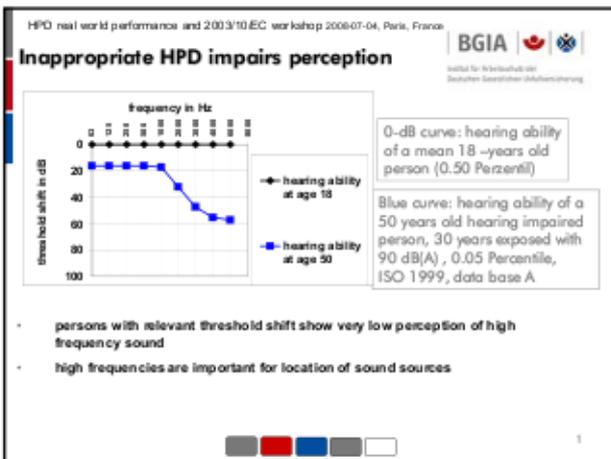
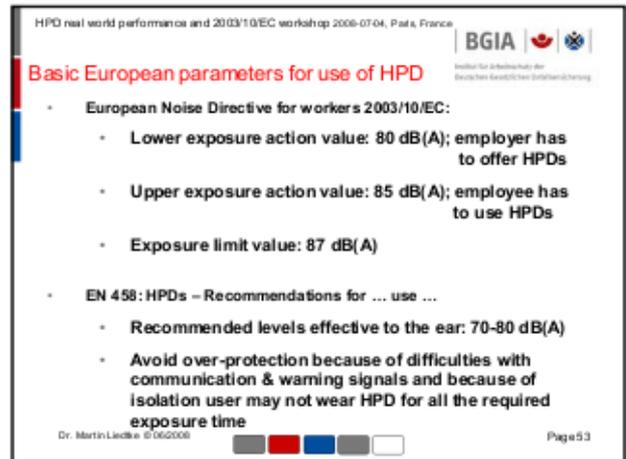
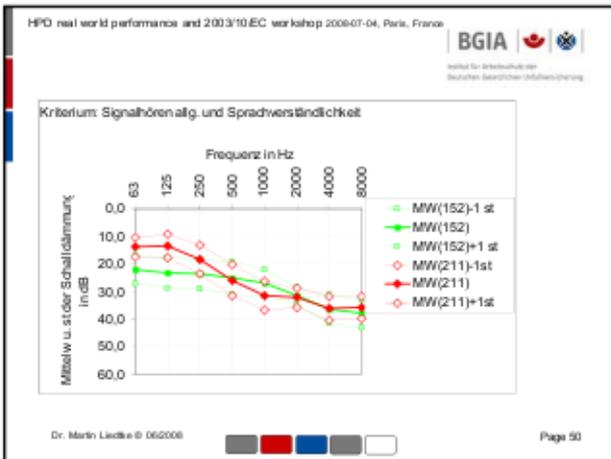
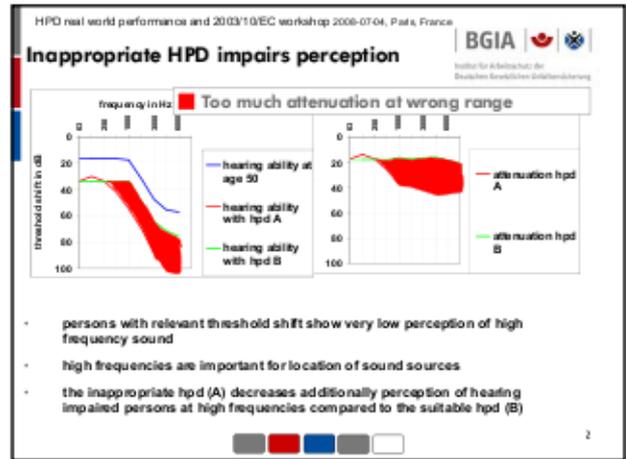
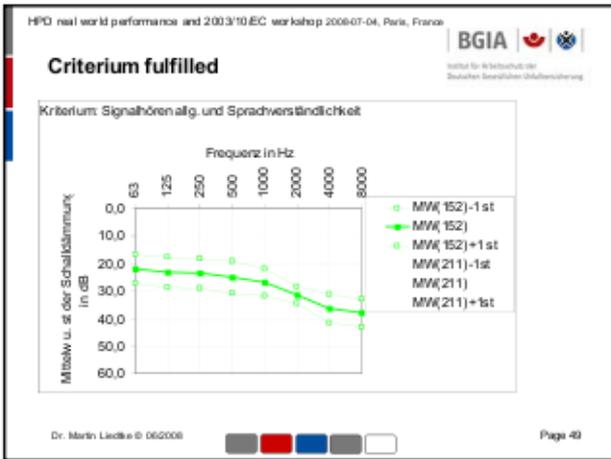
**Selection and use of PPE**  
(European Council Directive 89/656/EEC)

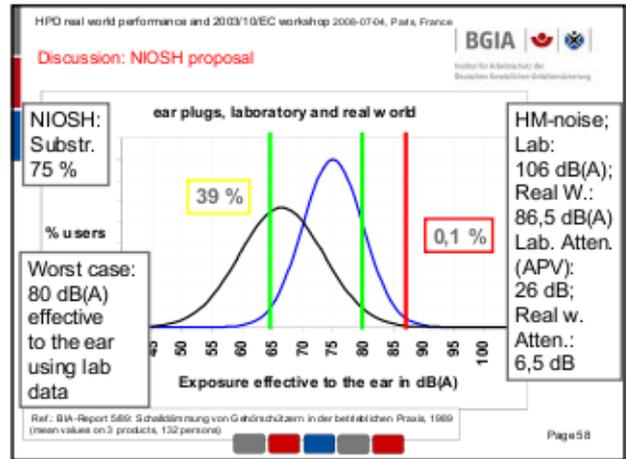
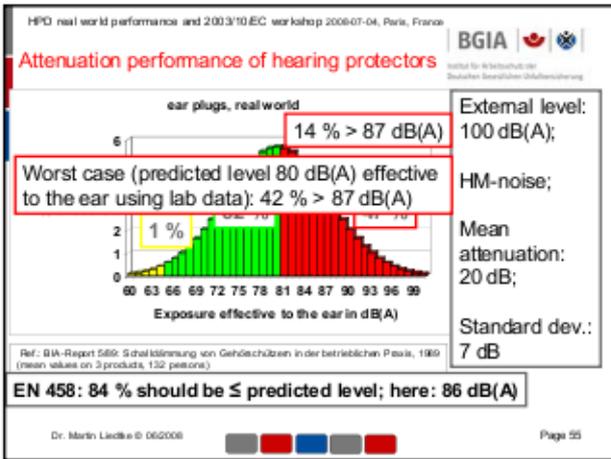
- Information on available types of PPE and their field of application
- List of activities which may require PPE
- Specimen risk survey table for use of PPE
- Assessment of PPE itself

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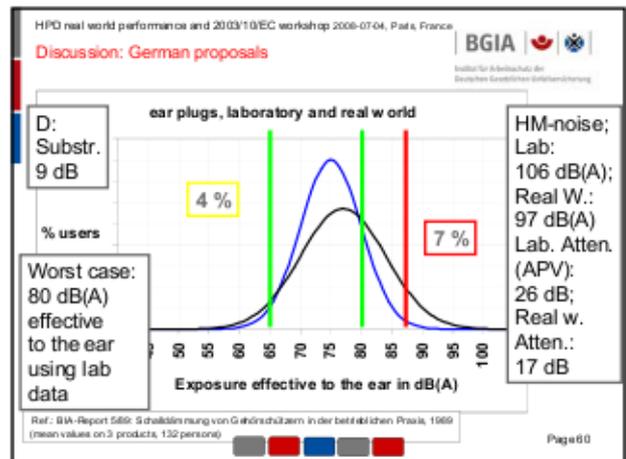
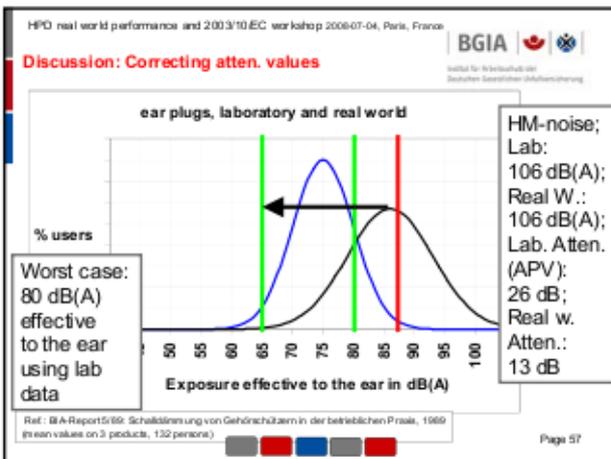
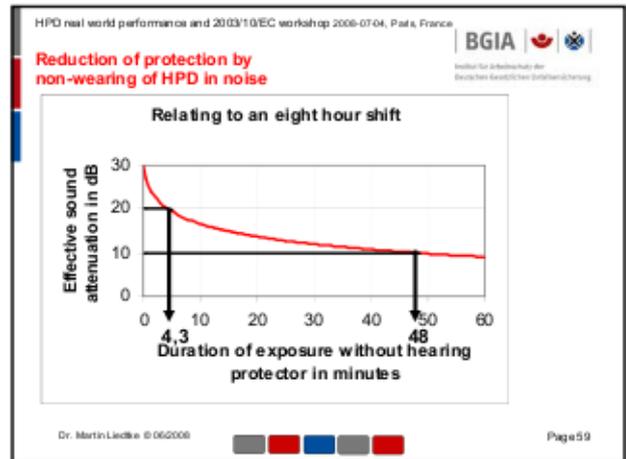
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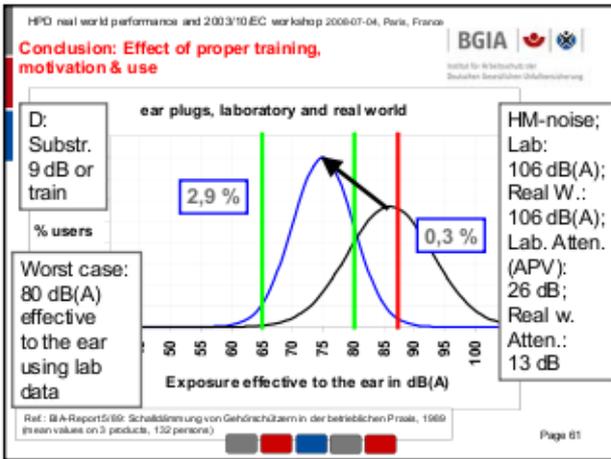






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- Approaches to consider „real world attenuation“ (examples)**
- **NIOSH:**
    - Ear muffs: Subtract 25 %
    - Ear plugs to be formed by the user: Subtract 50 %
    - All other types of ear plug: Subtract 75 %
  - **German BG technical committee "Hearing protection":**
    - Custom moulded ear plugs: Subtract 3 dB
    - Ear muffs: 5 dB
    - Other types of ear plug: 9 dB
  - **In case of special measures – e.g. training, motivation and exercise is provided – subtraction may be omitted**
  - **UK**
    - Subtract 4 dB for all kind of HPD (only for  $L_{p,eq}$ ) (as far as workers are trained to HPD wearing)
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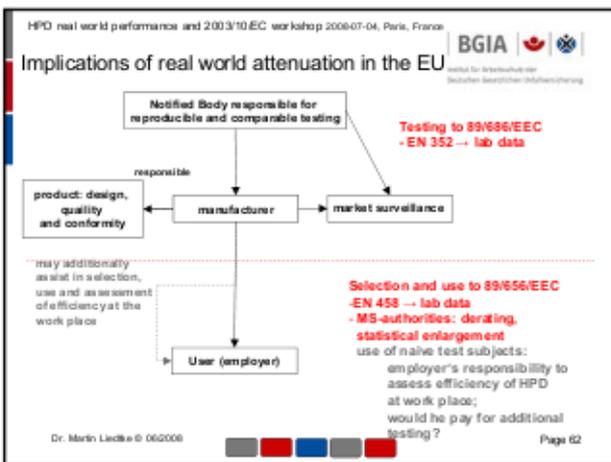
**Implications of real world attenuation in the EU**

**Deratings, statistical enlargement or use of naive test subjects? Part 2**

- The European systems requires testing which does provide comparable results in between laboratories (i.e. lab data)
- CEN TC 159 "Hearing Protection" and Vertical Group 4 "Hearing Protection" of the "Horizontal Committee of Notified Bodies - PPE" have each decided to use ISO 4869-1 for EC-type examinations. Both expert boards recommended to provide assistance to employers for deratings within the standard EN 458 "Hearing protectors - Recommendations for selection, use, care and maintenance - Guidance document"
- For a long period now for respiratory equipment different assumed protection values (deratings) are in use in different member states.

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**Implications of real world attenuation in the EU**

**Deratings, statistical enlargement or use of naive test subjects? Part 3**

- Summary - items for discussion:
  - we need in the EU at least ISO 4869-1 data (lab data)
  - how can we obtain additional data provided to user/employers representing "real world"?
  - this item is addressed to authorities too; are they prepared to support additional standardisation and testing?
  - how to specify several different data sets for users/employers avoiding confusion?
  - how many target groups do we have to consider? 0.85 percentile, 0.50 percentile, 0.15 percentile ...
  - For LEs training and information can be improved. What's about SMEs? Effect of short term non-usage of HPD in noise?

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**Implications of real world attenuation in the EU**

**Deratings, statistical enlargement or use of naive test subjects? Part 1**

- In Europe it is up to the employer to assess the efficiency of HPD at work place within the risk assessment; i.e. employer has to select level of protection within his risk assessment what is required and decide how to obtain that level (corresponding use of data)
- According to European regulations the authorities could assist the employer by deratings, statistical enlargement or data out of additional testing by use of naive test subjects - but who will take action?
- For high exposure we need the possibility of special training in use of HPD to reach protection levels represented by laboratory data in order to be able to provide protection (e.g. abrasion workplaces,  $L_{Aeq} = 120$  dB)
- For workplaces with high accident risks (e.g. tracklayers, vehicle drivers) we need as well this possibility to get a (the) specified protection (lab mean values)

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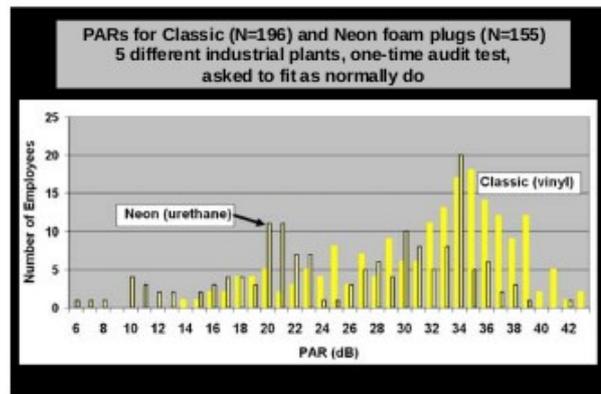
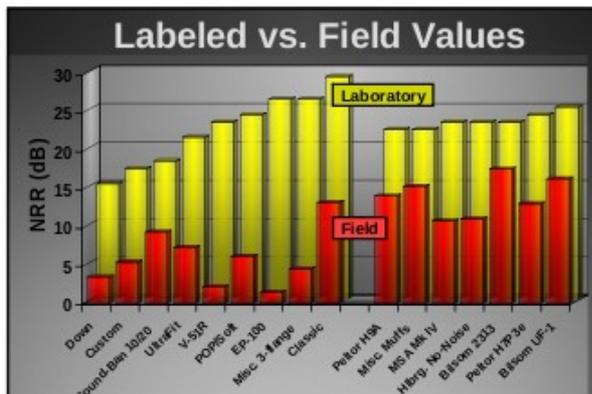
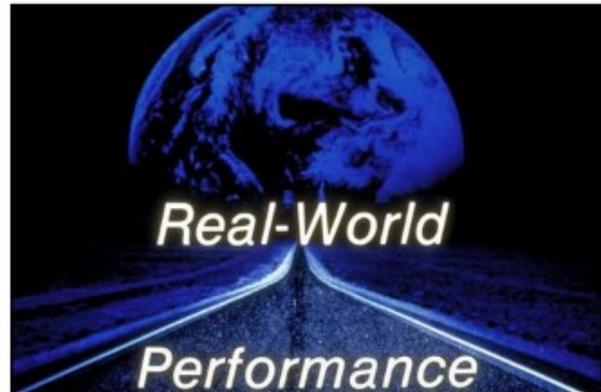


**APPENDIX D-3: E. Berger's Presentation**

**OBSERVATIONS ON LABELING AND RATING HEARING PROTECTORS, THE AMERICAN EXPERIENCE**

Invited Presentation for International Workshop on Hearing Protector Performance Measures, Paris, 2008

Elliott H. Berger  
 Chair ANSI S12/WG11  
 US Representative to ISO/TC43/SC12/WG17  
 Senior Scientist, Auditory Research, Aearo Technologies

**Summary Outline**

- Regulations and standards in the US
- Background and overview of two new US (ANSI) standards on measuring HPD attenuation and estimating protection
- Future US regulatory possibilities – EPA rulemaking
- Various methods of derating
- Matching HPDs to noise exposures
- Closing remarks and suggestions

**Current US Regulations and Standards**

- Environmental Protection Agency (EPA)
  - HPD Labeling Regulation (40CFR Part 211) – 1979
- Voluntary consensus standards (ANSI)
  - ANSI S3.19-1974, S12.6-1997(2002), S12.6-2008(?) - REAT
  - ANSI S12.68 – number ratings (NRS)
  - ANSI S12.42-1995(R2004) – MIRE and ATF
- In process voluntary consensus standards (ANSI)
  - ANSI S12.42 update to address testing electronic products
  - ANSI S12.71 performance of fit-test measurement systems

### ISSUES IN ESTIMATING USER PROTECTION

- Accurate noise exposure estimates  
Accounting for calibration errors, microphone frequency response errors, and sampling issues, ISO/DIS 9612 reports the 2-sided expanded uncertainty = 4 – 13 dB
- Individual susceptibility

### ISSUES IN ESTIMATING USER PROTECTION

- Accurate noise exposure estimates
- Individual susceptibility
- Valid HPD attenuation data + effects of wearing time

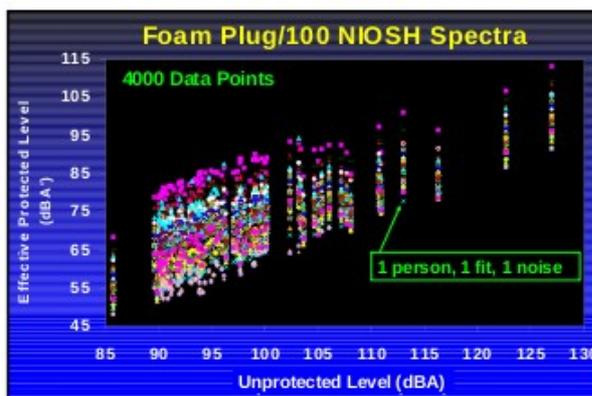


### ISSUES IN ESTIMATING USER PROTECTION

- Accurate noise exposure estimates
- Individual susceptibility
- Valid HPD attenuation data
- Suitable computational scheme or derating scheme

### HOW GOLD IS THE “GOLD STANDARD”

- For years we have used the octave-band method of computation based on mean attenuation data less a multiple of the standard deviation, as our “gold standard”
- The unspoken assumption – we know what the user’s protection is



### WHAT METRICS SHOULD WE CONSIDER?

- The octave-band method is essentially a 7-number rating
- How can we simplify life, and reduce the likelihood of errors?

### MULTI-NUMBER RATINGS

- dBA Reduction (Waugh)
- 2-Number Method (Johnson and Nixon)
- HML (Lundin) and  $NRS_G$

### SINGLE-NUMBER RATINGS

- C to A':  $NRR$ ,  $SNR$ , and  $SLC_{80}$
- A to A':  $(NRR-7)$ ,  $NRR_{(SF)}$ , and  $NRS_A$
- Classes or grades: AU/NZ and Canada

### ANALYTICAL METHODS

- Waugh (1976 and 1984)
- Sutton and Robinson (1981)
- Gauger and Berger (2004):  
Replication of the prior work with new and current data, and new analyses and metrics.

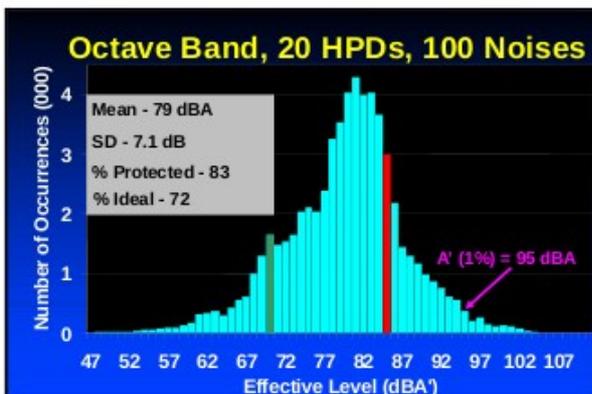
The key is use of the OB method computed *individually for each subject* in each noise to construct error distributions.

### THE INPUT DATA

- 100 NIOSH noises
- S12.6-1997 Method-B Data for:  
10 earplugs (1 flat attenuation)  
9 earmuffs (1 flat attenuation)  
1 dual combination
- Also some testing with other noises and HPD data sets

### COMPUTING PROCEDURE

- For a given rating method such as the  $SNR$ , take 1 noise and 1 HPD, and estimate A'
- Shift the noise, so estimated A' = 85 dBA
- Now - use the individual-subject data, and the OB method to estimate the true A' for each person
- Repeat for all subjects, all noises, and all hearing protectors



### Hearing Protector Rating: New ANSI Standard S12.68-2007

- New rating called the  $NRS_A$
- Will likely be part of a new EPA labeling regulation
- Has been proposed for consideration by ISO

### Key Features of the New Rating

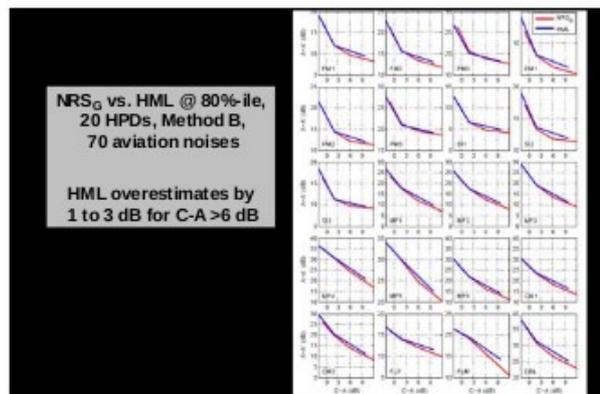
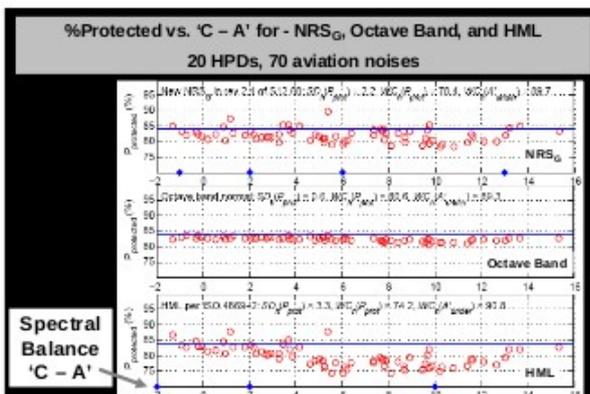
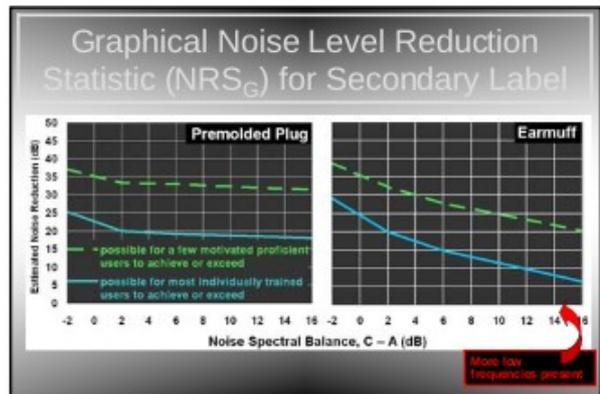
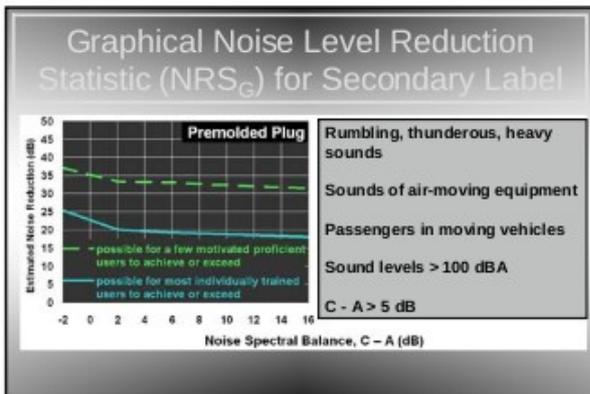
- ☞ Directly subtracted from dBA without adjustments (no 7-dB correction as with current NRR)
- ☞ Improved computational methodology (subjs. x noises)
- ☞ Presented as two numbers –  $NRS_{A80}$  and  $NRS_{A20}$
- ☞ A single value fosters an unwarranted sense of precision
- ☞ Two values indicate a range of performance is anticipated
- ☞ The range itself says something about the HPD
- ☞ Provides a conservative number and also a goal to shoot for
- ☞ Indicates possibility of overprotection

### A Future EPA Label?

- ☞ Rating to be called the NRR, but computed like  $NRS_A$
- ☞ Based on somewhat more realistic data, but just slightly smaller values than with current numbers
- ☞ Electronic / specialized HPDs to get additional graphic

$NRS_A$  21 possible for most individually trained users to achieve or exceed      34 possible for a few motivated proficient users to achieve or exceed

Noise Reduction Statistic



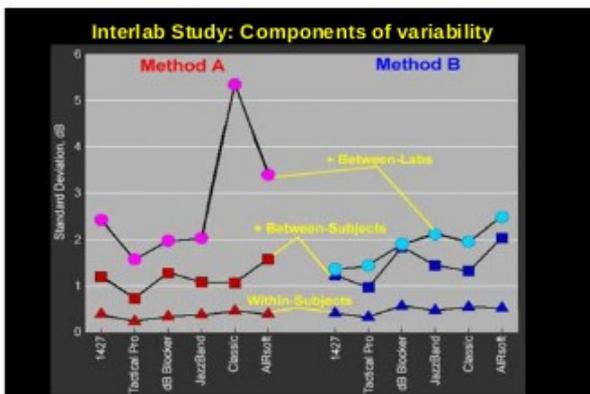
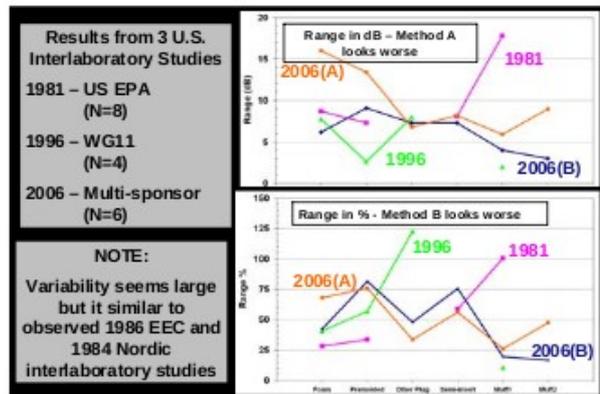
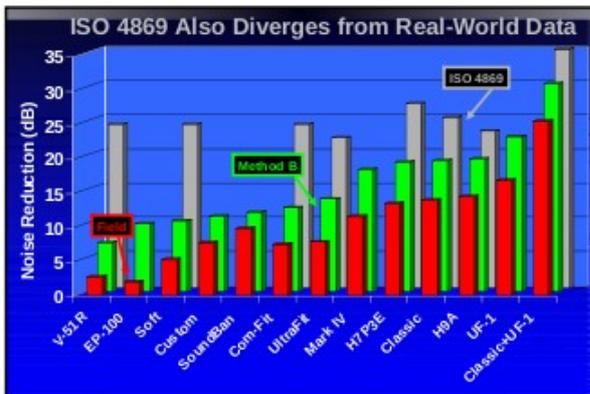
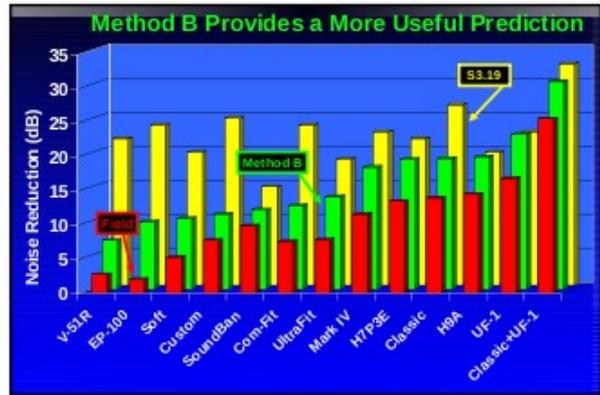
### ANSI S12.6-2008(?)

**Method A – Trained-Subject Fit**

- Corresponds to prior ANSI standards
- Currently out for vote in S12 and ANSI
- Less open to interpretation (ISO 4869 example)

**Method B – Inexperienced-Subject Fit**

- Approximates upper limits of attenuation for groups of workers – best real-world estimate
- The myth of the “experienced/trained worker”
- May not provide sufficient reproducibility



### Arguments regarding Method-A vs. Method-B testing

Issue	Meth. A	Meth. B	Either
Within-lab reproducibility is better	✓		
Between-lab reproducibility is better		✓	
Cost of testing is less	✓		
Speed with which tests can be conducted	✓		
Provides best estimate of device's inherent performance	✓		
Provides realistic estimate of magnitude of field attenuation		✓	
Provides best estimate of rank ordering of field attenuation		✓	
No derating needed		✓	
"Justifiable" and/or understandable to typical person	✓		
Can be used with dual number-rating system			✓
Compatible with international standards and regulations			✓

### What's Up at the EPA?

- ⌚ Labeling is governed by 1979 EPA regulation; revision has been in process since 2003 and activity has stepped up in 2008
- ⌚ Proposed new regulation is likely this year, with hearings to follow shortly thereafter
- ⌚ New regulation will likely use:  
ANSI S12.6-2008 (?) Method A,  
ANSI S12.68-2007 NRS<sub>A</sub>

### Attenuation Measurements per ANSI S12.6-2008 (?)

**Method A – Trained-Subject Fit**

- ⌚ Should have better reproducibility than prior Method A (less open to experimenter interpretation) and should provide more emphasis on manufacturers' instructions
- ⌚ Should better predict, to some extent, field performance than prior Method A, since subject does fitting on his/her own

### Proposed derating methods



- Derating
  - %-age or dB values; may vary for classes of products
- Improved laboratory simulation, sometimes called "modified" testing
  - ANSI Method B, also used in Brazil
  - Australia 1270 and ISO 4869 Part 5
- Adjustment per laboratory standard deviations, also called range enlargement
- Reduce the "Exposure Limit Value" below 87 dBA
- None of these account for individual variability

### MATCHING HEARING PROTECTION TO NOISE EXPOSURE



INSUFFICIENT	85 dBA (Action Level)
ACCEPTABLE	80 dBA
GOOD	75 dBA
ACCEPTABLE	70 dBA
(RISK OF) OVERPROTECTION	

CSA Z94.2-02 and EN 458

### Closing Remarks

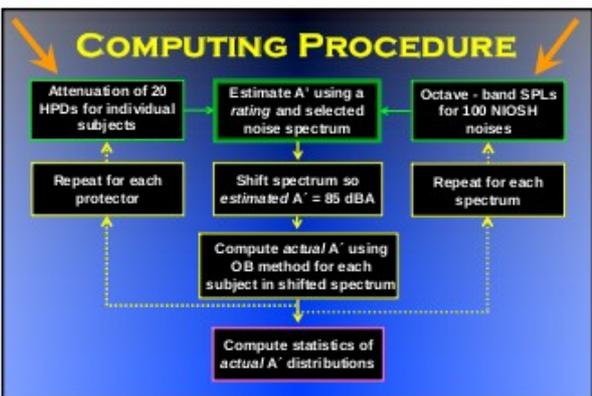
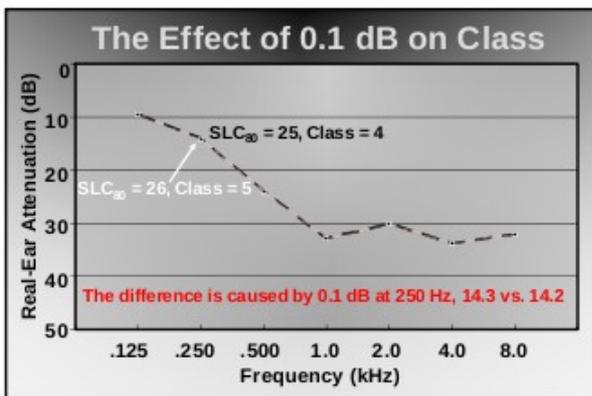
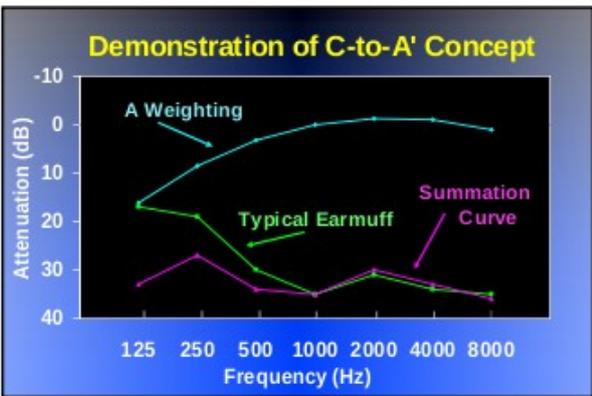
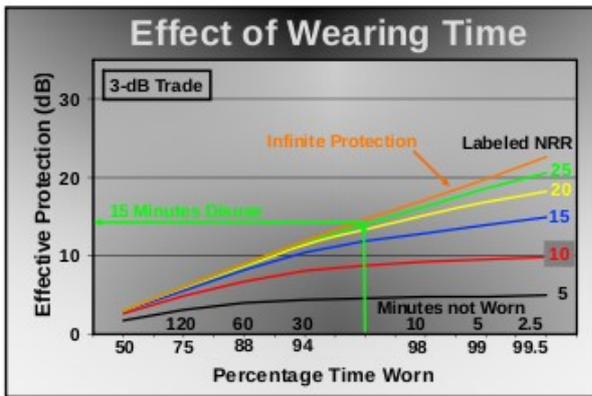
- ✓ Variability exists in all aspects of HPD predictions: noise measurement, individual susceptibility, attenuation measurement, use-time estimates, and the computational approach.
- ✓ In "extreme spectra," if you know "true" attenuation and OB noise levels, OB computation will be the most accurate.
- ✓ Because of inherent variability, especially individual variability, a single-number dBA-reduction value, like the NRS<sub>A</sub>, is a simple suitable alternative to the OB method.
- ✓ Derating, after the fact, cannot be done with precision and can only provide approximate guidance; it is not clear that any one method is the best.

### Closing Remarks (contd.)

- ✓ If real-world estimates are desired, a Method-B approach is best, but it too has limitations.
- ✓ The one answer to estimating real-world performance that clearly does not make sense, is the current approach with each country going its own way.
- ✓ The best approach, in place of derating, is individual field fit-testing; in the absence such data, ALL predictions for individual wearers are highly suspect.
- ✓ And finally, even with fit-test data, the 15-dB target window is not always the best method of matching HPD attenuation to user noise exposures.



Following slides are extras that were not presented at the talk



**APPENDIX E : DEBATE DEBRIEFING HANDOUTS**


**Results from discussion in sub committees**

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**Group 1**

Martin Liedtke

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**Results from discussion in sub committees**

- **Starting point: EU-Noise Directive**
- **real exposure of employees**
  - **Average or worst case?**
    - **Measures should be taken immediately when the action value is exceeded**
  - **Assessment for groups or for locations or for individuals?**
  - **Application of EU-Directive is different in the MSs; should be harmonised**
  - **Fast action is required by the employers**
  - **Exposure is not well known in companies**
  - **Exposure by HPDs equipped with communication facilities**
  - **HPDs measuring the noise dose**
  - **Assessment of impulse noise; assessment of levels under the HPD**

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## Results from discussion in sub committees

- **Starting point: EU-Noise Directive**
- **real exposure of employees**
  - **Use compliance (HPDs are not all the time especially helmet mounted ear muffs)**
  - **Find a way how to determine diffuse field related SPL in an ear canal obstructed by an ear plug in order to be compared with limit values**
  - **Assessment of speech sound**
  - **Audiometry is too uncertain to be used for assessment of risk (TTS)**

## Results from discussion in sub committees

- **Attenuation**
  - **Custom moulded plugs may be a solution to guarantee a specific attenuation**
  - **Difference of attenuation of ear muffs and helmet mounted ear muffs**
  - **Training of users in lab and in field is different?**
  - **Not possible to find approach for all kinds of HPDs and situations**
  - **Comfort**
  - **Time usage**
  - **Motivated user**
  - **High attenuation data can only be used by good training and/or individual fit testing**

## Results from discussion in sub committees

- **Attenuation**
  - **Deratings in Europe are too small?**
  - **Deratings can be too large (overprotection)**
  - **Specification in ranges?**
  - **Next step: Individual fit testing**
  - **Field attenuation: hearing threshold has to be measured precisely for comparison with lab data – background noise; test subject should have good hearing and no TTS**
  - **Bone conduction is not an objective for attenuation**
  - **Compromise in between enough protection not leading to over protection**
  - **How the employer can guarantee continuous protection in terms of usage and protection function**

## Group 2

Elliott Berger

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- Additional Notes:
- 1. for most people a single number rating is quite adequate.
- 2. arguments made for dual derating
- 3. whatever derating scheme we use we must know what it means, i.e. what it takes into account, what percentage coverage does the derating provide.
- 
- QUESTIONS
- Is the specific derating important?
- What is preferred derating option?
- Dual rating system, such as  $NRS_A$
- Percentage
- Constant dB
- Enlarged range

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- 1. Short term action – must use current label values with statistical enlargement since it is product specific; but long term likes  $NRS_{A \text{ with Method A}}$
- 2. Short term: Must use current lab values; no particular choice on derating.
- 3. Is not concerned so much about derating but prefers a dual rating system.
- 4. Derating is of no value; will it change anything.
- 5. Short term: no derating but clear info on need of motivation/training
- Long term: use a Method A and Method B.
- 6. Short term: use S12.68
- Long term: rationalize NR, REAT, and field data to devise better test standard.
- 7. Short term: not in favor of derating; wants individual test method that is available to all, that isn't owned by one manufacturer.

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- 8. (two votes for this) Short term: must use current label values with statistical enlargement since it is product specific; Long term: NRS<sub>A</sub> and individual fit testing
- 9. Short term: no change, but emphasize training with definition on what is the training
- Long term: must specify use life of hearing replacement requirements, likes NRS<sub>A</sub> with Method B, but is concerned if the high to low range is too large
- 
- 10. Short term: no derating but clear info on need of motivation/training
- Long term: dual rating with Method B
- 
- 11. Short term: EN data with statistical enlargement for muffs and for plugs use Method B test results from Australia; if not available use NIOSH derating; explain applicability of conditions
- Long term: must specify use life of hearing replacement requirements, likes NRS<sub>A</sub> with Method B, but is concerned if the high to low range is too large, with individual fit testing.

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- Principal Concerns
- 1. people want to know exposed level
- 2. find agreement on penalties / derating
- should we derate?
- Is there a RW estimation problem?
- 3. Must do individual measurements
- Doesn't want to consider individual susceptibility
- 4. Doesn't agree with TS because NIPS may already be present
- Better than measure HL is to educate, train, and fit test.
- Doesn't want standard derating values
- Must consider individual susceptibility
- 5. We fail to account for sound field and sound level issues, and how that may affect performance
- Motivation is critical
- Comfort is important
- No way to measure susceptibility

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- 6. Looking for a simple ideas on how to account for HPD uncertainty, derating
- 7. What is important is how to measure exposure. Does not feel answer is REAT.
- Lab and individual testing are both needed. individual data may not actually be any more precise than lab data.
- Most important is that we have the same method; must not endorse poor use.
- 8. Wants recognized method to determine if his company complies with the permitted exposure levels. It must account for training, jaw movements, use time, and variations in noise exposure.
- How can someone fit test?
- What is field test uncertainty?
- 9. Training is a key issue. Providing dual ratings for good / poor training is valuable.

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- 10. Training is key issue. Std. should specify details on how to train.
- Very few workers know the SNR as it is; concerned that a dual rating may be even more confusing.
- Specifying deratings for types of products is blatantly wrong.
- Issue is not what is exact attenuation, but just that HPDs are used.
- Wants realistic and simple standards.
- 11. Is there a new need for standards or a need for revision of current standards?
- 12. Needs a study of uncertainty in acoustic measurements.
- Most any HPD will give 10 dB, but not 30 dB; there is not any need to get very precise in our HPD measurements.

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- 13. Switzerland – most workers have 85-90 dB exposures so specific attenuation isn't key. use time is more important.
- Simple rules are beter to actually protect workers.
- Derating decisions may influence future devices; wants devices that are user proof.
- 14. Individual fit testing is important.
- people aren't wearing their HPDs so we need better training and individual testing, mor dedicated efforts to improve use.
- Comfort is important – teach people to use the correct product.

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## Group 3

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- Noise control engineering ,must be the first priority
- Pressure should be put on government and companies to set up effective HCP involving end-users; including penalties;
- Derating is unsatisfactory
- Individual testing is the way to go for Tomorrow
- A standard is needed to cover individual testing
- Additional labelling Impulse noise is needed
- Manufacturers of HPD should work on improving the comfort of their products

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