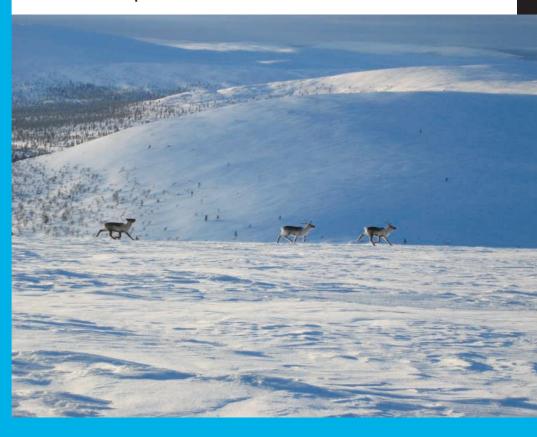


10th EUROPEAN SEMINAR ON PERSONAL PROTECTIVE EQUIPMENT

26 – 28 January 2010 Saariselkä Tunturi Hotel, Lapland, Finland

Seminar Report



WORK ENVIRONMENT RESEARCH REPORT SERIES **56**Finnish Institute of Occupational Health, 2010



10th EUROPEAN SEMINAR ON PERSONAL PROTECTIVE EQUIPMENT

26 - 28 January 2010 Saariselkä Tunturi Hotel, Lapland, Finland

Seminar Report



SUMMARY OF PUBLICATION

Reference: WORK ENVIRONMENT RESEARCH REPORT SERIES 56

Finnish Institute of Occupational Health, 2010

ISBN 978-952-261-055-3

ISSN-L 1458-9311 ISSN 1799-4470

Editor: Susanna Mäki

Finnish Institute of Occupational Health

Work Environment Development, Protection and Product Safety Team

Topeliuksenkatu 41 a A FIN-00250 Helsinki, Finland

Date: Helsinki, 9 December 2010

Pages: 84

Edition: 1st

Layout of the cover pages: Arja Tarvainen Cover photograph: Nilla S. Hirvasvuopio

Printed by Vammalan Kirjapaino Oy, Finland 2010



SUMMARY

This seminar report publication contains papers presented at the 10th EUROPEAN SEMINAR ON PERSONAL PROTECTIVE EQUIPMENT, held in Saariselkä, Lapland 26 - 28 January 2010. The PPE seminar in cold and northern Lapland, near the Arctic Circle, was very successful and had nearly one hundred registered participants from 15 different countries. During this seminar, participants got to personally experience cold weather and freezing wind because of the strong Nordic wind.

The main aim of the seminar was to provide information regarding the changes to the PPE Directive and recommendations for possible PPE solutions. The second aim of the seminar was to bring together European PPE experts dealing with standardization, testing, certification, research, manufacturing, and market surveillance. This seminar provided a unique forum for disseminating findings in the PPE field, and gave speakers and participants the opportunity to exchange experiences and participate in debates. The PPE seminar featured expert speakers on the situation in the PPE sector and issues related to the revision of the PPE Directive.

Participants had the opportunity to attend workshops on issues related to the future development, selection and use of the PPE. The three workshops were as follows:

- Innovations, lifetime, performance and physiological indicators
- Training requirements for sales persons and users, and
- Practical performance and requirements in real situations.

In the posters session, Longo Giovanna of 3M Germany provided a short overview on poor visibility, Bonafini Enrico of Flower Gloves Italy discussed an integrated clothing system for fire fighters, and Kirsi Jussila of Finnish Institute of Occupational Health (FIOH), Finland gave a presentation on the safety of tourist and tourist workers. A Finish polar explorer, Kari Poppis Suomela, presented his own experience with protection during expeditions to the North and South Poles, and their protection against extremely low temperatures, freezing winds and physical exhaustion. This seminar was organized and financially sponsored by the FIOH Finland, BG BAU Germany and the Finnish Ministry of Social Affairs and Health.

Organizing Committee:

- Helena Mäkinen and Eero Korhonen, FIOH, Finland
- Petra Jackisch and Karl-Heinz Noetel, BG BAU, Germany
- Hannele Jurvelius, Ministry of Social Affairs and Health, Finland
- Martti Humppila, European Safety Federation

A PDF version is available for download. Please visit our web-site at: www.ttl.fi/ppeseminar.

Helsinki, 9 December 2010 Susanna Mäki, Finnish Institute of Occupational Health, FIOH Work Environment Development, Protection and Product Safety Team

CONTENTS

SUMMARY	3
CONTENTS	4
1. Opening of the seminar	5
2. Revision of the PPE Directive, preparation for impact assessment study - state	
of play	7
3. Situation in the PPE sector – perspective of the manufacturers	8
4. Situation in the PPE sector – perspective of the Notified Bodies	L3
5. Situations in the PPE Sector – perspective of a market surveillance authority $\dots 1$	L9
6. Suitable modules for PPE	22
7. Information and markings2	29
8. Revision of (harmonised) PPE standards	31
9. Legal Responsibilities with regard to supply, selection and use of PPE	34
10. Selection, use and maintenance of Respiratory Protective Devices (RPD) within	l
the new ISO-Standard	39
11. Methods for evaluating PPE performance in real work situations5	50
12. Does chemical protective clothing gives real protection? A review of recent	
French investigations5	51
13. The differences between laboratory results and real protection during use –	
hearing protection5	52
WORKSHOPS5	59
14. Workshop 1: Innovations, lifetime, performance and physiological indicators5	59
15. Workshop 2: Training requirements for sales persons and users	51
16. Workshop 3: Practical performance and requirements in real situations6	53
POSTERS	55
17. Poor visibility: same hazard, different risks6	55
18. The ultimate fire fighter's suit, integrated clothing systems, ergonomics,	
fabrics, performances, and integrability in accordance with EN 469:2007 Level 26	56
19. The protection and safety of tourists and tourism workers	58
20. The effect of oil resistance of footwear outsoles on slip resistance	
characteristics in winter conditions	70
21. From Pole to Pole, Arctic Challenge	75
Programme of the Seminar	76
List of lecturers and participants	79
Work environment research series publications	32



1. Opening of the seminar

Hannu Anttonen, Finnish Institute of Occupational Health, FIOH, Finland

I have the great pleasure of wishing all of you a warm welcome to the 10th European Seminar on PPE. It is always astonishing that so many participants choose to visit this cold but beautiful part of Northern Europe. Once again, we have nearly one hundred participants and experts from 15 different countries. This seminar is now not only traditional, but it is also historical: the 10th European seminar on PPE. And all of them have taken place here, in Finnish Lapland, the land of reindeer and Father Christmas.

So, we began in December 1992 with specific topics concerning the implementation of PPE, and we continued with the standardization, testing and certification of PPE. Also, the coordination and exchange of experience between Notified Bodies was discussed. This was important because the directive came into effect in 1994. Marketing and market surveillance were also discussed, especially concerning current problems; all in all, the common requirements of the directive were discussed in these seminars. The lectures were also of high quality: they included talks by the EU-ambassador, an expert from the Efta secretariat and such as Alain Mayer from INRS France, Eero Korhonen and Helena Mäkinen from FIOH Finland.

Now, we are in a situation in which requirements and practices exist but co-operation is still needed to reach similar practices in different countries and all parties should have similar opportunities and same safety demands for PPE.

Compared to those early days, today the participants represent more fully all the active operators in the field of PPE: manufacturers, authorities, researchers, end users and sale persons. During these years we have understood the value of networking among all of these experts.

It is good to remember that during these seminars more than 600 participants and experts have influenced our development of standards, practices, information and networking. And the number of the topics we have dealt with is over 30, relating to, for example:

- The implementation of directives
- Risk assessments
- Globalisation
- PPE markets
- Market surveillance
- The real service life of PPE
- Information
- Use of indicators and warning devices
- The conformity assessment process
- The assessment of innocuousness of PPE material
- Risk levels and standards requirements
- Market surveillance
- New approaches
- The selection and use of the new PPE standard



- Workers' and end-users' points of view
- Risk assessment and selection
- Pesticides
- Motivation
- Compatibility and the system
- The safety of workers
- Safety products
- Industry and business.

Although these seminars have been arranged during a darkest part of winter (*in Finnish: kaamos*), the activities offered in the seminars have shed some welcome light on the subject of PPE. Today, the needs of PPE experts are clearer than ever before. For example, smart PPE, new materials, a systematic approach, cost effectiveness, ergonomics and usability, performance and anti-microbial properties are all new and important challenges, which will demand more and more knowledge in the future.



2. Revision of the PPE Directive, preparation for impact assessment study - state of play

Előd Ajtony Dudás, European Commission

Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to Personal Protective Equipment (PPE Directive) became applicable in the early 1990s. It is based on Article 114 of the treaty on the functioning of the European Union and is a total harmonization directive, which now requires a review in order to bring its provisions / requirements up to date. At the time of its entry into force it represented the new wave of legislation, called the New Approach. The Directive therefore bears this framework's advantages and, in some cases, its deficiencies. The experience gained during the last two decades shows that there is space for improvement for both the New Approach framework as well as for the PPE Directive. In 2008 the review of the New Approach was successfully finalized, now called New Legislative Framework (NLF). It resulted in two legal acts: A decision that is regarded as a toolbox for future legislation and a regulation directly applicable to all Member States.

Following that review the Commission decided to restart the revision process for the PPE Directive in 2008. To that end, the Commission has organized several meetings with stakeholders in order to identify elements of the Directive to be candidates for the exercise.

As the European Commission is required to prepare an Impact Assessment (IA) before any legislative proposal is made, the initial steps towards preparing for an Impact Assessment Study, preceding the IA, are now underway. The objective of the study is twofold:

- 1. Get a clear picture on the competitiveness of the PPE sector,
- 2. Determine the impacts of the policy options set out for certain elements of the Directive.

The first part of the Impact Assessment Study will consist of two subsections: the collection of information and the analysis of the collected information. The study has the aim of assessing the Directive's impact on the EU economy and the competitive situation of EU industry in the field. On the other hand, the subsequent part will analyze the identified policy options that are PPE-specific issues, for example scope and conformity assessment. Such an analysis will help the Commission to choose the most suitable policy option when drafting the actual proposal. The issues relating to the alignment with the NLF do not form part of the Impact Assessment Study but will be dealt with at a later stage of the revision process.

Finally, it is hard to give an exact date upon which the revision process can be finalised. Nevertheless, the Commission in 2008, at the PPE WG meeting held in Brussels, informed the stakeholders that it intended to present its proposal to the Council and the European Parliament in 2012. This date still seems viable provided that no major difficulties occur during the various legislative steps preceding it.



3. Situation in the PPE sector – perspective of the manufacturers

Henk Vanhoutte, Secretary General, European Safety Federation (ESF)

Introduction

In this paper, a few issues that are of concern to PPE manufacturers are discussed. These are, first of all, the coming revision of the PPE Directive, the validity of EC-Type Examination Certificates, a case in which a standard is withdrawn from the list of Harmonised Standards, the current situation with market surveillance in the different Member States, the influence of the economical crisis on the use of PPE and, finally, some points about innovation in the PPE sector.

Revision of the PPE directive

As the current PPE directive is working quite well in the majority of cases, there is no need for drastic changes. However, we need to take the opportunity to improve and strengthen the current system.

In doing that, there are a few priorities. Of course the first priority is the safety of PPE users, and, thus, the correct functioning of the products within all foreseeable circumstances. But, for manufacturers, certainly there is also the priority of ensuring a transparent and open market for PPE products within Europe. These two principles must be kept in mind at all times when discussing revisions to or interpretations of legislation.

Already, with the New Legislative Framework (regulation 765/2008 and decision 768/2008), both the system of market surveillance and Notified Bodies are improved. The parts of the decision dealing with these issues must be included in the revised PPE directive, as they will improve harmonisation between Member States in these matters.

On the other hand, we must monitor that the burdens (such as economic costs or the indirect cost in labour) for the suppliers are not unnecessarily increased. As we see with the revision of standards, there are usually extra burdens, for which, in several cases, the added value for the safety of the user or product is questionable. A careful assessment of the impact must be made - which was foreseen by the EU Commission in the Impact Assessment Study prior to the revision. Questions about how to comply with the different directives that apply to one product are becoming more and more common. Clear rules about conformity assessment procedures, the role of different notified bodies in the conformity assessment and the (EC-Type Examination) certificates following this assessment, the declaration of conformity, labelling and user instructions should be included. For the user, there is only one product, regardless of how many different directives apply. But, in some cases, the directives almost contradict each other in certain aspects, which make the life of manufacturers far from easy.

It is clear that, in the period between the preparation of the current Directive and now, not only the markets in Europe but also the behaviour and awareness of citizens have been changing. This means



that some products that were not considered in the current Directive must be taken into account in the revision. In most cases, correcting the categorisation of the PPE is quite clear for all stakeholders; in other cases, the impact for the market (both manufacturers and users) could be very important.

The definitions and responsibilities for different economic operators as foreseen in the decision 768/2008 are certainly an important improvement for the system. If applied properly, the decision will prevent a number of non-compliant products from entering the EU market, certainly when it comes to the sales of PPE products to consumers by non-specialist distributors.

From time to time we hear discussions about the need for an additional quality mark for PPE products, be it Europe-wide or at the national level. For manufacturers, this would be going back to the days before the unified open market in the EU, and, thus, would represent a step back instead of a step forward. Therefore, any strengthening of the CE mark for PPE products is welcomed and the purpose must be that the CE mark is, in and of itself, proof of quality safe products.

In the process of changing the PPE directive, sometimes we tend to change things that are working to the satisfaction of all stakeholders. We must be careful not to go that route. For instance, the current conformity assessment procedures have worked well for the last 20 years. There is no reason to change them, as that would have a major impact on the market without offering any improvement to the products. For instance, module H has always been and remains a strong no-go for manufacturers.

Validity of EC-Type Examination Certificates

The discussion about the limitation of the validity of EC-Type Examination Certificates is still ongoing. In the current PPE Directive, there is no mention at all of a validity period. In the past there was a Recommendation Sheet (RfU) from the Horizontal Committee of Notified Bodies (HCNB) recommending that the EC-Type Examination Certificates were to have no limitation in terms of validity. However, following several discussions and some input from the legal services of the EU Commission, in 2009 the HCNB issued a new RfU in which they recommended limiting the validity of the EC-Type Examination Certificates to five years for all new certificates.

This presents manufacturers with many potential problems and questions. First of all, we wonder what the added value is for the safety of PPE. In this respect, we do not see any advantage. On the other hand, this raises a number of questions. For instance, will there be harmonisation so that all NBs throughout the EU act in the same way? What about the national legislation on notification of NBs? Does this allow for such a change in all countries? Will the Member States enforce this recommendation in the same way in all countries? Will there be a harmonised approach throughout Europe? Will this lead to the retesting of existing products? Will there be clear procedures for everyone involved?



Manufacturers are not at all in favour of this situation, as the only certainty they have is that it will bring extra costs for them. So far the only signs of how these changes will affect manufacturers have been even more confusion in the market and a risk of serious disturbances to the market, and all this without added value for the users of PPE products.

Only if it can be guaranteed that there will be full transparency and harmonisation (both in legislation and application) – which will be difficult to achieve unless laid down in legislation – will the limitation on the validity of the certificates be acceptable to manufacturers.

Withdrawn standards

If a standard is withdrawn from the list of Harmonised Standards, there is a very good reason for doing so and there is no argument. However, each time this happens we end up in a period of uncertainty for all stakeholders, including manufacturers. Indeed, what should we do with products that are produced and tied to the stock market? How do we get products certified, since, in most cases, there is no agreement yet on revised or additional tests for the products? How will market surveillance act and will they act in a harmonised way in all countries?

We should be able to come up with a procedure to solve these types of cases in a structured and harmonised way. Even from the very beginning of discussing the withdrawal of a standard, all consequences should be assessed – it may not be that, because of the withdrawal, an even more dangerous situation occurs for the users of PPE products. Close cooperation between all stakeholders is necessary to ensure that the period of uncertainty is reduced to the absolute minimum or, even better, nonexistent.

Market Surveillance

For manufacturers, effective Market Surveillance is a key factor for ensuring safe PPE and fair competition. Too often, we have the impression that compliant actors are punished for the behaviour of noncompliant actors, instead of the other way around. Indeed, adding rules and burdens without any effective Market Surveillance will have the opposite effect. The compliant actors will follow the added rules and, thus, have extra costs, while the non-compliant actors will not follow these rules and, thus, will end up with an even bigger cost advantage. This is the world turned upside down and we have to work together to avoid this kind of situation.

Market surveillance is the referee in the playing field of the PPE sector and it has to be able to do its job effectively. Only then can the game will be played in a fair way for all competitors. ESF has been and is willing to cooperate with market surveillance authorities as long as it leads to safer products and a fairer market where the non-compliant actors realise that there is no place for them in the European market.

Use of PPE in times of crisis



The recent economic crisis hit the European economy hard and of course this has also had an effect on the PPE market. The number of occupational accidents and work-related health problems remains too high in Europe (and also in the rest of the world). The influence of the crisis on these numbers is not yet visible, but it is feared that the situation will worsen because of savings made in all industries. Another aspect is the fact that authorities are also bound to find savings; if these savings affect market surveillance and labour inspection, they will have a negative impact on safety within companies. Specialised PPE suppliers make efforts to make clear that PPE (and OHS in general) represents not a cost but an investment for their customers. If the principles of selection, use, care and maintenance are properly followed, the users will be better protected and the total cost of PPE ownership will decrease.

Unfortunately, OHS is not perceived in a positive way. Indeed, in the media we only get news about work accidents or serious health problems and then only in a very negative way. Even if the environmental issues are as negative as safety issues, the perception by the public is totally different. It is more than time to start promoting PPE in a positive way. The involvement of PPE stakeholders in the general OHS community is certainly necessary to make sure that PPE is considered as an essential part of OHS and not as a 'bad medicine' that needs to be avoided. ESF had many positive experiences through their partnership in the European Campaign, set up by the European Agency for OHS, and will continue to work together with the agency in the future. Training at different levels, as well as for PPE experts and users (all social partners) and authorities, is also an essential part of the work needed to ensure that PPE is viewed in a positive light.

Innovation

Even if sometimes we hear that the PPE sector is not innovative, it is clear that the PPE industry is making many efforts to bring innovative products and the safety and comfort of PPE to an even higher level. Unfortunately, because of the economic crisis, it is not always easy for companies to spend numerous resources on research and development, even if it is clear that these will be a key to success in the future.

Initiatives such as the Lead Market for Protective Textiles and the Technology platforms for Industrial Safety and for Textiles and Garments are supporting efforts to innovate with PPE. At the moment, at least seven research projects supported by the EU commission have a link to the Lead Market Initiative. As ESF, we can only support these initiatives and make them known to our members so that they can benefit from the support given by the EU and national authorities.

Under the Lead Market Initiative there is also a project concerning the role of public procurement in innovation. The idea is to set up a network of public procurers where information and expertise on innovative protective textiles can be exchanged. ESF is – together with Euratex and ETSA – closely monitoring this project as we do not want to see this network being used to put even more price pressure on PPE bought through public procurement. At this moment, public procurement is indeed putting too much weight on price and too little



weight on quality and innovative solutions. Any effort to turn this around deserves our support and will get it.

Conclusion

Even if the PPE sector is not the worst organised sector or performing poorly, there are still many issues that need to be resolved in order to improve the situation for suppliers and also for the users of PPE. Any concern on the part of ESF is based either on providing improved safety for the users at all times or on fair competition for the suppliers. We hope to be able to continue this strong cooperation with other stakeholders and even to strengthen this cooperation.



4. Situation in the PPE sector – perspective of the Notified Bodies

Karl-Heinz Noetel, BG BAU, Germany

Introduction

Together with manufacturers, authorities, market surveillance and users, the Notified Bodies are an important stakeholder in the PPE sector, as the majority of PPE products have to be subjected to type examination before being placed on the market. The New Legislative Framework and developments with regard to the revision of the PPE Directive will have an impact on the work of the Notified Bodies active in the field of PPE, and their experiences and views can contribute to defining the best possible approach for optimising the system.

The European Coordination of Notified Bodies for PPE

The European Coordination of Notified Bodies in the field of PPE was established in 1991 in order to allow Notified Bodies to discuss questions that arise in the implementation of the PPE Directive, for example with regard to in the context of certification procedures or with regard to the actual testing of products and to propose common solutions.

The structure of the Coordination of Notified Bodies was set up at the initiative of the Notified Bodies themselves. Later, the EU decided that coordination is needed in order to harmonise procedures and activities among the Notified Bodies within the framework of New Approach Directives and to have a contact point for the stakeholders in case of questions. For a number of years now, the Technical Secretariat of the Coordination of Notified Bodies has received some financial support from the EU Commission, and is supported by an administrative secretariat and financed by the EU for the organisation of meetings.

The main body of the Coordination of Notified Bodies for PPE, the Horizontal Committee, discusses general questions in the context of conformity assessment that apply to all types of PPE. Documents and discussions for the Committee meetings are prepared an Advisory Panel made up of a smaller number of Notified Bodies.

Questions in the context of quality assurance (Article 11 of the PPE Directive) are discussed in a separate group, which consists of those Notified Bodies that offer services to Article 11 of the PPE Directive.

In addition, for each individual type of PPE, there is a so-called Vertical Group which meets to discuss questions relating to the application of test procedures for specific products, for example those specified in the standards. There are 10 Vertical Groups altogether, numbered 1 to 5 and 7 to 11.

The working results of the Coordination of Notified Bodies are laid down in so-called "Recommendation for Use" sheets. They summarise the



discussion results of the Notified Bodies and recommend solutions to questions relating to a harmonised approach to certification procedures, the application of PPE standards, PPE test methods, etc.

The recommendations agreed to by the Coordination of Notified Bodies certainly are of interest, not only to the notified bodies themselves but also to manufacturers, market surveillance authorities, or even users of PPE, and they should be made available to all stakeholders. Therefore, the "Recommendation for Use" sheets are being published via the EU website, although not all of the Vertical Groups have their documents uploaded yet so far.

To ensure transparency, and to allow for an exchange of views and the discussion of certification-related issues among all stakeholders, representatives from the EU Commission, AdCo (market surveillance) and CEN, as well as representatives from the European manufacturers' federations, are invited to participate in Horizontal Committee meetings as observers.

The Notified Bodies – via the Chairmen / Technical Secretariat of the Coordination of Notified Bodies – are involved in the discussions of the Standing Committee at the EU Commission about implementing the PPE Directive at the level of the PPE Working Group. The Technical Secretariat has also been involved in the drafting of the Guidance Document that the EU Commission publishes on the PPE Directive, so that the contents of the Recommendation for Use sheets could be transferred to the guidelines.

In addition, in order to ensure a flow of information and cooperation with regard to issues of standardisation, the Technical Secretariat of the Coordination of Notified Bodies is one of the stakeholders represented in the PPE Sector Forum at the CEN level.

Unfortunately, AdCo does not always facilitate such cooperation, although the exchange of views was found important at the rare occasions that a representative from the Coordination of Notified Bodies was invited for parts of an AdCo meeting.

Especially now, in the discussions on the Revision of the PPE Directive, the Notified Bodies consider it extremely important to build up on these relations and to continue an exchange of views and experiences between all parties.

The New Legislative Framework and the revision of the PPE Directive

The Notified Bodies generally welcome the New Legislative Framework, which has been developed following a general review of the New Approach.

Regulation 765/2008/EC deals with the requirements for accreditation and market surveillance, and so does not have direct consequences for the Notified Bodies. However, changes and improvements to the accreditation and notification systems and market surveillance are of great interest to the Notified Bodies.



Accreditation

In discussions about the certification procedures applied by the Notified Bodies and attempts to bring about a high level of harmonisation, the Notified Bodies often find that differences are caused by the different approaches of the Member States when it comes to issues such as:

- The monitoring of / reporting by Notified Bodies to the Member States
- The obligation for Notified Bodies to be involved in standardisation and coordination activities
- The rules for sub-contracting tests
- The way in which uncertainties of measurement are handled.

An exchange between the Member States and the discussion and harmonisation of accreditation practices in the various Member States through the EA will hopefully help create a level playing field for the Notified Bodies.

Market surveillance

With regard to the market surveillance aspects of the regulation, there seems to be general agreement among all stakeholders that market surveillance is important within the single market and needs to improve and be strengthened for the PPE system to work. The regulation, with its demand for transparency in the Member States' cooperation and a harmonisation of programmes, seems to be a good starting point for such improvement.

From the perspective of the Notified Bodies, it is important to improve cooperation with the authorities. Within the context of safeguard clauses, or when non-compliant products are found on the market, Notified Bodies should be involved to clarify whether the product actually conforms to the type that was submitted for type examination procedures. Also, with regard to the increasing number of false certificates, there should be early contact with the Notified Bodies to check out the situation.

Although Notified Bodies should not be involved directly in market surveillance activities, authorities in some Member States do involve Notified Bodies for re-testing. Others rely on their own laboratories. Since not all test laboratories used by the Member States are aware of the discussions in the Coordination of Notified Bodies and the Recommendation for Use sheets, contact with the Notified Body that was involved in the type-examination procedure would be important in order to check the test procedures and test results.

Decision 768/2008/EC, on a common framework for the marketing of products on the work of the Notified Bodies, is even more important for the Notified Bodies. Although the Decision does not automatically apply, it sets out a common framework and will have a harmonising effect when directives are revised. The imminent revision of the PPE Directive offers a good opportunity to introduce some aspects from the Decision, so that the entire PPE system can benefit.



Participation in the activities of the Coordination of Notified Bodies

One of the most important issues for the Notified Bodies is the possibility given by the Decision to introduce into the revised Directive a requirement which makes it mandatory for the Notified Bodies to participate in the work of the Coordination of Notified Bodies and in standardisation activities.

At present, the corresponding requirements for the notified bodies vary considerably between Member States. Some Member States require the Notified Bodies to participate in coordination activities at a national level and even to apply decisions taken in the national committee. In other Member States, there is no national coordination, and participation in the European coordination group is not on the agenda.

As a consequence, only about 50 to 60% of the approximately 110 Notified Bodies in the PPE area attend the meetings of the Coordination of Notified Bodies or participate in round robin testing, which is organised within the Vertical Groups in order to ensure that test results obtained by the Notified Bodies are comparable. By non-participation, Notified Bodies not only save costs, they also lack knowledge of ongoing discussions and the underlying problems, for example with regard to test methods or the improvement of their test equipment. A similar argument holds for standardisation activities that provide detailed knowledge about developments as well as the possibility of actually improving test methods and the assessment of the use of the product.

Also, the application of Recommendation for Use sheets could be made mandatory, so that the same criteria are applied to the testing and certification by the Notified Bodies. This would help reduce discussions with manufacturers and authorities about PPE specifications, test results and the compliance of products. An example from current discussions where this is extremely important is the application of the Recommendation for Use sheet to the validity of certificates. Against the background of experiences from the past, the Notified Bodies agree that it is beneficial for the system if areview of EC-Type Examination Certificates would be required after five years. This will, for instance, allow for a monitoring system for certificates for the manufacturer and the deletion of certificates for products that are no longer produced. The time limit on certificates is also regarded as one step towards better control of the application of revised standards, when safety requirements were substantially changed. The Recommendation for Use sheet has been confirmed by the Member States, and the sheet is going to become applicable soon. However, due to business interests as well as the need to ensure uniform application by all Notified Bodies, there are as yet some Notified Bodies reluctant to apply the recommendation. The issue of defining a common procedure for reviewing certificates once the five-year period is up will remain on the agenda at the next Horizontal Committee meeting.

Other examples where there are difficulties in the application of Recommendation for Use sheets come from the area of the implementation of Article 11 of the PPE Directive. Based on the traditional testing schemes before the PPE Directive was enforced, Notified Bodies developed very different ways of carrying out Article



11A procedures, especially with regard to sampling and checking for homogeneity of production. A relevant recommendation has been issued some time ago, but not all Notified Bodies follow it. With regard to Article 11B, there seem to be some Notified Bodies who consider ISO 9000 testing to be sufficient, without the involvement of a PPE expert. To maintain the quality of category 3 PPE, the application of a procedure in line with the PPE Directive has to be ensured.

Conformity assessment modules

The conformity assessment modules defined in the annex of the Decision are based on the old modules decision document, with some changes and precisions. The conformity assessment procedures in the current PPE Directive do not match the modules and, when the PPE Directive is revised, the application of the different modules to PPE will be re-discussed.

One of the issues in this regard is Article 11A. Currently, many manufacturers, especially SMEs, opt for that article to verify their quality control measures. The implementation of Article 11A has been a discussion point among Notified Bodies for a long time, because the text of the Directive is not very clear about the procedures. With the descriptions given in the current Recommendation for Use sheets – and when they are applied by all Notified Bodies – the procedure could be maintained. Otherwise, a suitable module will have to be chosen, which will bring about the need for manufacturers to change their procedures or change to what is currently Article 11B. There is a need to carefully consider the implications that such a change in the application of quality control would have.

Another discussion that has been on the agenda for quite a while is the application of module H (full quality control). This is not considered to be a suitable module for PPE, mainly because of the lack of a type test. The Notified Bodies have presented their arguments several times, and in previous discussions their objection against the introduction of module H has been supported by a number of Member States. Still, there is a need for further discussion, one which would also take into account the effects that the introduction of module H would have on market surveillance.

Finally, there is no module that would clearly be applicable to custommade equipment, such as eye protection with corrective glasses, orthopaedic footwear, ear-moulded hearing protectors, etc. With the lack of clear requirements in the current Directive, various procedures have been developed for assessing the conformity of products that are adapted to the wearer. Those solutions should now be included in the Directive, based on the experience of manufacturers and Notified Bodies.



Harmonised standards

The New Legislative Framework Decision also proposes new text with regard to Harmonised Standards. One discussion point for PPE has been the question of whether a Harmonised Standard has to cover all basic health and safety requirements, and whether a standard can be considered to provide presumption of conformity if it does not cover all basic requirements. The revision of the Directive will be an opportunity to settle the argument and to make sure that all safety aspects of the product are taken into account during product design and certification. At the same time, what is urgently needed are better, or rather more complete, PPE standards, so that the Notified Bodies do not have to draft their own test methods. If there is to be testing beyond what the standard considers necessary, the Notified Bodies should agree on a common approach.

And finally, there is still a need to define what is required when a standard has been revised. There needs to be a common understanding of manufacturers, Notified Bodies and market surveillance authorities on when the old standard loses its validity, when the changes are so significant as to require new certification, and how to make sure that products are modified when a new standard has been published. So far, there has not been any full answer on those questions, and the revision of the PPE directive should be a chance to make progress in this field.

Outlook

There are many other questions within the context of the implementation of the PPE Directive that the Notified Bodies follow with interest or concern. Those include an increase in the number of formal objections against standards, the way safeguard clauses are dealt with, points of overlap with other Directives and new products that require decisions as to whether or not they are PPE and which category they should be in.

The revision of the PPE Directive comes at a time when the PPE market is also affected by the global crisis. PPE users are looking for low-cost solutions and trying to buy products at lower prices and use them for as long as possible without replacing them. Manufacturers try to cut down on certification costs by having certificates amended or extended instead of carrying out full type-examination procedures for new product lines or after the revision of a standard. And, some Notified Bodies may try to keep up their business by reducing their commitment to common procedures and recommendations.

Particularly in such situations, is it necessary to join efforts to keep up and improve a system that has worked quite well in the past? The New Legislative Framework and the revision of the PPE Directive are a good opportunity for all stakeholders to address the issues at hand and to find clear and practicable solutions that will ensure a transparent and stable PPE system.



5. Situations in the PPE Sector – perspective of a market surveillance authority

Pirje Lankinen, Ministry of Social Affairs and Health, Finland

In Finland, the market surveillance of personal protective equipment is divided between two authorities. The occupational safety and health administration deal with the PPE primarily used in workplaces. The administration consists of the Ministry of Social Affairs, which is responsible for coordinating market surveillance activities and cooperating with the European Commission and Member States. The Ministry is the authority with the power to restrict or ban the use or the marketing of non-compliant PPE products. The second authority in the OSH administration is labour inspectorates, or, currently, five areas of responsibility for occupational safety and health, which operate in the organization of regional state administrative agencies. Inspectors are responsible for checking PPE at workplaces, stores and fairs. In cases in which a PPE is considered dangerous for the user, the inspector may temporarily ban the use and sale of the product. Information pertaining to the temporary ban will then have to be sent to the Ministry for a hearing and, when there are grounds for it, a decision.

PPE intended for consumers is an entity of its own and is supervised by the Safety Technology Authority (earlier Consumer Agency), which takes care of its field independently.

In the beginning of 2010, the EU Regulation on Accreditation and Market Surveillance (765/2008) came directly, without implementation, into force in all EU Member States. This so-called NLF regulation outlines the requirements of market surveillance for Member States. The basic requirement is to make sure that there are enough resources for market surveillance. This is essential, because a lack of resources is the main obstacle when it comes to effective activity.

The Regulation requires the Member States to establish, implement and also update market surveillance programmes. This is expected to bring good structures and intensity to market surveillance, even though in many Member States there have been programmes in place already before the requirement to publish them. Every Member States has to inform the Commission, the other Member States and the public about its market surveillance programs for different products. With ever-developing programmes, it is hoped to ensure that the efficiency of surveillance can be maintained to as great a degree possible given the limited resources.

There are or will be new information channels for market surveillance authorities in the Member States. The Community Rapid Information system is meant to inform what measures are taken or intended to be taken on products presenting a serious risk. In Finland, this presents three important problems. First, the information system does not yet exists, even if the requirement to use it came into force at the beginning of 2010. Second, there seems to be a problem concerning informing about the intended measures. What if it all turns out to be a false alarm? The legal protection of economic operators has to be taken



into consideration. Third, as the concept of a serious risk is not defined, it could be interpreted in different ways in the various Member States.

Another information system will also be created for products that are dealt with in market surveillance. With this general information support system, it will be possible to share information on both compliant and non-compliant products that have been checked. Hopefully, in this way the amount of overlapping work, that is, checking the same products in many countries, will be diminished. The information system will help market surveillance authorities to concentrate on products that have not been examined yet.

Cooperation between national and international market surveillance authorities, including the customs, should be developed and deepened. This has already been discussed in the PPE-ADCO, which is a group for administrative cooperation of market surveillance authorities operating within the European Economic Area (EEA). Hopefully, there will be many successful joint market surveillance projects in future.

In Finland, the PPE market surveillance programme will be updated yearly, even though the purpose is to plan market surveillance projects for four-year periods. The programme is available on the Internet since that is the most efficient media for reaching the public. However, we must consider how much an authority can reveal without damaging or endangering the quality and purpose of market surveillance. Because of this, the programmes are kept rather general, while still offering the required information.

In Finland, cooperation in market surveillance is carried out at three levels. Nationally, the Ministry cooperates with labour inspectorates, the Safety Technology Authority and Customs. Until now, activities with the Customs have been relatively rare and case-specific, but actions to create a functioning cooperation began last year. Internationally, Nordic cooperation has long traditions in the form of PPE market surveillance projects and sharing views on matters dealt with at the European level. Five countries take part: Denmark, Finland, Iceland, Norway and Sweden. For 2010, there are plans to develop Nordic cooperation to make it even more efficient and beneficial. Europe-wise, PPE-ADCO is an important forum for market surveillance authorities. The group meets twice a year to discuss and solve problems encountered in market surveillance and to share information between authorities.

The NLF regulation puts a new kind of emphasis on market surveillance and its importance. This means facing new challenges. Surveillance needs structures to maximise the time that can be spent on actual market surveillance operations. Cooperation on all levels is needed and there is still room for development. The European market is changing, as it seems that more and more products are imported from third-party countries (meaning countries outside the EEA). In third-party countries, the European requirements for PPE are not always familiar and the importing of non-compliant products can pose a challenge to the European market surveillance. Once put into use, the systems will enhance information exchange between the Member States, which will benefit the work of market surveillance authorities.



All the improvements made to market surveillance will help in achieving the goals of having safe and compliant personal protective equipment on the European market as well as ensuring the smooth functioning of the internal market.



6. Suitable modules for PPE

Hans Christian Simanski, DEKRA EXAM GMBH, Certification Body, BOCHUM, Germany

6.1 Introduction

A comparison of the existing modules of Directive 89/686/EEC (PPE directive) and Decision 768/2008/EC by the European Parliament on a common framework for the marketing of products, which replaces Decision 93/465/EEC, could be elaborated upon to a much greater degree and, thus, be beyond the scope of this presentation. This is the reason for some necessary assumptions for such a comparison in order to keep it as short as possible:

- The implementation of a new PPE directive or the implementation of new modules should not result in increased demands, whether for manufacturers or for the Notified Bodies, which would lead to the further result of the customer needing to pay for this additional work.
- 2. The modules of the existing PPE directive and decision seem to be quite similar, but they, in fact, vary, and not just in the details. Under the estimation that the actual modules of the PPE directive represent an approved and consensual approach, the modules used for type examination and production control should be replaced with a similar approach from the decision on so-called adequate modules. The requirement for adequate modules could support the planned omnibus approach for the revision of the PPE directive.

Nevertheless, we should make use of the opportunity to introduce new modules so that it becomes necessary to comment on the modules that are different from the existing ones, such as Module H. Awareness acclaim of the reasons for choosing a module is necessary. As the author works for a Notified Body, it will be – of course – more from the perspective of a notified body.

Even if we were to replace the old modules in the PPE directive with adequate modules from the decision, it would result in different requirements for the stakeholders. Thus, it is important to be aware of the consequences of deciding for or against a particular module.

For the last ten years there was a lively discussion about the revision of the PPE directive. A first draft of a revised PPE directive was discussed from about 2001 until about 2005. Already at that time the Notified Bodies agreed to the disapproval of conformity assessment procedures for PPE category 2 or 3 without any third party type testing. The Machinery Directive 2006/42/EC includes Module H as an alternative to type examination. There is a strong suspicion that other directives will follow this example. Even within the field covered by the machinery directive, Module H is still being discussed, even though the module has already been used in the pressure equipment directive and the lifts directive for years.



6.2 Category 1: Internal production control

Even if a manufacturer does not need to involve a Notified Body, for PPE category 1 there are methods, mechanisms and differences for the conformity assessment procedure similar to the other two categories. The basis for this is the same for the three categories and for the different modules.

Module A, the so-called "internal production control" module, is, generally speaking, similar to the existing conformity assessment procedure for PPE category 1. As the existing PPE directive has already been in effect in the field of the new approach directives for a long time, its wording and structure are out of date. It is welcome that the decision about the new modules follows a clear straight line. This comprehends a clear statement that the manufacturer is responsible for the compliance, safety and conformity assessment of his or her products.

The decision also mentions Modules A1 and A2. Both modules do not seem to be adequate with the existing approach. They require supervised testing and checks. Compared to the existing conformity assessment procedure, this may entail an additional expense for the manufacturer. Our experience with the actual internal production control for PPE category 1 does not demonstrate the need for additional controls during production. Since 2005, only 9 out of 45 RAPEX alerts for PPE correlate with category 1 products. Most of these 9 alerts have pertained to chemical hazards.

Module A, as well as the other modules, includes the requirement to add an "adequate analysis and assessment of the risk(s)" to the documentation, which is necessary for the conformity assessment procedure. This approach seems to follow the other new approach directives, in which the manufacturer usually assesses the risks and has to determine how his product should or could be used. With this goes the hope that PPE products will be designed even more for the needs of the users than for testing according to the standards.

Two other changes would also affect the technical documentation. A description of the test facilities is no longer required. This issue is in conjunction with production and not related to the design of the PPE.

Considered as a whole, it appears that module A from Decision 768/2008/EC is an adequate replacement for the existing conformity assessment procedure of category 1 PPE.

6.3 Category 2 and 3: EC-type examination

The EC-type examination Module B is probably the least controversial module of the decision. The reason for this is that there are only minor variations between the existing EC-type examination module and Module B in the decision.

An agreement between the manufacturer and the Notified Body about the test location is required by Module B. However, notifying authorities often insist on conducting tests with the Notified Bodies' test equipment. The differences in the technical documentation as well



illustrate only minor changes and reflect common practice. For example, should it be self-evident for a Notified Body to issue on a test report.

In the view of a Notified Body are the duties for information the interesting topics of Module B. The Notified Body shall inform his or her notifying authority about the issue and withdrawal of certificates. This requirement can already be found in existing national notifying requirements. Regardless of the ongoing discussion about the validity of EC-type certificates and the state of the art, as it is reflected in the discussion about the Recommendation for Use Sheet number 136a, monitoring of the certificates is required. The Notified Body has the duty to "keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of the legislative instrument, and shall determine whether such changes require further investigation." If they do, "the Notified Body shall inform the manufacturer accordingly." This legislation holds the Notified Bodies responsible for their certificates, regardless of a limitation on the certificate's validity. To charge the Notified Bodies with the monitoring of their certificates is a self-evident solution. Nevertheless, this is not a solution for outdated certificates.

There is enough room for interpreting the duties of a Notified Body as reflected by the duty to inform the manufacturer.

- Does this mean that it is sufficient to send an e-mail?
- Or, does it mean that the Notified Body should withdraw the certificate?

This is an example which shows that a strict rule for the limitation of the validity of certificates is desirable. This simple rule will dispense with outdated certificates.

6.4 Category 3 – article 11A: Conformity to type

For category 3 products, there exists production control according to Articles 11A and 11B. The 11A Module, for the control of production or products, has been criticised by the Notified Bodies for some shortcomings. It was also discussed if a module like Article 11A is still necessary or whether only modules which cover the quality system approach should be used. Experience shows that small and medium sized enterprises in particular, which produce only products with few variants, favour the 11A approach as it is less complex and less expensive. Against this background, a module similar to Article 11A should be introduced in a new PPE directive. This was already emphasised by the Notified Bodies in 2004.

In Decision 768/2008/EC you can find several modules called "conformity to type" modules. Module C relies exclusively on the manufacturer, without any involvement by a third party. This would lead to a lower level of safety compared to the involvement of a third party. Module C1 requires tests for each product, which causes additional expenses for a manufacturer. These are only two examples of why Modules C and C1 are not adequate together with Article 11A. The requirements of module C2 are, in general, very similar to Article 11A. The Article 11 ad-hoc group agreed during its last meeting that Module



C2 is a suitable replacement for Article 11A. In 2004, the group discussed the suitability of Module F, too. This module requires batch or lot testing of the products. Modules C2 and F would introduce the following differences: Samples of the final product should be taken on site.

This was discussed by the Article 11 ad-hoc-group during the last few years. Now there is a clear statement in the modules that samples must be taken on site by the Notified Body.

The requirement for the assessment of inhomogeneity and the selection of samples will be replaced with product checks in order to assess the quality of the internal checks. This and the reference in the modules to the EC-type certificate and standards shall guarantee a check of product conformity. The reference to the essential health and safety requirements, which were criticised for some time by the Article 11 adhoc group, will disappear. This leads to a clear definition of the tasks during the first phase (EC-type testing with a check of the essential health and safety requirements) and the second phase (production control) of the conformity assessment procedure.

When applying Module C2, the manufacturer can choose between an accredited in-house body and a Notified Body for product checks. If a Notified Body checks the product, the number of the Notified Body must be affixed on the PPE product. Up until now, it was good practice for inhouse bodies and Notified Bodies to have different levels of independence. It could be assumed that a Notified Body acts more independently. This could lead to a different level of safety. In the view of the users, that would be a disadvantage. The user cannot rely on an equivalent level of safety for the same category of product and she or he must have a deep knowledge of the PPE directive and the required marking in order to discover the difference after the CE mark.

On the other hand, a manufacturer must choose between batch testing or lot release testing when applying Module F. Similar to Module C1 could, this leads to additional expenses for the manufacturer. It should be similar when a manufacturer manages to develop a smart and suitable solution for the tests.

In summary, a modified Module C2 as well as Module F are adequate together with Article 11A. Both modules are, in important sections, similar to a draft for a new article 11A by the Notified Bodies from 2004, which help allay the Notified Bodies' concerns. Nevertheless, it must be stated that the choice between an accredited in-house body and a Notified Body is not an equivalent solution; this is true not only from the viewpoint of a Notified Body. When Module C2 will be introduced, it is desirable that the possibility for adapting the module because of "sectoral needs", as mentioned in paragraphs 5 and 6 of the considerations of Decision 768/2008/EC, is used to delete the accredited in-house body in this module in order to achieve an improved and adequate replacement for Article 11A.

6.5 Category 3 – article 11B: Quality assurance

During the last meeting of the Article 11 ad-hoc group in 2009, the group favoured Module D as a replacement for Article 11B. The group noticed that Module F is a possible solution, too, and, in 2004, Module E



was found to be acceptable by the Notified Bodies in general. This reflects that the Notified Bodies have been holding lively discussions on the module issue since the start of the first attempt to revise the PPE directive.

When we compare the three modules, we find that only Module D includes the production process and does not only focus on the final product, as Module E or F do. Considering the aforementioned established presumption of adequacy, only Module D is adequate for Article 11B. The differences between Article 11B and Module D can be seen as negligible. Module D may even represent an improvement. For example, the manufacturer must submit a written declaration acknowledging that the same application has not been filed with any other Notified Body, that he has to hand over copies of the corresponding EC-type certificates and that the Notified Body may carry out product tests where necessary.

Module D is an acceptable replacement for Article 11B.

6.6 What is left?

At the end, there are still some unresolved issues with the existing PPE directive. It is important that revision of the directive also be used to stimulate a lively discussion about the decision modules and a search for solutions which could improve the PPE directive.

All the major and minor improvements which have been laid out in about 83 horizontal Recommendation for Use sheets, in the PPE guidelines and in the discussions from 2004, during the last attempt to redraft the PPE directive, have been neglected in this presentation. But it is highly desirable that this experience will influence a new PPE directive.

For years, the Notified Bodies discussed the handling of custom-made products like orthopaedic footwear, adapted safety glasses and hearing protection. The finished products are usually made outside the industrial environment by specialised shoemakers, opticians or hearing aid audiologists. The existing PPE directive contains no explicit approach for these products. Use of Module G is, in principle, possible but will multiply the costs for these products, as each product would be checked by a Notified Body and, should destructive tests be necessary, Module G is not really applicable for a unique product. On the other hand, it is possible to use proper instructions or manuals for the support of these specialists. This approach is covered by the existing modules. It follows a proposal by the Notified Bodies from 2004 and would be a simple solution which implies that the assembly is part of the use of the PPE. At this point, the question was raised regarding where the duties of a manufacturer end and the use of custom-made products begins. It is also possible to declare that the adaptation is part of the production. This solution is nearly similar to an agreement by the Standing Committee about the conformity assessment procedure for orthopaedic shoes. It would mean that production control is necessary for assembly or modification. A further discussion on this topic, which ends in a clear definition of the descent from production to use, seems to be necessary.



It is conceivable that the modules of other directives, like the ATEX Directive 94/9/EC, can be applied with the voluntary involvement of a Notified Body for products with a lower category, like category 1 products. Usually Module G is used to open the third-party tests for all product categories and it is also used as an adequate alternative for EC-type testing. These cases might be rare but the opportunity for manufacturers to use an alternative approach, especially for small batch series, should be discussed.

Module H has been discussed at different levels since the last attempt at revising the PPE directive in 2000/2001. Article 4 of Decision 768/2008/EC specifies the approach for the selection of conformity assessment procedures. Clause 1 (c) says that "where third party involvement is mandatory, the need for the manufacturer to have a choice between quality assurance and product certification modules" shall be possible. This demonstrates a strong demand for at least thinking about Module H as an appropriate conformity assessment procedure for PPE. If we look at the requirements of Module H, we will even discover that every manufacturer that claims to have applied the PPE directive will pretty much have fulfilled the duties of Module H. This shows that the issues which have been raised could not be rooted in the procedure itself.

It is, for example, difficult to know how to interpret the requirement in Module H to hand over the "documentation for one model of each category". The term "category" is not in all cases clear. If we look at the example of a self-contained breathing apparatus (scba) the term category can refer to scbas as a whole and to diving equipment or emergency equipment and to closed circuit or airline systems. The limits of the modules and categories have to be discussed and set in more detail. Otherwise, it could also come down to differences between the manufacturer and the Notified Bodies during the review of the documentation. The ideas of the manufacturer and the Notified Body of a model and its documentation, which is complex enough for Module H, must not necessarily be the same.

The manufacturer will have an additional challenge when it wants to use Module H. It will need personnel with two types of competence:

- 1) Knowledge about quality management, the system, responsibilities, and so on, and
- 2) Technical knowledge about the PPE directive, its modules and the PPE itself.

If you have only one of these types of competence you focus only on half of the problem. If you focus on the products, you could fail because you have no system for handling failure and, if you have no technical personnel, no one can identify problems with the product. These two types of personnel issue apply also to Notified Bodies [Jacques, 2009].

The experience of personnel is closely connected to product testing. Only if you test a reasonable number of products and a reasonable number of different products can you evaluate the small difference between safe and dangerous. If the personnel focus on the quality management system, they will be good at evaluating systems but no one will be able to evaluate the products in the future. The Notified Bodies can only preserve their knowledge when they employ experienced personnel to test the PPE.



The same loss can happen with test equipment. PPE must be tested both without Module H and with Module H. Tests are very often the only way to identify deficiencies in safety and the experience of the Notified Bodies resides in the fact that tests are necessary for exactly this purpose. If Notified Bodies cannot refinance their costs for test equipment for a sufficient number of tests they will have to close their laboratories. This will result not only in market adjustment and a loss of expertise. Small- and medium-sized enterprises in particular depend on external experts and test equipment. They often cannot afford laboratories like large companies.

When a Notified Body wants to issue an EC-type certificate it is, for the purpose of independence, usually not allowed to use the test equipment of the manufacturer or to accept test reports from the manufacturer. When the same Notified Body issues a certificate based on Module H for the same product, it must accept the same test equipment and test reports. That is a paradox and not an equivalent safety level.

6.7 References

- 1) Council directive 89/686/EEC on the approximation of the laws of the Member States relating to personal protective equipment
- 2) Decision 768/2008/EC on a common framework for the marketing of products
- 3) Minutes of the Article 11 Ad-hoc group, PPE Directive 89/686/EEC, held on 18 February 2004 (unpublished). Brussels. 2004
- 4) European Coordination of Notified Bodies for PPE, Comments relating to the amendment of the PPE directive (unpublished). Brussels. 2004
- 5) Article 11A, draft revision, a proposal of the Notified Bodies. Brussels: January 2004
- 6) Jacques, Guy: Report from the notified bodies, Conference Machinery in Europe. Brussels. 09. December 2009.



7. Information and markings

Guido Van Duren, Ansell Healthcare, President - Febelsafe

PPE have an important role to play in providing adequate protection in the workplace. There need to be good procedures for the selection of PPE and users should be fully trained and instructed about the PPE he or she is using. The choice of the appropriate PPE is extremely important because inappropriate materials can cause serious skin and/or health problems (short-term or long-term) to the users. The choice of correct materials and proper PPE is extremely difficult and sometimes very complex.

The "Information supplied by the manufacturer" – as required by the 89/686/EEC Directive – should be an important tool in the selection and use of the PPE. During an internal study conducted in Europe by Ansell in the glove market, the following facts were revealed:

- 50% of the manufacturers, importers or distributors have difficulties in implementing the Marking & Information requirements, due to financial concerns or due to compliance difficulties
- 50% of the employers and users have difficulties in understanding the Marking & Information requirements, due to insufficient information received or due to interpretation problems
- 50% of the glove wearer's do not know why they are wearing the gloves they are wearing
- 80% of the users or safety specialists have difficulties in understanding the instructions or do not even read them at all.

Moreover, a lot of the information mentioned in the instructions for use is based on data obtained through lab tests and this information may or may not reflect the actual conditions of end-use. Therefore, some information will need some interpretation that would only be applicable for safety specialists while other information would indeed be suitable specifically for the wearer of the PPE.

For example, EN performance levels achieved during lab tests (mainly achieved by tests in accordance with European EN standards), and the corresponding pictograms, are not well understood by the market and require real specialist knowledge to understand what they really mean.

Laboratory tests are static, while real-life is dynamic. In real-life, there is usually a combination of different hazards taking place, whereas with lab tests the PPE is only subjected to one particular static test. For example, with chemical protection, lab tests usually provide permeation breakthrough time test data, which are performed through constant contact of the PPE film with the chemical under static conditions. In real-life, there is also a combination of additional mechanical influences, such as the possible degradation of the PPE film, the issue of splash versus immersion, and higher working place temperatures, which could have an effect on the service life of a PPE.

Therefore, the EN performance levels and pictograms only provide an indication of and not the actual full service life of a PPE. This information could only be useful in defining the limitations on the use of



a PPE. This information is, therefore, only valuable for specialists but not really for the wearer of the PPE.

In addition, providing instructions for use each time, even with the smallest commercial packaging units, is quite environmentally unfriendly. Most of the instructions are disposed of anyway without having been read, and adding all the paperwork to each PPE item would contradict the objectives of Packaging & Packaging Waste Directive 94/62/EC, which requires that packaging waste be reduced to a minimum.

In conclusion, it is recommended to simplify the Instructions for Use for the wearer/user and to have additional Instructions for Use only for the safety specialist, which she or he would only then need ONCE for the selection process of his PPE. Moreover, training and education remain an absolute need in order to understand the information indicated in the Instructions for Use and for the user to know why the PPE has to be used and against which hazards it can be used and for how long. A suggestion could be to split the information in three parts:

- 1. The first part consists of the information essential for the selection of the PPE it is not necessary that this be attached to every single PPE product; rather, it can be provided prior to the selection to the specialists of the company that is buying the PPE or to the consumer at the place of sale and it is not even necessary to have this in a printed version and it is maybe not even necessary to have this in all languages.
- 2. The second part consists of the actual user instructions, which shall only contain information that is necessary for the wearer of the PPE to make sure she or he uses the product in the correct way this should be as short and simple as possible, since we all know that wearers do not read (or have the time to read) several pages of information. It would be better that this part be quite condensed. This part is certainly necessary in all languages and should be provided with every single product.
- 3. The third part consists of the information necessary for correct care and maintenance again not the information that is usually needed by the actual wearer, but the information needed by the specialists dealing with these matters and, again, it should be made available to the company that buys the PPE (and not with each product) or to the consumer (in that case, it will have to be with each initial commercial packaging).



8. Revision of (harmonised) PPE standards

Henk Vanhoutte, CEN rapporteur for the PPE sector and Secretary General, European Safety Federation (ESF)

Introduction

In this paper a few thoughts about the revision of standards and the impact on the PPE sector will be discussed. No solutions are given. Rather, I just provide some food for thought, which might be considered by the stakeholders in the standardisation process.

The PPE sector forum in the CEN system

Sector forums are advisory groups within the CEN system. The PPE sector forum is chaired by the PPE rapporteur. It provides a forum for the PPE TC's to discuss horizontal matters and it also provides links to other TCs, to CEN management and to other stakeholders.

The mission of the PPE sector forum is to support the work of the PPE TCs by providing relevant information on legislation, standards and other relevant horizontal issues, including emerging risks. The PPE sector forum also enhances networking amongst the PPE TCs and stakeholders, and, finally, discusses and offers solutions for horizontal issues.

At the moment, a library is being built for the PPE TCs that includes information on horizontal issues such as innocuousness, uncertainty of measurements, environmental matters and ergonomics. The library also has information on emerging risks and the discussions at the meetings of the sector forum.

Questions for TCs when revising standards

When EU legislation is being revised, an impact assessment study must be made. It would be useful if TCs made a simple impact assessment when revising standards as well. What will the impact be for the manufacturers and other market actors, for the Notified Bodies, and for the market surveillance authorities? Most importantly, what impact will it have for the safety of the users of the PPE?

If there is a revision, is it necessary to question all parts of the standard? Or, can the revision (and thus the impact) be limited to only those parts that are giving problems and that are not up-to-date with state of the art? Why is it that with a revision of a standard there are always extra requirements? Why not delete those requirements that do not offer any added value for the safety of the user of the PPE covered by the standard?

Should it be necessary with each revision to check whether or not all applicable Basic Health and Safety Requirements from the PPE directive are covered by the standard? If not, is it possible to cover the missing ones?

Just as standards should follow the state-of-the-art requirements, standards should also be innovation friendly. Therefore, it should be



checked if the test methods and requirements are also applicable to new materials or products. But, at the same time, existing PPE that have proven their value in the field must still be covered by the revised standard.

And, finally, the end user of the PPE must be kept in mind at all times. Will the revision be a source of confusion for them? Is there added value for the end users? The safety of the users should be the sole priority of the standardisers.

Some other considerations

To be able to create standards (or revisions to them) that take into account the concerns of all stakeholders, it is important to have balanced TCs and working groups. This is certainly a challenge as the work is time consuming and not all stakeholders are organised to spend the resources necessary. However, all the stakeholders who are involved must strive to include not only notified bodies and manufacturers, but also, for instance, users and authorities in their work. Good balanced groups working to prepare the standard should have a positive influence on the quality and acceptance of the document.

In recent years, the importance of environmental aspects has only increased and both the EU Commission and the CEN are encouraging standard makers to take these aspects into account. At CEN, there is an environmental helpdesk to assist TCs and working groups with including these aspects in their work. Of course, these aspects must also be considered for PPE products and included as much as possible, without at the same time forgetting the first priority: the safety of the users of the PPE.

Innovation in standardisation

Through several initiatives, innovation is promoted. What can the role of standardisation be in PPE innovation?

When it comes to innovation, the first big concern is the speed of the work in standardisation. On the one hand, standards should not hinder innovation and, on the other hand, before publishing a standard the quality of the document needs to be assessed. This dilemma is not always easy to handle, but it must not be an excuse for slow work. In some cases, other deliverables, such as a Workshop Agreement or a Technical Report, might be a first step towards a standard.

In order to allow innovative products, it is important to work on performance standards – which is in PPE very often the case – rather than on standards describing products.

Standards describing test methods must be robust. This means that the method needs to be repeatable and reproducible. Round-robin testing to evaluate the test methods is key to guaranteeing the quality of the test methods and should be encouraged by all means necessary by the stakeholders. And at the same time, the test methods should be such that they are independent of materials or products, so that innovative



solutions can be tested using the same test methods as those used for the existing products.

Unfortunately, today we see too little involvement by researchers in standardisation. With the current research projects co-funded by the EU Commission, the link with standardisation is strongly encouraged. TCs and working groups must also consider how they can include these researchers in their work.

But, of course, there is the concern of competitive advantages when it comes to innovative products or services. Those companies developing the new products or services need to be able to get a return on their investment, so the fear of bringing the developments too early to standardisation, and thus to the competition, is realistic. At the same time, questions about intellectual property need to find answers within this context.

Without question, standards help to translate innovations into economic growth and productivity, but, at the same time, they must not hinder innovations. A balance needs to be found; this is not always an easy exercise.

Conclusion

Standardisation is a key element in the PPE system and needs our full attention. Balanced working groups must guarantee that they take into account all aspects of standardisation in their work.



Legal Responsibilities with regard to supply, selection and use of PPE

Thomas Klindt, Partner with Noerr LLP, Germany

9.1 Introduction

Personal Protective Equipment (PPE) includes two types of safety risks. On the one hand, there are safety deficits arising from the design, the manufacturing or the placing on the market of the PPE. On the other hand, there are safety risks resulting from the use of PPE (for example, a use ignoring specific instructions given by the manufacturer). Responsibility for these different types of risks is spread between the manufacturer and the PPE user. There are different Community Directives and national legislation regulating legal responsibility.

The placing of PPE products on the market is fully harmonised by Directive 89/686/EC (according to the following PPE-Directive), which contains safety requirements for PPE. Full harmonisation means that these provisions replace existing divergent national and European legislation which covers the same subjects as stipulated by the PPE-Directive. Fulfilling these requirements is the responsibility of the manufacturer. With regard to the use of PPE, Directive 89/656/EEC sets minimum safety requirements. In effect, this means that national authorities, following the agreement of other Member States by means of the notification procedure under Directive 98/34/EC, can put in place further requirements relating to "use" and selection as long as these do not constitute a barrier to trade.¹

The background to the European regulation in this field of law is the removal of obstacles and difficulties related to the free movement of goods within the European Community. Within this context, the new Regulation (EC) No 765/2008, repealing Regulation (EEC) No 339/93, applies from 1 January 2010. The framework established by this Regulation is supposed to complement and strengthen existing provisions in Community harmonisation legislation relating to market surveillance and the enforcement of such provisions. Chapter III Section 3 of this Regulation stabilizes customs controls on products of all kinds entering the Community market.

9.2 Legal responsibilities with regard to the supply of PPE

The PPE Directive establishes Basic Health and Safety Requirements (BHSR) to ensure the health protection and safety of users. It is left to standards, primarily European harmonised standards, to give technical expression to the relevant requirements contained within the directive. According to Article 1 of the PPE Directive, these conditions govern the placing of PPE products on the market and free movement within the Community.

Incidentally, a small, but taxing, problem occurs concerning the scope of application of the PPE-Directive with regard to the development in fashion trends. Increasingly, light-reflecting elements are attached to sportswear and clothing. According to the objective of the PPE-



Directive, high visibility clothing protecting from being overseen in the dark (high visibility) falls within the definition of PPE in Article 1 paragraph 2 of the PPE Directive. However, this result is not convincing when taking into consideration the extensive duties of PPE manufacturers. Normal clothing with light reflecting elements should be exempted from the scope of the Directive with an amendment of Annex I point 3.

1. Civil Liability of the manufacturer under tort law and product liability law

The civil liability of the PPE manufacturer may arise out of a contract, out of product liability law or out of tort law. This provides a specific risk for PPE manufacturers. Most quality defects on manufactured products are, automatically, safety defects. Whereas manufacturers of other products might be confronted with claims relating to a quality defect based solely on contract law, in most cases the PPE manufacturer is, automatically, also liable under the very strict product liability rules and under tort law. A liability for safety deficits on PPE products may arise under tort law, assuming the national legislation provides a mechanism for unsafe products within this institute. Liability in tort requires a default on the part of the manufacturer. Product liability is regulated by Directive 85/374/EWG and, therefore, must be implemented within the legal system of every EU Member State. Product liability law provides a civil liability for damages arising out of faulty products. The Product Liability Directive constitutes strict liability for the manufacturer, that is to say, a default on the part of the manufacturer is not necessary.

a) The concept of a defective product

Both, negligence liability and strict liability refer to a defective product. The product is defective in this sense if it does not provide the safety which a person is entitled to expect, when taking all circumstances into The above-mentioned Directives relating to safety requirements substantiate these safety expectations. PPE is presumed to meet all safety requirements if the manufacturer has attached the CE-marking attesting to the fact that the product conforms to all the provisions of the PPE-Directive. Article 1 paragraph 4 of the PPE-Directive, together with Annex I, provides some exemptions from the applicability of the Directive. According to Annex I point 1, the PPE product falls outside the scope of that directive if it was designed and manufactured specifically for forces which maintain law and order. According to the ECJ, the exemption is only applicable if the specific activity which is supposed to be performed using the PPE product is part of the maintenance of law and order. The ECJ stated that PPE products intended to protect fire fighters from the dangers to which they are exposed while rescuing people or property from fires does not fall within the exemption. These normal duties of fire fighters do not imply any specific powers of public authority. It is not sufficient that the powers and duties of the fire brigades in general are a part of the exercising of public authority according to national law.³



b) Manufacturer's obligations

Article 3, together with Annex II, of the PPE-Directive provides specific safety requirements applicable to PPE products. The PPE product must be appropriate for the risks involved in the special purpose it is dedicated to, without leading to any increased risk. It must be possible to optimize the PPE product adaptation to fit the user's morphology by all appropriate means. Annex II also contains requirements about the information to be supplied by the manufacturer and additional safety requirements for specific types of PPE products. Whereas other products might not be fit for a particular purpose (as agreed upon in the contract), but still be safe, PPE products are typically safety-related in all their characteristics. This means that, in practice, every time a specification is not fulfilled it leads to a safety problem. Therefore, the manufacturer of a PPE product must pay special attention to the Quality Assurance Management (QA Management). Every manufacturer of PPE products needs a program for the systematic monitoring and evaluation of the various aspects of the production and marketing process (design, manufacturing, marketing, instructions).

The manufacturer must consider the normal use of the product as well as foreseeable misuse. He or she is primarily obliged to take all reasonable action in the design and manufacturing of the product. A warning with regard to specific safety problems is only sufficient if there is no possibility to avert a risk through appropriate design and manufacturing.

The manufacturer's responsibility for the safety of a product does not end with the marketing of the product. She or he is still obliged to monitor the products in use and the developments in science, as well as the products' performance on the market. If a risk which was not known or existent at the time of the marketing of the product suddenly becomes known, the manufacturer must either warn the users of this product or even recall the product. Marketing reasons can also lead to a voluntary recall. A product recall should always be supported by a legal practitioner specialized in this field, as there are many legal aspects to be taken into account (for example, the wording to avoid an infringement of competition law).

c) Damages covered

The user of the PPE or a third person must have suffered damage beyond the mere defect of the product. These include damages caused by death or personal injury as well as damage or destruction of any physical property.

2. Liability under administrative law

Member States are obliged to establish the rules regarding the penalties for infringing on national provisions relating to product safety and to take all measures necessary to ensure that they are implemented. This obligation refers to the necessity of effective market surveillance. The increased placing on the market of PPE produced outside of the EU leads to more competition and pricing pressure. The increasing numbers of cheap articles on the market often do not fulfil European safety requirements. A breach of safety provisions can also result from unknowingly interpreting or applying the directive in an incorrect



manner.⁴ Therefore, the national authorities conducting market surveillance have an obligation to take all appropriate measures to ensure that products which do not comply with the provisions of the PPE Directive are removed from the market.⁵ In case of a serious risk requiring rapid intervention, the authority can prohibit placing the PPE on the market. A German administrative court dealt with the conditions which served as a precedent for such a far-reaching measure for the first time in March 2009.⁶ It stated that the risk assessment of the competent authority can justify the assumption of such a serious risk even if an EC-Type Examination Certificate and an EC Quality Control Certificate exist for the PPE in question. To conduct the risk assessment, the national authority may require manufacturers to make available documentation and information regarding safety issues.

3. Criminal liability

A personal criminal liability for decision-makers within the production process is possible in cases o personal injury caused by a safety defect on the PPE. Criminal liability is determined solely by national law. In general, at least negligence is required to trigger criminal liability.

9.3 Legal responsibilities with regard to the selection and use of PPE

Legal responsibility with regard to the use of PPE can also arise from civil law, from administrative law and from criminal law. Additionally, in some Member States there are Employer's Liability Insurance Associations. These are self-governed corporations with their own rules of compliance regarding the safety of the workplace. These rules do not have any legally binding force.

The use of PPE by employers is ruled by Directive 89/656/EEC. Article 3 and Article 4 section 6 of this Directive specify the obligation of the employer to provide PPE to his employees in case the risks arising at the workplace cannot be avoided or sufficiently limited by technical means of collective protection or by measures of work organisation. Thereby, the PPE Directive is supposed to be a subsidiary measure for protecting workers from safety risks at the workplace.

Article 4 of Directive 89/656/EEC demands the employer to choose PPE products which comply with the relevant Community provisions on design and manufacture with respect to safety and health. In this regard, the most reliable criterion for choosing the right PPE product is the CE-marking. Additionally, there are supplementary safety requirements related to the specific purpose of use of PPE products.

9.4 Summary

The manufacturer and the user of PPE can be made liable for safety deficits regarding PPE. Whereas the manufacturer is responsible for the product-related safety requirements being relevant for designing, manufacturing and marketing PPE, the user is responsible for the choice of the appropriate PPE and for using it safely. A particularity of PPE lies in their purpose to protect people from safety risks. Therefore, almost every discrepancy with regard to a specification of the product is, at the same time, a safety deficit. This leads to a particularly high risk for the



manufacturers of PPE to be held liable for damages under tort law and product liability law.

9.5 References

- 1) European Commission, Guidelines on the application of Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to Personal Protective Equipment, p. 3
- 2) Article 6. Directive 85/374/EEC (Product Liability Directive)
- 3) ECJ, Judgement of 22 May 2003, C-103/01, ECR 2003, I- 5369 par. 37
- 4) Lehnecke/Klindt, Persönliche Schutzausrüstungen im Sport- und Freizeitbereich, Beuth Verlag, 1st edition 2005, p. 21
- 5) European Commission, Guidelines on the application of Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to Personal Protective Equipment, p. 9
- 6) Administrative Court Aachen (Verwaltungsgericht Aachen) Judgement of 10 March 2009, case 3 K 1729/08



10. Selection, use and maintenance of Respiratory Protective Devices (RPD) within the new ISO-Standard

Wolfgang Drews, Chairman of ISO /Technical Committee 94/ Sub Committee 15

Introduction

This presentation can be seen as a follow-up to the one given at the previous meeting of the 9th PPE Seminar 2008 in Kittilä, with a focus on selection procedure. The Sub Committee 15 (SC 15) within ISO TC 94 was founded in 2002 to start performance-orientated standardisation-based tests on the demands of wearers in their working environments. Human factors are the drivers for deriving the performance characteristics of future RPD.

SC 15 has structured its task by installing three Working Groups, WG2 and WG3, with their Project Groups, which are responsible for writing the two main standards for filtering devices and supplying breathable gas devices. WG1 handles general topics such as the human factors and the classification of RPD's. *Figure 1.* It was and still is essential that this WG is ahead of the standard writers' work and supports defining the performance criteria of RPD. The Technical Specifications prepared by PG5 forms the core of these criteria.

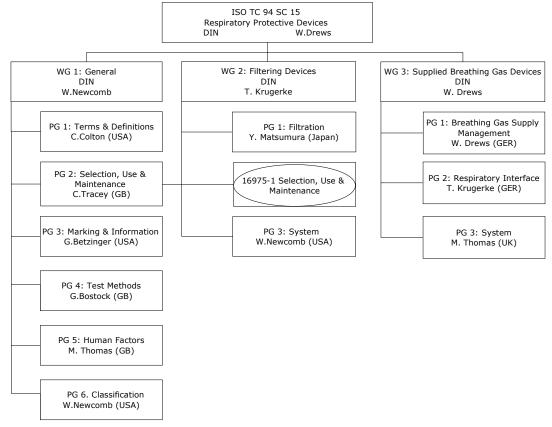


Figure 1. ISO TC 94 SC 15 Structure, Respiratory protective devices



Selection, Use and Maintenance of a guidance standard

Project Group 2 is in charge of generating the standard for Selection, Use and Maintenance, ISO 16975 part 1. This document, in its second draft, describes the elements of an RPD programme: risk assessment, the selection procedure, the physiological and psychological conditions evaluation, fit testing, use, maintenance procedure, storage and the programme review. An Annex explains the new ISO concept for RPD classification.

The protection of the wearer, the human being, in all working environments is the main focus of the standard writers, while at the same time defining the performance criteria of the RPD. Selecting the most suitable and adequate respiratory device is very much related to these performance criteria. And, without knowledge of the classification scheme, the selection procedure cannot be derived properly. These three elements are interlocked and cannot be treated independently. The gear-wheel "classification" is the link between the "performance-and selection-wheel" in this picture - see *Figure 2*.

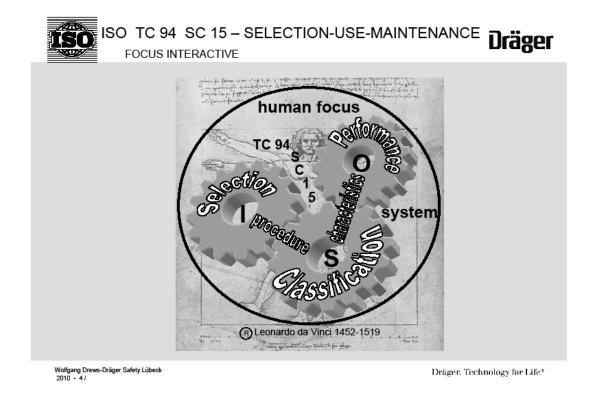


Figure 2. The gear-wheel "classification", the link between the "performanceand selection-wheel"

Classification Scheme

The RPD's of tomorrow will be classified according to their performance characteristics, which will result in a new scheme valid for both standards: the standard for supplied breathable gas devices, ISO 17420 part1, and the filtering device standard, ISO 17420 part 2.



In the classification scheme – see Figure 3 and 4 - two basic performance characteristics, the Protection Level (PL) – 6 levels: PL1/4, PL2/10, PL3/30, PL4/250, PL5/2000, PL6/10000 - and the work rates (W1/moderate, W2/very heavy and W3/maximal), describe an RPD-System.

Each work-rate level corresponds to minute volume numbers: W1:35 L/min; W2:65 L/min and W3: 135 L/min for a period of 5 minutes only. For filtering devices, the efficiency levels in particle penetration (F1/20%, F2/95%, F3/99% and F4/99%), as well as the determination of the gas capacity in various gas filter classes, are additional classification elements.

For supplied breathable gas devices, the distinction between self-contained devices with limited capacity and those where the breathable gas is supplied by an airline system is given by an "S" followed by the usable volume of breathable gas in litres and the symbol "SY".

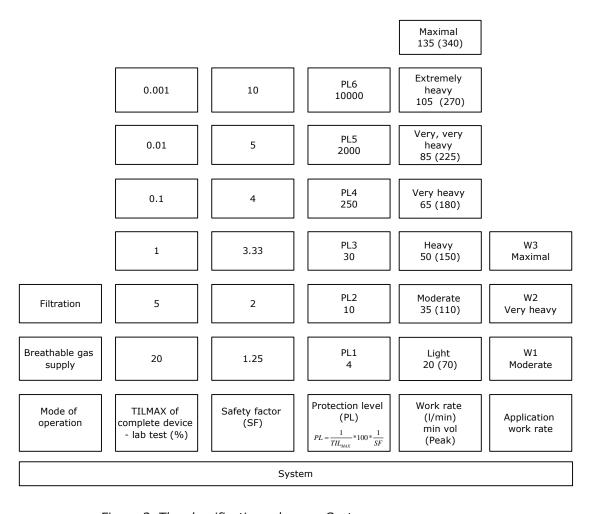


Figure 3. The classification scheme - System



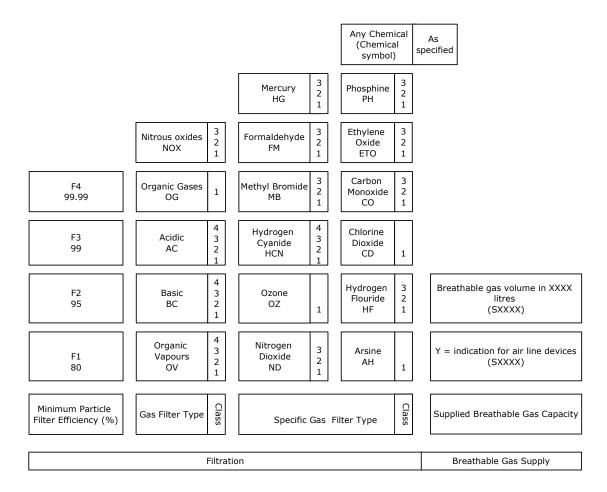


Figure 4. The classification scheme - Filtration and breathable gas supply

In addition to the basic performance characteristics, another classification area is assigned for special application performance characteristics - see *Figure 5*.

These classes reflect additional requirements derived from specific working environments, called special application, such as Fire fighting(FF), CBRN, Marine(MA), Mining(MI), Abrasive Blasting(AB), Welding(WE), Abnormal Pressure Work Environment(PW). All escape scenarios are listed under Escape (ES).

Where an RPD is marked as PL5 W2 S2040 FF4 CBRN2, one can read from the labelling that this RPD has a very good Protection Level PL5 of 2000. It delivers enough breathable gas to support the wearers' demand for a very heavy ventilation rate, W2. The device is self-contained, with a breathable gas capacity of 2040 litres, and, additionally, it is classified to fulfil the special application requirements of structural fire fighting, FF4, within a CBRN environment.



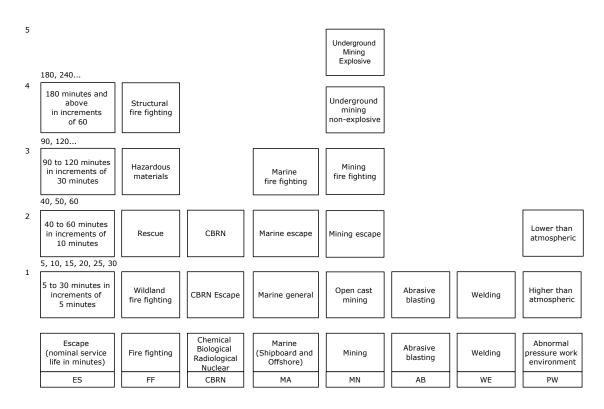


Figure 5. Special application performance characteristics

Selection Procedure

The third "gear-wheel"- selection comes into contact with classification driven by performance. To select the most adequate and suitable RPD for the task, it is necessary to conduct a comprehensive risk assessment with its three elements – a Hazard, Adequacy and Suitability Assessment of the work place has to be derived - see Figure 6.

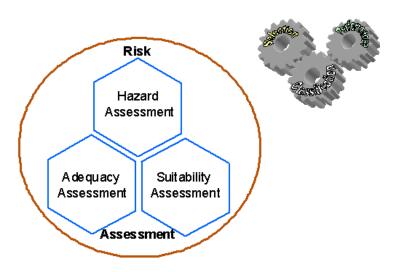


Figure 6. Selection procedure

A good way for a responsible person to undergo a risk assessment is to follow a step-by-step questionnaire in the form of a flow chart. The following charts are taken from ISO Standard 16975-1.



The first step in identifying a hazard is the question: Is there enough oxygen in the atmosphere? The answer opens one or the other page-oxygen deficiency or oxygen sufficiency. When there is oxygen deficiency, knowledge about the contaminant is essential. If there is no further contaminant in the environment the flow chart aligns with the principal piece of advice: to select a supplied breathable gas device with a Protection Level of at least PL4. If there is a contaminant, but the concentration is not known, one has to select a supplied breathable gas device with the highest Protection Level, PL6, from the scheme. If the concentration is known, further questions are relevant, such as: Is the concentration level compared with OEL-values lower or higher? And, have IDLH levels been achieved already? According to the answer "yes" or "no", clear selection advice is given, as shown in Figure 7.

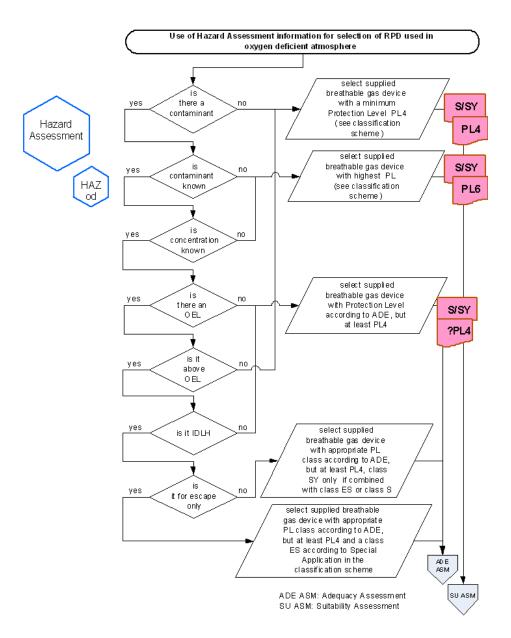


Figure 7. Hazard assessment ODA



The Adequacy Assessment serves to allocate the necessary Protection Level in cases where there are no National Regulations - please bear in mind that the document is seen as a guidance standard for all those countries where no National Standards or Regulations exist. An ISO Standard will not supersede those Regulations at all.

This document describes methods for how to identify the adequate Protection Level for protecting wearers from those specific hazards. *In Figure 8*, the method chosen derives a value of equal to or less than 2000, which leads to a Protection Level of PL5.

From this page, connecting symbols guide the user to the next assessment step, either directly to the Suitability Assessment (SU-ASM), when the Protection Level is clearly identified, or to the Adequacy Assessment (ADE-ASM), when the Protection Level has to be derived first. A similar flow chart is available once the first question has been answered "yes" there is enough oxygen in the atmosphere! This chart is not addressed in this presentation due to time constraints.

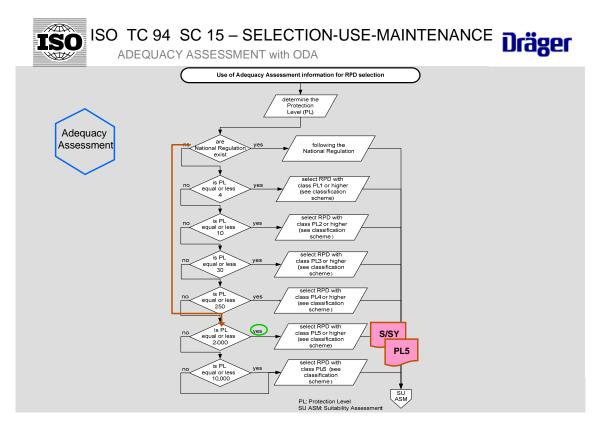


Figure 8. Adequacy assessment with ODA

The Suitability Assessment takes on all the detailed questions related to the wearer (*Figure 9*), task (*Figure 10*), work rate, filter assessment and filter-change programme (*Figure 11*), environment and, finally, the demands for special applications (*Figure 12*). Each question in this assessment that is answered "yes" is followed by an appropriate action to be taken: to identify the individual requirements.



The wearer-related issues in Figure 9 identify the need for corrective lenses. The duration is estimated at 30 minutes for the example used. The task involves high mobility, which eliminates the choice of "SY"classified RPD: in today's terms, an airline system is not suitable. In the example chosen, the required work demands a ventilation rate of at least a high work rate, which means W2. The minimum volume of breathable gas can be calculated easily: the corresponding value for W2, 65 L/min, will be multiplied by 30 minutes, which results in 1950 litres, meaning that it is classified as "S1950". No filters are involved because the previous selection steps have already identified a supplied breathable gas device, marked "S". Finally, when it comes to the Special Application, all the specific requirements according to the selected level have to be fulfilled, such as the ones for Fire Fighting/ Hazardous Materials (FF3) and, in our example the CBRN requirement related to entering the "hot" zone of a terrorist attack scenario must additionally be taken into account.

Finally, after following all the steps of the guided tour through the flow chart, the result is the clear designation of an adequate and suitable RPD for our chosen example: PL5 W2 S1950 FF3 CBRN2 – corrective lenses.

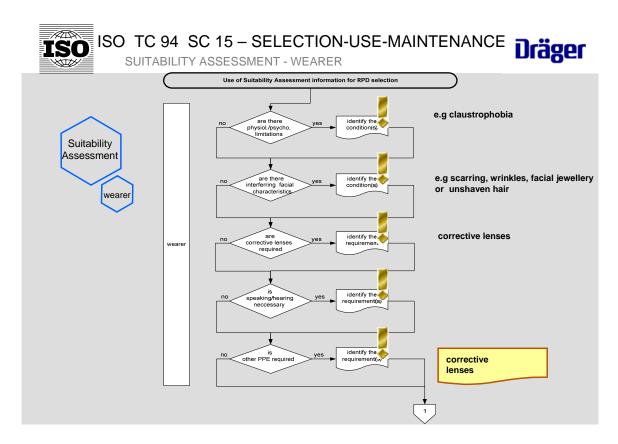


Figure 9. Suitability assessment - to the wearer



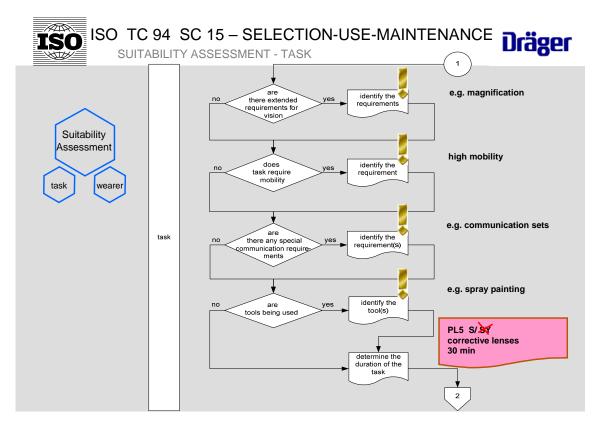


Figure 10. Suitability assessment - task

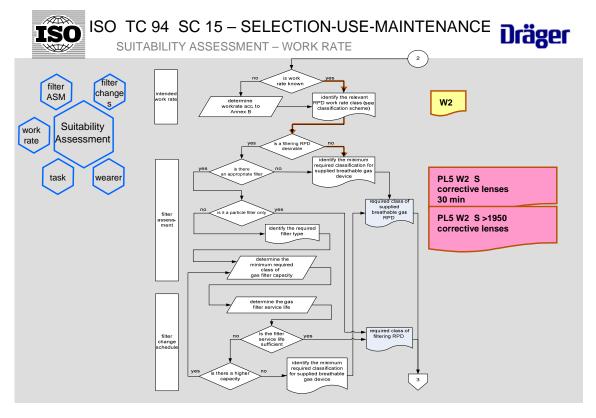


Figure 11. Suitability assessment - work rate



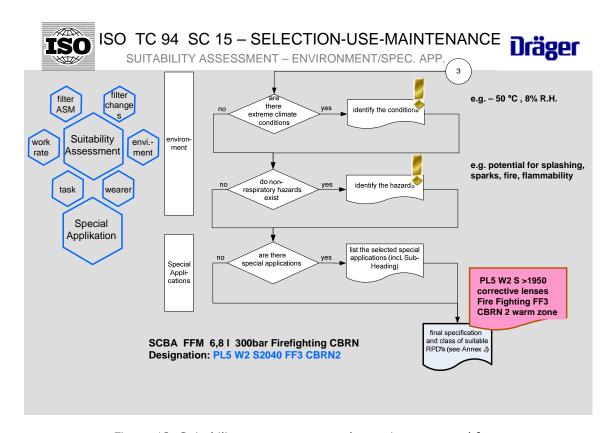


Figure 12. Suitability assessment - to the environment and for special applications

Consulting a manufacturer or supplier by asking for an RPD with this designation will possibly lead to the following answer: there is a self-contained breathing apparatus (SCBA) available with the required protection level of PL5. This supports a very heavy work rate of W2. The necessary breathable gas volume of 1950 litres will be converted to a cylinder size of 6.8 litres operated at a pressure of 300 bars. The calculated designation is S2040 (6,8x300). And the demand for corrective lenses leads to the accessory of special goggles designed to fit the respiratory interface.

One might say that this is too complex. And "yes", the standard writers have taken this statement into account when generating a simpler guide for the selection process: ISO 16975 part 2 will come soon. But also "no", it is not too complex because ISO 16975 part 1 is valid for all those ISO Member States which have no RPD programme in place. See *Figure 13*. This standard will help them to develop and deploy it and the detailed flow chart might be a good tool for the further development of training courses and electronic selection processes once all the ISO RPD standards become available in the year 2014!





ISO TC 94 SC 15 - SELECTION-USE-MAINTENANCE Dräger

Conclusion:

too complex !?

yes: hard to understand by users

no: comprehensive document with all background information

answer to "yes": NWIP ISO 16975 part 2 is in progress (simplified version using different language, symbol based)

response to "no":

- ISO 16975 part 1 is necessary for those ISO members/markets where there is no RPD programme known
- flow chart based selection procedure is a good tool for further development of education and training programmes

Availability of all ISO RPD related Standards and documents > 2014!

Wolfgang Drews-Dräger Safety Lübeck 2010 • 16 /

Dräger. Technology for Life*

Figure 13. Conclusion



11. Methods for evaluating PPE performance in real work situations

Peter Paszkiewicz, Institute for Occupational Health and Safety of DGUV (IFA), Germany

Problem

The selection of personal protective equipment (PPE) for use in workplaces requires a careful risk assessment and a profound knowledge of the different types of PPE, their performance levels and the limitations of their use. Even though there will still remain uncertainty regarding whether the PPE which is used under conditions of exposure to, for example noise, chemicals, biological agents, heat, cold and mechanical impact, will give the expected protection. Field studies, for example for respiratory protective devices (RPD) and chemical protective gloves, have shown that the protection achieved at workplaces is, in most cases, much lower compared to the theoretical protection which can be derived from the requirements of the standards. Inappropriate risk assessment and selection, underestimating the risk, individual factors (the device not fitting correctly, lack of training & education), incorrect use, lack of acceptance and motivation due to discomfort and increased work load are the most important reasons.

Activities

A European project will be initiated to elaborate harmonised protection factors for the various types of RPD that can realistically be achieved in workplaces. The study will involve an international group of test laboratories mainly from OSH institutes under PEROSH (Partnership in European Research on Occupational Safety and Health) and will cover a broad range of real-life working fields. One of the key objectives of this project is to elaborate a standardized protocol which includes the measurement strategy, measurement methods and a statistical evaluation of the results in order to determine workplace fit factors. At a later stage, a series of measurements will be undertaken to carry out workplace studies in order to obtain figures for the real performance of various types of RPD which are accepted European wide. Another objective is to look at the effectiveness of training by comparing the "as is" situation with that after training has been given to the wearer.



12. Does chemical protective clothing gives real protection? A review of recent French investigations

Patricia Le Frious, French Ministry of Labour and Amandine Paillat, AFSSET, France

A previous study, conducted at the University of Bordeaux, suggested that coverall protection was inadequate against mixtures used during agricultural activities. To address this issue, the French Ministry of Labour entrusted Afsset (the French Agency for Environmental and Occupational Health and Safety) to conduct objective investigations on chemical protective coveralls placed on the market with regards to permeation.

These investigations only deal with protective coveralls used for protection against liquid chemicals, that is, coveralls of type 3 (liquid-tight connections) and 4 (spray tight connections), as defined in the standard EN 14605. Tests were conducted by a notified body.

The study was conducted using two steps:

- First, permeation tests were performed to check the conformity of the coveralls: the substances which were mentioned by the manufacturers in the user instructions were tested.
- Then permeation tests were performed with certain chemicals actually used by workers in certain business sectors (agriculture, paints...).

These investigations highlight the relevance of the current testing and labelling practices. They will contribute to discussions about whether the current harmonised standards should be revised in order to improve health and safety conditions in workplaces.



13. The differences between laboratory results and real protection during use – hearing protection

Martin Liedtke, Institute for Occupational Safety and Health of the German Social Accident Insurance (IFA), Germany

13.1. Introduction

Specific aspects have to be considered in relation to performance levels dealing with the selection and use of hearing protectors: On the one hand, a certain (at least minimum) protection level has to be guaranteed and, on the other hand, too much protection may result in accidents because the audibility of warning signals or warning shouts is impeded.

13.1.1 European background

Selection and use of hearing protectors aim at an 84% protection level according to harmonised standards (for example EN 458). That level of protection is based on laboratory data, I.e. 84% of the test subjects obtained at least the level of protection specified when in the laboratory.

The so-called "Real World Attenuation" was found to be lower than the values obtained in the laboratory. The "Real World Attenuation" specifies the attenuation found at real occupational settings. At the European and international level various experts discussed "Real World Attenuation".

European Directive 2003/10/EC requires that, 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. The exposure action values shall not take account of the effect of any such protectors.

Therefore, a German study was carried out which was initiated by the Working Group "Hearing Protection", a part of the Expert Committee "Personal Protective Equipment" of the German Social Accident Insurance. The actual sound attenuation of hearing protectors used at workplaces in various branches of industry was determined to obtain an estimate on the deviation of "Real World Attenuation" when compared to laboratory data.

Considering the European background and the results obtained by studies of "Real World Attenuation", we have to find an answer to the question: Which solution should be adopted for European workers/users?

13.1.2 Harmonized CEN standards relating to 89/686/EEC

The standard series EN 352 specify general requirements. For acoustic test methods, it refers to EN 13819-2, which refers in turn to EN 24869-1 and EN ISO 4869-2. EN 13819-2 specifies that a = 1.



The standard, which specifies the acoustic test conditions and use of test subjects, is EN 24869-1. The requirements for test subjects are the following:

- Reproducibility of hearing threshold as specified in ISO 4869-1
- Unskilled test subjects should be trained before measurements.

The calculation procedure for the estimation of effective A-weighted sound pressure levels when hearing protectors are worn are specified by EN ISO 4869-2.

It specifies: attenuation = mean $-a \bullet$ standard deviation. (1)

For the selection and use of hearing protectors, EN 458 uses the same approach, as do the other European standards, i.e., a = 1, which results in an 84% protection level referred to laboratory data.

13.2 "Real World Attenuation"

13.2.1 Laboratory data on hearing protectors

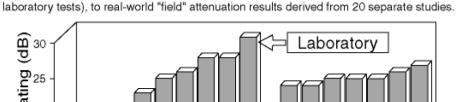


Figure 1 - Comparison of NRRs published in North America (labeled values based upon

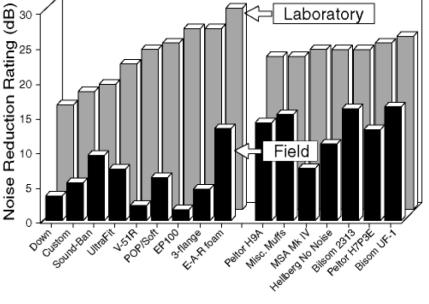


Figure 1 was published by E.H. Berger et al. in 1996 and subsequently became famous within the field. It exhibits a comparison of NRRs (Noise Reduction Rating) published in North America (labelled values based upon laboratory tests) with real-world "field" attenuation results derived from 20 separate studies. Especially for plugs (on the left in Figure 1), surprisingly low "filed" attenuation levels are shown.

13.2.2 Experts' discussions about "Real World Attenuation"

Experts discussed how to consider "Real World Attenuation" when assessing the sound pressure level effective for a user's hearing.



Sometimes they refer to 89/686/EEC and sometimes they refer to 2003/10/EC, which may be confusing, because 89/686/EEC is addressed to manufacturers and Notified Bodies, whereas 2003/10/EC is addressed to employers. However three methods were proposed by the experts:

i) Derating: This means that the protection level obtained from laboratory tests, according to European harmonized standards, is subtracted by a specified value or values to get an estimate of the "Real World Attenuation".

Table 1 shows an example of derating specified for ear muffs and disposable (formable) ear plugs in France and Germany.

Hearing protectors	France	Germany
Ear muffs	- 5 dB	- 5 dB
Disposable (formable) ear plugs	- 10 dB	- 9 dB

Derating often refers to the type of hearing protector.

ii) Another proposal is the subject fit method: ISO/TS 4869-5. This method was developed and introduced for standardisation by the USA. ISO/TS 4869-5 specifies that, "The method is designed to provide estimates of the sound attenuation obtained by typical groups of users in real-world occupational settings, who may lack the training and motivation to wear hearing protectors in an optimum manner."

Therefore, the values reflect the attenuating characteristics of the hearing protector only to the extent that users wear the device in the same manner, as did the test subjects. For testing according to ISO/TS 4869-5, test subjects who are experienced with hearing protectors are not permitted. The technical specification ISO/TS 4869-5 therefore specifies the extent of experience with hearing protectors which is not permitted:

"5.1.3 Previous experience with hearing protectors

Subjects shall not have had significant previous experience with hearing protectors. Potential subjects shall be questioned as follows:

- Have you ever received one-to-one personal instruction in fitting of hearing protectors?
- Within the past two years, have you attended a lecture on, or watched videotaped or computer-based instruction about how to fit hearing protectors?
- Within the past two years, have you participated in an experiment designed to measure hearing protector noise reduction?
- Within the past two years, on how many days have you worn any kind of hearing protector to protect yourself from noise, and for how many days have you worn ear-plugs while sleeping or swimming?

Potential subjects shall be rejected if they answer "yes" to questions (a), (b) or (c) or if in response to (d) they indicate use of any kind of ear-plugs for more than ten days or use of ear-muffs for more than two months."



iii) The third method is statistical range enlargement: In formula (1) the "a" is increased to get an estimate of the "Real World Attenuation". For example, in the UK, Italy and Portugal $\alpha=2$ is introduced - sometimes as an alternative to another method, under specific circumstances.

Another development is introduced by the new work item proposal for revising ISO 4869-2, based on ANSI/ASA S12.68-2007:

"The three methods, the Noise Level Reduction Statistic for use with A-weighting (NRSA), the Noise Level Reduction Statistic, Graphical (NRSG), and the octave-band method are presented in order of increasing complexity of use and potential accuracy. Furthermore, the standard specifies in the case of the NRSA and the NRSG that values will be presented for both the 80th and 20th percentiles, indicated as NRSA80 and NRSA20, and as NRSG80 and NRSG20, to reflect the range of attenuation that can be anticipated." (Text from ANSI/ASA S12.68-2007)

On the one hand, when looking at ANSI/ASA S12.68-2007, the increasing complexity of the statistics used in particular tries to make us believe that a very high accuracy in estimating "Real World Attenuation" is obtained. On the other hand, the concept of specifying a range of attenuation rather than a single value is new and may by interesting. Brad Witt, in his presentation at the congress A+A 2009 in Düsseldorf, Germany, showed the labels given in *Figure 2*.



Figure 2. Labels shown by Brad Witt in his presentation at the congress A+A 2009 in Düsseldorf, Germany.

13.2.3 Hearing Protectors' "real world" performance and the European directive 2003/10/EC – international workshop at INRS, Paris 2008

There are various approaches for implementing the 2003/10/EC with regard to "Real World Attenuation" in Europe. Various North American researchers and regulators have considered "Real World Attenuation". Can Europeans learn something from this? Some North American standards on this issue are already available. This was the basis for an



international workshop carried out at INRS in Paris in 2008. The minutes and presentations of that international workshop are available at: http://erest.etsmtl.ca/Paris_HPD_Meeting_Source_Book_V2.pdf

13.2.4 German study

To get an estimate of "Real World Attenuation" for current products at German workplaces, a German field study was carried out. That study was a repetition of another German study performed about 20 years ago. A vehicle for hearing conservation programmes was used. Technical changes made it possible to use a measuring method, which replicates, as much as possible, the one used for type testing in the laboratory in accordance with ISO 4869-1. The workers came from their workplaces to the vehicle for testing without being allowed to touch their hearing protectors. This enables an investigation of the use of hearing protectors under realistic conditions. 582 data sets (13 products) were analysed. Significantly reduced mean attenuation values and increased standard deviations were obtained. *Figure 3* shows an example of the data obtained for formable plugs.

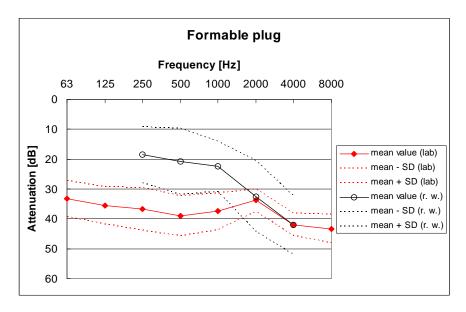


Figure 3. Example from a German study of the comparison of laboratory data and the "Real World Attenuation" data obtained for one product.

The study's results were used by the German Social Accidents Insurance authorities to agree on a correction (derating) to the laboratory data for a real-world use: the laboratory attenuation values shall be reduced by the derating factors shown in *Table 2*.



Table 2: Derating factors as agreed to by the German Social Accidents Insurance authorities

Туре	Derating [dB]
Formable plugs	9
Pre-formed plugs	5
Banded plugs	5
Ear muffs	5
Custom moulded plugs	3

The English version of the study's report is available at www.dguv.de, Webcode:e99112.

13.3 Which solution for European workers/users?

"Real World Attenuation" in the US is found to be considerably lower than in Europe. One reason which has been identified is that, since 1986, the European Directive 86/188/EEC required "information and, when relevant, training concerning ... [the] wearing of PPE" for European workers to be provided by the employer. The US stakeholders tried to solve the inefficient use of PPE products by increasing the complexity of testing and specification procedures; that is to say, they focused only to those measures which might be applied by PPE manufacturers and testing bodies. Contrary to the US approach, European Directives differentiate between the responsibilities of the PPE manufacturer, (89/686/EEC), and the responsibility of the employer, (89/656/EEC and 2003/10/EC). At the A+A 2009 in Düsseldorf, Germany, Brad Witt presented the recent results from a US study, in which 192 users of a formable plug showed, on average, a considerably increased attenuation of about 14 dB after 3 minutes information and training.

13.4 Conclusion

European experience shows that more than one approach is appropriate for solving the problems found associated with using PPE in real life. At least one approach for experienced users and another one for inexperienced users are necessary.

Therefore, in France and Germany derating is specified for use of hearing protectors in small enterprises and by private users, whereas enterprises providing specified training are allowed to use laboratory data as specified by the manufacturer.

Another difference depends on the type of hazard: a private end user may not be exposed long-term (i.e. 40 hours a week over a number of decades) to noise. The risk of hearing impairment for the required short-term use of hearing protection is usually smaller than found for a worker employed in noisy areas. But a private end user using personal protective equipment designed to prevent him or her from falling from a height may be at a higher risk than another worker because she or he may lack appropriate information, training, and experience. The specific



situation of the PPE user - as described in the two examples here - has to be taken into account when looking at "Real World Protection Levels".

Therefore, in the end it turns out that not all problems detected during use of PPE can be solved exclusively by PPE manufacturers. Sometimes ISO standards may not meet European requirements and practice because they might not consider European Directives, which require taking into account more than just the responsibilities of manufacturers and test laboratories.

13.5 References

- 1) EN 458:2004 Hearing protectors Recommendations for selection, use, care and maintenance Guidance document
- 2) 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), Official Journal of the European Union L 42, 15/02/2003, p. 38 44
- 3) Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment, Official Journal L 399, 30/12/1989, p. 18
- 4) EN 352-1:2002 Hearing protectors General requirements Part 1: Ear-Muffs; Part 2: Ear-plugs; Part 3: Ear-muffs attached to an industrial safety helmet
- 5) EN 13819-2:2002 Hearing protectors Testing Part 2: Acoustic test methods
- 6) EN 24869-1:1992 Acoustics Hearing protectors Subjective method for the measurement of sound attenuation (ISO 4869-1:1990)
- 7) EN ISO 4869-2:1995 Acoustics Hearing protectors Part 2: Estimation of effective A-weighted sound pressure levels when hearing protectors are worn (ISO 4869-2:1994)
- 8) Berger, E.H., Franks, J.R., and Lindgren, F. (1996). "International Review of Field Studies of HPD Atten.," In Scientific Basis of NIHL, eds. Axlesson, et al., Thieme Med. Pub., New York, NY. 361-377
- 9) ISO/TS 4869-5 Acoustics Hearing protectors Part 5 Method for estimation of noise reduction using fitting by inexperienced test subjects'
- 10) ANSI/ASA S12.68-2007, 'Methods of Estimating Effective A-Weighted Sound Pressure Levels When Hearing Protectors are Worn'
- 11) Council Directive 86/188/EEC of 12 May 1986 on the protection of workers from the risks related to exposure to noise at work, Official Journal L 137 , 24/05/1986 p. 0028 0034
- 12) Council Directive 89/656/EEC of 30 November 1989 on the minimum health and safety requirements for the use by workers of personal protective equipment at the workplace, Official Journal L 393, 30/12/1989 P. 0018 0028



WORKSHOPS

14. Workshop 1: Innovations, lifetime, performance and physiological indicators

Karl-Heinz Noetel, BG BAU, Germany

General remarks

- PPE does not take into account the specific differences between men and women. More and more women are asking for special PPE which take into account the specific female body shape. Unisex PPE is not sufficient. Unisex full body harnesses, for instance, can hurt a woman during a fall. Manufacturers are asked to produce PPE that suit the body of women.
- Persons responsible in organisations/companies for buying PPE are always a problem. Safety experts often select the correct PPE, but when the responsible persons in a company are asked to buy that particular PPE they change the order for cheaper products on the market. They are not aware that an inadequate PPE can influence the working ability, the work quality and the well-being of employees. The employer should be aware of this and should oblige his staff to follow the advice of the safety experts.
- End users must be more involved in all processes. Often the companies select PPE without involving the end user, their employees. If the end user is asked about his or her ideas and is asked to take part in a trial wearing of the product, at the end the product will be accepted by the end user and be worn. This means that the PPE will protect the user in the best possible way.
- RFID can offer solutions for the lack of use of PPE. Radio Frequency Identification (RFID) describes an auto-ID system that transmits the identity (in the form of a unique serial number) of an object (for example, a PPE product) wirelessly by using radio waves. This technique will help to check that the end user is wearing the right PPE for the specific work place conditions.

Innovations

- Need platforms. We have to be open for innovations, even though
 we may not believe in them in the beginning. Seminars and
 conferences could be a good platform, but also the organisations
 responsible for HSE at the workplace also need to promote
 innovations.
- Standards should not block innovations. For a product, we mostly follow standards. But innovations are not covered by standards. We should be open to testing these new products and then start to create standards.
- **CEN-guidelines for how to handle innovations.** To get a clear procedure for this, we ask CEN to elaborate specific guidelines as a common approach for all involved parties.
- **Tendering**. Very often a tender refers to PPE, with references to a particular standard. That means that a product innovation without a standard reference is not part of the tender. Calls for tenders have to be more flexible and should contain an opening clause.



Lifetime

- Indication via RFID (tag and sensor technology). When using the RFID technology, it will not be a problem to identify the lifetime of a PPE automatically.
- **Very critical to estimate (right parameters for RFID).** Experts have to identify the necessary parameters for the RFID technology.
- **Responsibility of the manufacturer**. Nevertheless, the manufacturer is responsible for indicating the lifetime of the PPE. For this, she or he can use his experience with the products (her or his own experience and feedback from the end user), but she or he does not always know the chemical and physical exposure during use. Some of these problems can be solved with RFID.

Performance

- **Risk assessment.** First of all, we have to make the risk assessment before choosing the right PPE. Still, we are aware of the fact that the risk assessment is not carried out in a lot of companies. We have to think about ways for how to improve the situation.
- Bad knowledge of the end user. Often the end user does not have sufficient knowledge about the performance of the PPE. Training via safety experts is one solution; the involvement of specially trained dealers is another solution. In some countries the sales companies and organisations have installed a special training system for their staff. Many SMEs are using dealer advice, since they are often not able to do the risk assessment themselves.
- **Comfort / ergonomics.** Often the comfort of a PPE is related to its price. As long as Notified Bodies do not take into account the comfort and ergonomics during testing, we will not solve the problems related to performance. The manufacturer is primarily responsible for this, but if the Notified Body is not checking it, the manufacturer will not spend more money for an ergonomically better product. Companies will continue to buy inadequate products because they are certified by a Notified Body, even the products conform only to the lowest standard in order to be in line with the European Directive.

Physiological indicators

For best fitting and acceptance, the end user must be involved

The best way to develop a product to be accepted by the end user is

- To make field tests involving the user and
- To work together with a Notified Body to check the product already in the design phase.



15. Workshop 2: Training requirements for sales persons and users

Henk Vanhoutte, Secretary General, European Safety Federation

Fourteen participants from eight different countries exchanged ideas during the workshop on training.

The available training is different in each of the countries. However, all share a clear need for PPE training for different target groups: sales persons/advisors, safety specialists (engineering, medical, ergonomics, and so forth), users, teachers, officials (market surveillance, labour inspection, and so forth) and any other person with a professional interest in PPE.

During the discussions, the following ideas were expressed and supported by the participants:

- Training on PPE needs to be practical. Not only do the legal requirements need to be addressed, but the following questions need to be addressed as well:
 - How to select the correct PPE?
 - How to use them correctly?
 - How to maintain and care for the PPE?
 - How to motivate employees to use PPE and use them correctly?
 - How to convince employers to provide the best possible PPE?
- Training needs to begin at an early stage. It is best to begin education on PPE in the schools. Therefore, training for teachers (e.g., teachers in technical schools) is necessary. Ideally, safety in general and PPE more specific should be part of the official curriculum for school education.
- We felt that there is an important role for the trade unions in the training of their members. They need to be actively involved and can also have a 'train the trainer' effect.
- Also, the medical side of the Occupational Health and Safety community needs to be involved and trained. They often get complains or are informed by employees about problems with PPE and, therefore, need to be able to answer these issues in a correct way. They can also have an important role in the motivation to wear PPE, especially for those PPE that protect against health problems rather than against accidents (e.g., hearing protection, respiratory protection, and so forth).
- In order to make the training attractive for employers, there should be some economic benefit. This could be through insurance fees, for instance. But also making clear calculations for employers about the costs of accidents or health problems, calculation models for the 'total cost of ownership' of PPE and similar economic aspects need to be part of the training of PPE advisors and other OHS professionals.
- Agreements with insurance companies about the effect on the insurance fee for those employers that can prove proper training of their employees can give a boost to the quality of the training. This is clearly an aspect to explore when setting up training systems. The same is also valid for cooperation with Labour Inspection authorities.
- There is a clear preference for a European system or scheme for the PPE training. ESF could take a coordinating role to make this happen



- and to get recognition of the training by European and national authorities.
- Training is only part of the solution; we need to strive for safety (and PPE) education. This has a far bigger impact on daily life as well. Education is the only way to influence safety culture and safety behaviour.

All participants agree that there is very interesting work to do in this field, and that technology, such as e-learning, offers possibilities in this field.



Workshop 3: Practical performance and requirements in real situations

Korhonen Eero, FIOH, Finland

Many factors influence the protection level in real situations. For instance, the protection given by the chemical protective gloves and clothing depends not only on resistance against the penetration of chemicals, but also on the influence of temperature and mechanical hazards. In laboratory conditions these factors are only partly taken into account. The realistic breakthrough time, penetration time, concentrations and toxicity of chemicals are difficult to define so that they cover all possible use situations.

The standardization should start by defining the intended use of the PPE product. The real situation scenarios shall be established. Accordingly, the risk assessment in these situations shall be made. Standards shall classify the products according to the different performance levels needed in these use situations.

During the standardization working process, better documentation is needed. It would be good first to think about the intended use of the product and the foreseeable risks involved in this use. Then the relevant basic health and safety requirements of the directive should be identified. Based on the hazard and its magnitude, the performance requirements shall be set. It is very important that the documentation relating to the technical background of the requirements or test methods is available. The requirements can be based on expert evaluations, some surveys or even scientific research. Most of the existing standards contain requirements which are based mainly on the experience gained from the existing PPE product in use. This kind of documentation could be very useful when the standard is revised

The test methods shall be as realistic as possible when measuring the real performance based on the intended use in the foreseeable use conditions. It is, therefore, also very important to document the basis upon which the requirements and test methods are built. When we know upon which basis the requirements and test methods have been established, it is also easier to select the correct PPE product.

The documentation can be a separate document created during the standardisation process. The scope and informative appendices shall give enough information to the user of the standard to describe clearly the performance, area of application and limitations of use. Also, other documentation, like material safety data sheets, shall be improved to give exact guidance on selecting the proper PPE products.

The end users shall be properly trained. It has been shown that individual training is the most efficient way of teaching workers to use PPE products correctly. At the same time, the motivation to use PPE products will be strengthened. The real performance depends highly on the proper maintenance and supervision of use of the product. The correct selection and use of a PPE product clearly shows the overall safety culture of the workplace.



The possibilities given by new technical solutions shall be used whenever possible. Different kinds of performance or lifetime indicators are being developed and many new solutions are under study.



POSTERS

17. Poor visibility: same hazard, different risks

Giovanna Longo, 3M Deutschland GmbH, Germany

Current situation

The danger of not being seen is well recognised in the work environment. Garments conforming to standard EN 471 for high visibility are regularly worn everywhere in Europe. Parallel to EN 471, which is for professional use, is EN 1150, which has existed since 1999 for non-professional users. The distinction between professional and non-professional standards has been a quite clear and useful differentiation, yet EN 1150 has not been applied to a significant degree within the market, with some exceptions in the Nordic countries. This underlines the fact that, even if the hazard of not being seen for the two categories of people is the same, the final risk is different both in reality and perception. Nevertheless, it might generate some concerns, leading to the incorrect assumption that, because garments can be different, people are less protected in their free time. The opportunity has probably come to offer some clarity.

Target

The intention is to show an appropriate risk assessment; this is an easy tool that everybody could use to make a clear distinction between different risks. It takes away the distinction between professional and non-professional user by concentrating more on the risk level. The poster represents the discussion taking place in the TC 162/WG7 committee and shows the way the group experts would like to proceed. The discussion might have some consequences for future standardization work in WG7.



18. The ultimate fire fighter's suit, integrated clothing systems, ergonomics, fabrics, performances, and integrability in accordance with EN 469:2007 Level 2

Enrico Bonafini, Flower Gloves Srl, Italy

All technical working out of the details and all of the details themselves come from a specific costumer's operating need. The standpoint is a custom-made concept: nothing can be invented that our customers do not yet know. Only in this way can the produced PPE product meet real needs in operation and the PPE product be well accepted by the user.

- 1. Our first goal: to develop a safety EN 469 garment according to *real operating* people, their suggestions and experiences
- 2. We tried to collect as much information as possible starting from real use needs
- 3. We developed the garment in a step-by-step fashion, ensuring that it would meet the real operating needs stated by the costumers.

Guidelines in Project Developing:

- Ergonomics
- Fabrics
- Performances
- Integrability.

18.1 Ergonomics is the quality ratio in the relationship between a tool and its user

According to the troubles met using an older concept, EN 469 garment, we have considered that the garment:

- · Has to result in less bulkiness
- Must be useful during operations
- Must not obstruct legs when going up stairs
- Must allow for adequate movement of the knees
- Must allow for wide arm openings.

The solution was to use performed shapes closely related to extreme sportswear (alpine climbing). What do I mean by performed? This means giving the cloth a natural body shape so as to allow for non-steady movements.

18.2 Fabrics

Comfort troubles include a high sweat quantity during operations. Safety First! Therefore we wanted to combine the maximum comfort with the highest protection, without forgetting durability. The stated issues include:

- 1. High fire protection performances
- 2. Durability
- 3. Transpiration (wicking concept)
- 4. Summertime comfort
- 5. Waterproof and breathable clothing.

The new fabrics involved in this project have made all that possible.



External layer: antistatic Nomex® Diamond Plus results from a close cooperation with Dupont. So we achieved a great breathable textile with a high protection grade and a long lifetime and washing resistance. **Middle layer:** Gore-Tex® Airlock. It combines the breathability and waterproof capabilities of Gore membrane with a fire retardant (FR) aramidic insert for heat protection, in addition to silicon spacers, which create an additional air insulating layer. The transpiration of sweat to the outside is so made faster and more efficient, thanks to the "air cushioning" system.

Inner layer: we decided to use the ultimate "body sweat conveyer" all over the world; it consists of Polartec® Power Dry Fabric. It is well-known as the "next to Skin" champion in sports and alpine and outdoor activities. In our garment this property is obviously and for the first time in fire retardant (FR) version according to the new norm.

18.3 Performances

Test results are higher that EN 469 level 2 requirements. Field tests confirm this project as an answer to all declared costumer needs. An additional Dupont ThermoMan Test with an eight second flash fire exposure confirms 100% survival of the garment. We may provide more information and data upon request.

18.4 Integrability

The garment is designed and developed to allow the highest integrability with the *apparatus and tools* in use (breathing apparatus, radio, harness or other tools). We considered all of these elements during the project steps. Moreover, it is designed to fit a *temperature sensor* (Heat Electronic Analysis and Transmission), so that it has the double purpose of monitoring the stress on the garment during its lifetime and the punctual operating stress of the fire fighters during the activity.



19. The protection and safety of tourists and tourism workers

Kirsi Jussila, FIOH, Finland

Introduction and aims

Tourism is a progressive branch of industry in Northern Finland. It employs more than 60 000 employees year round, and is based on small and medium-sized enterprises (SME). Adventure tourism in particular has increased in northern areas.

The most common accidents among tourists in Finland on winter vacation are frostbite, slips or falling onto the ice. Development of the safety and protection of tourists and tourism workers can improve the safety of the industry in general, thus enhancing the quality and image of Finland's tourism industry.

This project aims to develop the safety and protection of tourists and tourism workers in extreme conditions and activities in Finland. A cooperative network can also develop safety knowledge, new products and methods to improve safety in the tourism industry's SMEs. Special attention is paid to the challenges of this industry, such as cultural and environmental factors, the development of protection and risk management, communication, documentation and education.

Material and methods

An innovative co-operative network, consisting of organizations from several fields, is working to improve safety within the tourism industry. It includes:

- Safety management
- Protective clothing and equipment
- Communication and the tracking industry
- The tourism industry
- Research and education institutes (textile and clothing technology, safety management, the tourism industry).

Cold protection research is carried out in laboratory conditions to find the optimum level of required cold protection. Measurements and questionnaires will be carried out in the largest tourist resorts in Finland to find the correct level of cold protection, safety equipment and safety protocol for winter tourism activities.











Expected results in 2012

- Protection for the snowmobile driver
- Tracking methods integrated into clothing
- Training methods for tourism workers
- Information packages for tourists
- A website and information channel featuring material related to travel safety
- Tools for risk and safety management for SMEs, to improve effectiveness and prevent accidents.

Acknowledgements

The project partners, which include the Finnish Institute of Occupational Health, Lappia Vocational School, Tampere University of Technology, Oulu Vocational School, Liminka Unit and Central Ostrobothnia University of Applied Science, wish to express their thanks for financial support to:

- The European Union,
- The European Social Fund and Centre for Economic Development
- The Transport and the Environment of Northern Ostrobothnia.

Joint the network!

Contact:

Kirsi Jussila, Research Engineer Venla Räisänen, Research Engineer Susanna Mäki, Assistant Research Scientist Helena Mäkinen, Team Leader Email: first name.surname@ttl.fi











20. The effect of oil resistance of footwear outsoles on slip resistance characteristics in winter conditions

Aschan Carita, Hirvonen Mikko, Rajamäki Erkki and Mannelin Tarmo, FIOH, Finland

Introduction

In European standards EN ISO 20345:2004 and EN ISO 20346:2004 oil resistance of outsoles is defined as an obligatory requirement for professional footwear.

- Non-oil resistant materials, such as TR or natural rubber, have been considered to be more slip resistant in winter conditions than oil resistant materials.
- Based on this requirement non-oil resistant outsole materials can not be used as outsoles in professional footwear.

The aim of this study

The aim of this study was to find out whether there is a major difference between slip resistance characteristics of oil resistant professional footwear and non-oil resistant footwear in winter conditions.

Materials

The following commonly used footwear types and outsole materials (23 in total) were selected:

- Oil resistant safety footwear with PU, TPU and NBR outsoles
- Separate outsole samples made of NR, TR, SBR, NBR, PU and EVA
- Ordinary winter shoes with TR outsoles
- Rubber boots
- Winter and leisure time shoes, the outsoles of which were made of various rubber compounds.

DCOF measurements

The slip resistance *i.e Dynamic coeffcient of friction* (DCOF), of the outsole samples was measured by using the Portable Slip Simulator of FIOH, *Figure 1*. The measurements were performed in a climatic chamber.

- Smooth ice at different temperatures: 0°C, -5°C and -20°C was used as the testing surface
- On wet ice of 0°C, there was a thin layer of approximately 1-2 mm of water on the icy surface
- Prior to the measurements, the samples were stored at measurement temperature in the climatic chamber for 8 hours
- For comparison, DCOF measurements were also performed at room temperature (20°C), using a steel surface with glycerol as a lubricant.





Figure 1. Measurement arrangements in the climatic chamber

Table 1. DCOF values of the tested outsole samples on an icy surface of 0 $^{\circ}\text{C}$

Surface	Sample no. ^a	DCOF	
		Mean	S.D.
Ice 0°C	12	0.081	0.008
	11	0.080	0.021
	5	0.076	0.009
	13	0.073	0.011
	18	0.065	0.005
	20	0.065	0.006
	17	0.063	0.009
	19	0.063	0.003
	1	0.061	0.006
	6	0.061	0.002
	22	0.060	0.003
	2	0.060	0.008
	21	0.057	0.005
	9	0.056	0.004
	15	0.049	0.005
	4	0.045	0.007
	3	0.042	0.004
	8	0.034	0.012
	10	0.033	0.012
	7	0.029	0.003
	14	0.025	0.005
	23	0.025	0.001
	16	0.024	0.002
	Average	0.053	

^aOil resistant materials marked as bold



Table 2. DCOF values of the tested outsole samples on an icy surface of - 5 °C

Surface	Sample no. ^a	DCOF	
		Mean	S.D.
Ice -5°C	13	0.239	0.033
	11	0.209	0.004
	12	0.187	0.014
	15	0.178	0.016
	22	0.177	0.003
	1	0.176	0.025
	3	0.173	0.006
	5	0.169	0.004
	18	0.156	0.020
	21	0.153	0.008
	17	0.152	0.023
	23	0.148	0.012
	20	0.133	0.005
	6	0.131	0.009
	2	0.131	0.017
	19	0.120	0.002
	14	0.119	0.005
	7	0.112	0.008
	4	0.105	0.013
	9	0.103	0.015
	8	0.101	0.009
	16	0.073	0.002
	10	0.068	0.021
	Average	0.144	

^aOil resistant materials marked as bold

Table 3. DCOF values of the tested outsole samples on an icy surface of -20 °C

Surface	Sample no. a	DCOF	
		Mean	S.D.
Steel + glycerol	23	0.200	0.013
	1	0.186	0.034
	2	0.163	0.011
	12	0.161	0.005
	5	0.161	0.006
	16	0.159	0.010
	17	0.156	0.005
	11	0.155	0.009
	4	0.147	0.007
	13	0.142	0.004
	15	0.141	0.014
	18	0.134	0.010
	20	0.133	0.025
	6	0.131	0.008
	21	0.116	0.014
	22	0.115	0.006
	19	0.115	0.018
	8	0.112	0.011
	14	0.109	0.006
	3	0.106	0.004
	9	0.096	0.002
	10	0.078	0.015
	7	0.072	0.005
	Average	0.134	

^aOil resistant materials marked as bold



Table 4. DCOF values of the tested outsole samples on a steel surface with glycerol as a lubricant

Surface	Sample no.a	DCOF	
		Mean	S.D.
Ice -20°C	12 ^b	0.878	0.091
	θ_p	0.714	0.117
	13 ^b	0.709	0.133
	17 ^b	0.678	0.070
	11 ^b	0.673	0.076
	21 ^b	0.591	0.073
	3^{b}	0.552	0.052
	1 ^b	0.476	0.050
	2 ^b	0.383	0.058
	22	0.319	0.055
	5	0.300	0.015
	14	0.293	0.017
	4	0.290	0.040
	6	0.283	0.043
	20	0.255	0.023
	23	0.227	0.025
	7	0.195	0.031
	18	0.180	0.015
	15	0.169	0.027
	19	0.166	0.007
	10	0.154	0.078
	16	0.146	0.012
	8	0.117	0.007
	Average	0.380	

^aOil resistant materials marked as bold

Hardness measurements

Hardness of outsoles was measured both at room temperature (20°C) and at -20°C. Change in hardness due to cold was found. Oil resistant footwear hardened more in cold than non-oil resistant ones. Difference was found to be statistically highly significant, *Figure 2*.

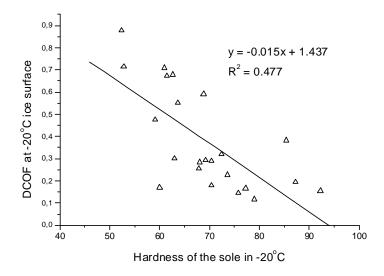


Figure 2. Linear regression line between the hardness of the outsole at -20 °C (Shore A) and the DCOF values measured on an icy surface of -20 °C

^bNormal force of 170 N was used.



Conclusions

The European and ISO standards with their obligatory requirement of oil resistant outsoles seem to restrict the use of more slip resistant outsole materials especially in icy conditions. It is recommended that the CEN and ISO standards for professional footwear should be altered to make oil resistance an additional requirement, so that more slip resistant outsole materials could be used on surfaces, where the accident risk from slipping outweighs the possible hazards caused by fuel oil.

Relevance to preparation of standards/standardisation

The obligatory requirement of the oil resistance of outsole was changed optional in standard EN ISO 17249:2004 - Safety footwear with resistance to chain saw cutting. The change was confirmed in amendment EN ISO 17249:2004/A1:2007. This gives better possibilities to develop more slip resistant footwear for forestry workers in winter conditions.

Acknowledgment

The work has been supported by the Finnish Ministry of Social Affairs and Health, Department for Occupational Safety and Health, and The Swedish Work Environment Authority.

Reference

 Aschan C, Hirvonen M, Rajamäki E, Mannelin T. Slip resistance of oil resistant and non-oil resistant footwear outsoles in winter conditions. Safety Science 2005;43:373-89.



21. From Pole to Pole, Arctic Challenge

Kari Poppis Suomela, Finland

Please visit web sites at:

http://www.poppicok.fi/

http://www.thepole.fi/

Reference

- 1) Suomela Kari Poppis. NORTH POLE arctic challenge, FINNISH NORTH POLE EXPEDITION 2006. POPPICOK, Karisto Oy, Hämeenlinna, Finland 2007. ISBN 978-951-98376-2-8
- 2) Suomela Kari Poppis. SOUTH POLE Windswept Dream. POPPICOK, Karisto Oy, Hämeenlinna, Finland 2009. ISBN 978-951-98376-5-9



Programme of the Seminar

10th EUROPEAN SEMINAR ON PERSONAL PROTECTIVE EQUIPMENT (PPE) 26 - 28.01.2010 Saariselkä, Finland - Saariselkä Tunturi Hotel

TUESDAY 26 JANUARY 2010

Introductory session, Chairman, Helena Mäkinen, FIOH, Finland

9.30 - 10.00	Registration		
10.00- 10.20	Opening of the seminar Hannu Anttonen, FIOH, Finland		
10.20 - 10.40	Revision of the PPE Directive Előd DUDÁS, European Commission		
10.40 - 11.00	Situation in the PPE sector – perspective of the manufacturers Henk Vanhoutte, ESF		
11.00 - 11.20	Situations in the PPE sector – perspective of the Notified Bodies Karl-Heinz Noetel, Coordination of Notified Bodies		
11.20 - 11.40	Situations in the PPE sector - perspective of a Market Surveillance authority Pirje Lankinen, Ministry of Social Affairs and Health, Finland		
11.40 - 12.00	Discussion		
12.00 - 14.00	Lunch break		
Issues relating to the revision of the PPE Directive Chairman, Petra Jackisch, BG BAU Germany			
14.00 - 14.20	Suitable modules for PPE Hans Christian Simanski, Germany		
14.20 - 14.40	Information and markings, Guido Van Duren, President of Febelsafe		
14.40 -15.10	Revision of harmonized standards Henk Vanhoutte, CEN Rapporteur		
15.10 - 15.40	Coffee break		
15.40 - 16.40	Panel discussion		
19.00 - 22.00	Get-together party		









10th EUROPEAN SEMINAR ON PERSONAL PROTECTIVE EQUIPMENT (PPE)

26 - 28.01.2010 Saariselkä, Finland - Saariselkä Tunturi Hotel

WEDNESDAY 27 JANUARY 2010

Issues relating to the selection and use of PPE, Chairman, Martti Humppila, STYL, Finland

9.00 - 9.30	Legal responsibilities with regard to supply, selection and use of PPE Thomas Klindt, Noerr Stiefenhofer Lutz, Germany
09.30 - 09.45	Discussion
9.45 - 10.00	Selection, use and maintenance of respiratory protective devices within new ISO-standards Wolfgang Drews, Chairman of ISO TC 94 SC15
10.00-10.15	Methods to evaluate PPE performance in real work situations Peter Paszkiewicz, BGIA, Germany
10.15-10.30	Does chemical protective clothing gives real protection? Review of last French investigations Le Frious Patricia, Ministry of labour, Amandine Paillat, AFSSET, France
10.30 - 10.45	Differences between laboratory results and real protection during use - hearing protection Martin Liedtke, BGIA, Germany
10.45 - 11.15	Coffee break
11.15 - 12.45	3 Workshops on issues relating to future development and the selection and use of PPE 1. Innovations, lifetime, performance and physiological indicators, **Variable RC RAUL Germany**

- Karl-Heinz Noetel, BG BAU, Germany
- 2. Training requirements for sales persons and users, Henk Vanhoutte, ESF
- 3. Practical performance and requirements in real situations, Eero Korhonen, FIOH, Finland

12.45 - 14.00 Lunch break

- 14.00 Poster session, Product presentation
 - 1. Poor visibility: Same hazard, different risks Longo Giovanna, 3M Deutschland GmbH, Germany
 - 2. Ultimate fire fighting suite, Integrated clothing system Bonafini Enrico, Flower Gloves Srl, Italy
 - 3. Protection and Safety of Tourists and Tourism Workers Jussila Kirsi, FIOH, Finland
 - 4. The effect of oil resistance of footwear outsoles on slip resistance characteristics in winter conditions Aschan Carita, Hirvonen Mikko, Rajamäki Erkki and Mannelin Tarmo, FIOH, Finland









10th EUROPEAN SEMINAR ON PERSONAL PROTECTIVE EQUIPMENT (PPE) 26 - 28.01.2010 Saariselkä, Finland - Saariselkä Tunturi Hotel

WEDNESDAY 27 JANUARY 2010

Practical demonstrations: Development of protective clothing and equipment for extreme conditions and Rescue activities (Indoors and outdoors)

14.20 - 14.55	From Pole to Pole, Arctic Challenge
	Kari Poppis Suomela, Finland

14.55 - 15.55 Poster session and product presentation continue

Coffee break

16.30 - Rescue drill, (Outdoors)

Finnish rescue service, Lapland, Finland

19.00 - 22.00 Seminar dinner

THURSDAY 28 JANUARY 2010

Future needs and possible solutions Chairman, Karl-Heinz Noetel, BG BAU, Germany Short summary of the workshops

9.00 - 9.30 1) Innovations, lifetime, performance and physiological indicators *Karl-Heinz Noetel, BG BAU, Germany*

2) Training requirements for sales persons and users Henk Vanhoutte, ESF

3) Practical performance and requirements in real situations *Eero Korhonen, FIOH, Finland*

9.30 - 10.30 Discussion

10.30 - 11.00 Summing up of the seminar and closing









List of lecturers and participants

Name	Organisation	Country
Anttonen Hannu	Finnish Institute of Occupational Health	Finland
Bezdek Milan	VOP-026 Sternberk, s.p.	Czech Republic
Bonafini Enrico	Flower Gloves Srl	Italy
Bryce Paul	Microgard Ltd	United Kingdom
Christ Eberhard	Institut für Arbeitsschutz - BGIA der Deutschen Gesetzlichen Unfallversicherung	Germany
Clayton Mike	Health and Safety Laboratory	United Kingdom
Dantscher Sandra	BGIA	Germany
Drews Wolfgang	Dräger Safety AG & Co. KGaA	Germany
Dudás Előd Ajtony	European Commission	Belgium
Ebner Gerhard	Federal Ministry of Economy, Family and	Austria
Einhaus Marco	Youth - BMWFJ Pr.	Germany
Ekelund Patrick	Suomen 3M Oy	Finland
Elg Peter	Suomen 3M Oy	Finland
Garrigou Alain	Dpt HSE, IUT, university of Bordeaux	France
Gonzalez Reyes Juan Carlos	Polartec, LLC	Spain
Helmus Manfred	Bergische Universität Wuppertal	Germany
Hoerup Poul	Danish Emergency Management Agency	Denmark
Humppila Martti	Suojalaite Oy - Safety Equipment Co.	Finland
Isotalus Nina	Lindström Oy	Finland
Jablonski Adam	FILTER SERVICE Sp. z o.o.	Poland
Jackisch Petra	BG BAU - Auslandsprojekte der Prävention	Germany
Jaques Michel	INRS	France
Johnsson Elin	Kompetenscentrum PPE at SP Technical Research Institute of Sweden	Sweden
Junno Sanna	Euromaski Oy	Finland
Jurvelius Hannele	Ministry of Social Affairs and Health	Finland
Jussila Kirsi	Finnish Institute of Occupational Health	Finland
Kelsall Ian	3M UK	United Kingdom
Kero AnnSofie	Swedish Work Enviroment Authority	Sweden
Klindt Thomas	Noerr Stiefenhofer Lutz	Germany
Korhonen Eero	Finnish Institute of Occupational Health	Finland
Kransdal Marie	3M Svenska AB	Sweden
Krolik Agnieszka	PANSTWOWA INSPEKCJA PRACY	Poland
Lagus Olai	Scott Health & Safety Oy	Finland



Name	Organisation	Country
Lankinen Pirje	Ministry of Social Affairs and Health	Finland
Larsson Einar S	Labour Inspection Authority Indre Østland	Norway
Le Frious Patricia	Ministry of labour	France
Liedtke Martin	BGIA	Germany
Lindstedt Maria	Swedish Consumer Agency	Sweden
Longo Giovanna	3M Deutschland GmbH	Germany
Madzivhe Thomas	NRCS	South Africa
Makowski Krzysztof	CIOP-PIB	Poland
Markkanen Päivi	Finnish Institute of Occupational Health	Finland
Mayer Alain	INRS	France
Merken Maries	Federal Public Service Economy	Belgium
Meyer Christoph	RICOTEST	Italy
Mäkelä Erja	Finnish Institute of Occupational Health	Finland
Mäki Susanna	Finnish Institute of Occupational Health	Finland
Mäkinen Helena	Finnish Institute of Occupational Health	Finland
Natorska Jolanta	PANSTWOWA INSPEKCJA PRACY	Poland
Nilsson Helena	Swedish Consumer Agency	Sweden
Noetel Karl-Heinz	BG BAU	Germany
Nordgren Michael	North Safety Products	Finland
Novák Michal	Czech Office for Standards, Metrology and Testing	Czech Republic
Nyzio Jaroslaw	PANSTWOWA INSPEKCJA PRACY	Poland
Paillat Amandine	AFSSET	France
Paszkiewicz Peter	BGIA (IFA)	Germany
Pitschner Udo	G.Schümer GmbH & Co.	Germany
Rademacher Klaus-Dieter	City of Essen	Germany
Reims Erkki	Euromaski Oy	Finland
Reponen Seija	Finnish Institute of Occupational Health	Finland
Reunanen Reijo	Multisafe Oy	Finland
Roskams Nele	Prevent vzw	Belgium
Ruud Arnfinn	Labour Inspection Authority Indre Østland, Norway	Norway
Schulze Marc	Federal Ministry of Labour and Social Affairs	Germany
Sickert Peter	Berufsgenossenschaft Metall Nord Sued	Germany
Sihvola Katri	Tukes	Finland
Silvente Eric	INRS	France

10th EUROPEAN SEMINAR ON PERSONAL PROTECTIVE EQUIPMENT Seminar Report



Name	Organisation	Country
Simanski Hans Christian	DEKRA EXAM GmbH	Germany
Stoerholt Hanne Cecilie	Directorate for Civil Protection and Emergency Planning (DSB)	Norway
Stoltz Per	Procurator AB	Sweden
Sulowski Andrew	Sulowski Fall Protection Inc.	Canada
Tammela Erja	Finnish Institute of Occupational Health	Finland
Tirilly Vincent	Ministry of agriculture	France
Van Duren Guido	Ansell Healthcare	Belgium
Vanhoutte Henk	European Safety Federation	Belgium
Vaughan Nick	Health and Safety Laboratory	United Kingdom
Zanco Sante	FLOWER GLOVES SRL	Italy



Work environment research series publications

- 1. Hongisto V, Helenius R, Lindgren M: Kaksinkertaisen seinärakenteen ääneneristävyys laboratoriotutkimus. Työterveyslaitos, Helsinki 2002.
- 2. Hongisto V: Monikerroksisen seinärakenteen ilmaääneneristävyyden ennustemalli. Työterveyslaitos, Helsinki 2003.
- 3. Työhygienian koulutuspäivät 2003. (Imatra 20.–21.5.2003.) Työterveyslaitos 2003.
- 4. Kaarlela A, Jokitulppo J, Keskinen E, Hongisto V: Toimistojen ääniympäristökysely menetelmän kehitys. Työterveyslaitos 2003.
- 5. 6th European Seminar on Personal Equipment Seminar Report. Ed. Eero Korhonen. Finnish Institute of Occupational Health, Helsinki 2003.
- 6. Petra Larm, Jukka Keränen, Valtteri Hongisto: Avotoimistojen akustiikka. Työterveyslaitos, Helsinki 2004.
- 7. Työhygienian koulutuspäivät 2004. (Helsinki 25.–26.5.2004.) Toim. Mirja Kiilunen. Työterveyslaitos, Helsinki 2004.
- 8. Valkeapää A, Anttonen H, Niskanen J: Liike- ja palvelurakennuksien tuulikaappien vedontorjunta. Työterveyslaitos, Helsinki 2004.
- 9. Kaarlela A, Jokitulppo J, Helenius R, Keskinen E, Hongisto V: Meluhaitat toimistotyössä pilottitutkimus. Työterveyslaitos, Helsinki 2004.
- 10. Toppila E, Laitinen H, Starck J, Pyykkö I: Klassinen musiikki ja kuulonsuojelu. (Myös pdf-versio.) Työterveyslaitos, Helsinki 2004.
- 11. Hirvonen A, Kiilunen M, Valkonen S: Biologisen monitoroinnin palveluanalytiikan vuositilasto 2003. Työterveyslaitos, Helsinki 2004.
- 12. Heikkilä P, Saalo A, Soosaar A: Työpaikkojen ilman epäpuhtausmittaukset 1994–2003. Työterveyslaitos, Helsinki 2005.
- 13. Työhygienian koulutuspäivät 2005. (Tampere 15.–16.6.2005.) Toim. Starck J ja Laitinen R. Työterveyslaitos, Helsinki 2005.
- 14. Maila Hietanen, Patrick von Nandelstadh, Tommi Alanko: Sähkömagneettiset kentät työympäristössä. Opaskirja työntekijöiden altistumisen arvioimiseksi. Työterveyslaitos, Helsinki 2005.
- 15. Biologisen monitoroinnin palveluanalytiikan vuositilasto 2004. Työterveyslaitos, Helsinki 2005.
- 16. Elo A-R, Korhonen E, Starck J (Eds.): 7th European Seminar on Personal Protective Equipment. Seminar report. Work Environment Research Report Series 16, Finnish Institute of Occupational Health, Helsinki 2005.
- 17. Puuntyöstöpölyn hallinnan kehittäminen (FineWood). Lappeenrannan aluetyöterveyslaitos, Fysiikan osasto ja VTT Tuotteet ja tuotanto. Työterveyslaitos, Lappeenranta 2005.
- 18. Hautalampi T, Henriks-Eckerman M-L, Engström K, Koskela H, Saarinen P & Välimaa J: Kemikaalialtistumisen rajoittaminen automaalaa¬moissa. Työterveyslaitos, Turku 2006.
- 19. Alanko T, Hietanen M, von Nandelstadh P: Työntekijöiden altistuminen tukiasemien radiotaajuisille kentille. Työterveyslaitos, Helsinki 2006.
- 20. Niemelä R: Virtual 4D. Loppuraportti. Työterveyslaitos, Helsinki 2006.
- 21. Valkonen S: Biologisen monitoroinnin palveluanalytiikan vuositilasto 2005. Työterveyslaitos, Helsinki 2006.
- 22. Larm P, Hakala J, Hongisto V: Sound insulation of Finnish building boards. (Work Environment Research Report Series 22.) Finnish Institute of Occupational Health, Helsinki, Finland 2006.
- 23. Hongisto V, Keränen J, Larm P, Oliva D: Työtilan ääniympäristön havainnollistaminen, Virtual Space 4D ääniympäristöosion loppuraportti. Työterveyslaitos, Helsinki 2006.



- 24. Liesivuori J, Naumanen P, Aromaa E, Pääkkönen R, Starck J, Kauppinen T, Savolainen K: Muuttuva työympäristö visio vuoteen 2015. Työterveyslaitos, Helsinki 2006. (Myös nettiversio.)
- 25. Aitio A, Hakala E, Kiilunen M, Laitinen J, Mikkola J ja Valkonen S: Biologisen monitoroinnin palveluanalytiikan vuositilasto 2006. Työterveyslaitos, Helsinki 2007.
- 26. Romppanen V, Sulander J: Hyvintointi koulutyössä ja opiskelussa. Työterveyslaitos, Helsinki 2007.
- 27. Mäki Susanna (Ed.): 8th European seminar on Personal Protective Equipment. 27-29.3.2007 in Saariselkä, Lapland, Finland. Work Environment Report Series 27, Finnish Institute of Occupational Health, Helsinki 2007. (Also pdf)
- 28. Liesivuosi J, Naumanen P: Visioita alueellisen työhyvinvoinnin ja työterveyden edistämisestä. Työterveyslaitos, Helsinki 2007.
- 29. Nurminen M, Norppa H: Metallisen kromin ja kolmiarvoisten kromiyhdisteiden ammatillinen syöpävaara. Työterveyslaitos, Helsinki 2008.
- 30. Räikkönen, T Työelämä murtuvan aallon harjalla mitä on tapahtumassa työhyvinvoinnin edellytyksille?, Helsinki 2008 (Also pdf)
- 31. Kasvio A, Nikkilä R, Moilanen L, Virtanen S: Työ murroksessa -kyselyn aineistoraportti. Työterveyslaitos, Helsinki 2008. (Also pdf)
- 32. Ahonen Ilpo & Liukkonen Tuula: Pellettivarastojen ilman epäpuhtaudet ja niiden aiheuttamien vaarojen ehkäiseminen. Työympäristötutkimuksen raporttisarja 32. Työterveyslaitos, Helsinki 2008. (Also PDF-versio)
- 33. Janhonen Minna, Laitinen Heikki, 3T-ratkaisut Oy: Pienyritysten kehittämishanke Mäntsälässä hankearviointi. Työterveyslaitos, Helsinki 2008.
- 34. Alanko Tommi, Tolvanen Tuomas, Hietanen Maila: Mastotyöntekijöiden altistuminen radiotaajuuskentille. Työterveyslaitos, Helsinki 2008. (Also PDF)
- 35. Hakala, Erkki, Kiilunen Mirja, Santonen Tiina, Mikkola Jouni: Biologinen monitorointi vuositilasto 2007. Työterveyslaitos, Helsinki 2008. (Also PDF)
- 36. von Bonsdorff Monika, Janhonen Minna, Vanhala Sinikka, Husman Päivi, Ylöstalo Pekka, Seitsamo Jorma, Nykyri Erkki: Henkilöstön työkyky ja yrityksen menestyminen vuosina 1997–2007-tutkimus metalliteollisuudessa ja vähittäiskaupan alalla. Työterveyslaitos, Helsinki 2009. (Also PDF)
- 37. Hongisto Valtteri, Häggblom Henna: MAKSI hankkeen loppuraportti Toimistojen mallinnettu ja koettu sisäympäristö. Työterveyslaitos, Helsinki 2009.
- 38. Mäki Susanna (Ed): 9th European seminar on Personal Protective Equipment. 29.–31.1.2008 in Spa Hotel Levitunturi, Levi, Finland. Work Environment Report Series 38, Finnish Institute of Occupational Health, Helsinki 2009. (Also PDF)
- 39. Saarinen Pekka: Ilmastoinnin virtausäänen laskenta. Työterveyslaitos, Helsinki 2009.
- 40. Häggblom Henna, Koskela Hannu: Toimiston ilmavirtaukset ja lämpöolot jäähdytyspalkkijärjestelmässä. Työterveyslaitos, Helsinki 2009.
- 41. Oliva D, Häggblom H, Hongisto V: Sound absorption coefficient multi-layered materials an experimental study (in english). Work Environment Report Series, Finnish Institute of Occupational Health, Helsinki 2009.
- 42. Laine Tarja, Peurala Marjatta, Rautio Maria, Manninen Pirjo: Asiakasorganisaatioiden työterveyshuollon toimintasuunnitelmien arviointi ja kehittäminen. Työterveyslaitos, Helsinki 2009. (Also pfd.)
- 43. Kandolin Irja, Tilev Kristina, Lindström Kari, Vartia Maarit, Ketola Ritva: Palvelualojen työolot ja hyvinvointi. Työterveyslaitos, Helsinki 2009.
- 44. Kasvio Antti, Nikkilä Riku, Räikkönen Timo: Work and its future as viewed by Finnish citizens and experts, Helsinki 2009.
- 45. Kiilunen, Mirja, Mikkola, Jouni, Santonen Tiina: Biologinen monitorointi, Vuositilasto 2008. Helsinki 2009. (Also PDF.)



- 46. Pesonen Sanna, Lindström Pia, Meyer-Arnold Marianne, Rautio Maria, Manninen Pirjo, Kämäräinen Markku, Mäenpää-Moilanen Eija, Ylikoski Matti: Työterveyshuollon pätevöittävän koulutuksen vaikuttavuus Työterveyslaitoksella, Helsinki 2009. (Also PDF.)
- 47. Saalo Anja, Vainiontalo Sinikka, Kiilunen Mirja, Tuomi Tapani: Työympäristön kemikaalien altistumismittaukset 2004–2007. Helsinki 2010. (Also PDF.)
- 48. Pahkin Krista, Leppänen Anneli, Kajosaari Katri, Ala-Laurinaho Arja, Welling Irma, Väänänen Ari, Joensuu Matti, Koskinen Ari: Työhyvinvoinnin kehittäminen ja sairauspoissaolojen hallinta paperiteollisuudessa. Työterveyslaitos, Helsinki 2010. (Also PDF.)
- 49. Vuorinen Helena, Kivistö Sirkku, Joensuu Matti, Haapanen Ari: Työhön paluun tuesta työssä jatkamiseen Osasairauspäivärahan tavoitteet, etuuden käyttöönotto ja jatkon haasteet. Työterveyslaitos, Helsinki 2010. (Also PDF.)
- 50. Holopainen Rauno, Salmi Kari, Hintikka Eeva-Liisa, Kekäläinen Pirjo, Kähkönen Erkki, Lappalainen Sanna, Niemelä Raimo ja Reijula Kari, Työterveyslaitos, Laadukas sisäympäristö -teema, Asikainen Vesa, Kalliokoski Pentti ja Pasanen Pertti, Itä-Suomen yliopisto, Ympäristötieteen laitos, Kakko Leila, Tampereen ammattikorkeakoulu: Sairaaloiden ilmanvaihtokanavistojen puhtaus ja puhdistuksessa leviävien epäpuhtauksien hallinta. Loppuraportti. Työterveyslaitos, Helsinki 2010. (Also PDF.)
- 51. Elo Anna-Liisa, Ervasti Jenni ja Kuokkanen, Anna: Hyvinvointi ja tuloksellisuus esimiehen haasteena. Tutkimus kolmessa julkisen sektorin organisaatiossa. TSR-projektin loppuraportti. Työterv eyslaitos, Helsinki 2010.
- 52. Kiilunen Mirja: Biologinen monitorointi. Vuositilasto 2009. Työterveyslaitos, Helsinki 2010. (Also PDF.)
- 53. Moilanen Liisa: Toiveet ja todellisuus Työn ominaisuudet eri työntekijäryhmien näkökulmasta. Työterveyslaitos, Helsinki 2010.
- 54. Oliva D, Hongisto V, Keränen J, Koskinen V: Control of facade sound insulation at low frequencies LFN. Measurement of low frequency noise in rooms Method for constant and intermittent noise.
- 55. Savinainen Minna, Peurala Marjatta, Manninen Pirjo, Rautio Maria, Oksa Panu: "Työterveyshuollon työpaikkaselvitys osana yritysten hyvinvointi- ja turvallisuustoimintaa" 2007-2009. Loppuraportti. Työterveyslaitos, Helsinki 2010. (Also PDF)
- 56. Mäki Susanna (Ed): 10th European seminar on Personal Protective Equipment, 26-28.1.2010 in Saariselkä Tunturi Hotel, Lapland, Finland. Seminar Report. Finnish Institute of Occupational Health, Helsinki 2010.

WORK ENVIRONMENT RESEARCH REPORT SERIES 56 Finnish Institute of Occupational Health, 2010

The WORK ENVIRONMENT RESEARCH REPORT SERIES 56 contains papers presented at the 10th EUROPEAN SEMINAR ON PERSONAL PROTECTIVE EQUIPMENT, held in Saariselkä, Lapland 26 – 28 January 2010. The PPE seminar in cold and northern Lapland, near the Arctic Circle, was very successful and had nearly one hundred registered participants from 15 different countries.

The main topic of the seminar was description of and discussions on the proposed revision of the PPE Directive. Market surveillance, Notified Bodies and the standardization of activities were also discussed. Specific items of the presentations and discussions were issues relating to the correct selection and use of PPE products in order to ensure a high performance level in real-use situations. Also, there was a follow-up on the development of performance and lifetime indicators.

The seminar succeeded in bringing together European PPE experts dealing with standardization, testing, certification, research, manufacturing, and market surveillance. This 10th seminar once again provided a unique forum for disseminating findings in the PPE field, and gave speakers and participants the opportunity to exchange experiences with different stakeholders.

Visit our webbsite at: www.ttl.fi/ppeseminar

ISBN 978-952-261-054-6 (book) ISBN 978-952-261-055-3 (pdf)

ISSN-L 1458-9311 ISSN 1458-9311 (book)

ISSN-L 1458-9311 ISSN 1799-4470 (pdf) Photo : Nilla S Hirvasvuopio

