BUSINESS PLAN

CEN/TC 79
RESPIRATORY PROTECTIVE DEVICES

EXECUTIVE SUMMARY

Scope

To prepare European Standards for respiratory protective devices (RPD) for work and rescue purposes, including self rescue. These devices shall protect against oxygen deficiency and/or the risk to inhale harmful particles (e.g. dusts, fumes), gases or vapours, as well as European Standards for underwater breathing apparatus.

Business Environment

- Europe represents nearly one third of the world RPD market
- Relatively small market compared to the whole PPE market
- High competition on the market
- Parties involved:
  - Manufacturers
  - test houses and notified bodies
  - public authorities
  - users
  - SME associations
- CEN/TC 79 operates in close cooperation with ISO/TC 94/SC 15

The following European laws are relevant to the work of CEN/TC 79:

1. Council Directive 89/686/EEC of 21 December 1989 plus amendments 93/95/EEC, 93/68/EEC and 96/58/EEC concerning PPE and

2. Council Directive 89/656/EEC of 30 November 1989 (plus Commission Communication for its implementation concerning the the assessment of the safety aspects of PPE with a view of the choice and use thereof (89/C 328/02)) concerning the use by workers of PPE at the workplace.

RPD do not fall under the PPE Directive only, but other directives like Pressure Equipment Directive (PED) or Medical devices (MDD) need to be regarded as well.

Benefits
Harmonized standards as developed by CEN/TC 79 provide a tool to demonstrate compliance with the essential requirements of the Directives. They build a framework for a harmonized regulatory process (testing and certification) within Europe.

Priorities
CEN/TC 79 has two priority items, which need to be worked on in parallel:

- Prepare and revise, when necessary, EN standards for RPD to give safe and effective products to the market
- Work on the evaluation of upcoming ISO standards for Respiratory Protective Devices and their possible Transfer into EN ISO standards, considering the impact that this may have on all stakeholders. Provisions shall be taken in order that sufficient time is given to adopt the new EN ISO, using an evolution as well as a transition period.

1 BUSINESS ENVIRONMENT OF THE CEN/TC

1.1 Description of the Business Environment

The following political, economic, technical, regulatory, legal, societal and/or international dynamics describe the business environment of the industry sector related to the scope of this CEN/TC, and they can significantly influence how the relevant standards development processes are conducted and the content of the resulting standards:

General information regarding the sector and product
At several workplaces the breathable air is polluted by impurities, which create a risk to the health or even to the life of the worker. If those risks cannot be reduced by elimination /reduction of the danger source or by collective protection, the application of respiratory protective devices is often mandatory. For underwater workplaces the application of the respiratory protective devices is in any case mandatory

Interested parties in the standardisation process
Interested parties in the standardization process are all kind of industries, producers, importers and distributers of respiratory protective equipment, public authorities, test institutes and laboratories, notified bodies, end users and their federations and other nongovernmental organizations. All of them are interested in having a set of standards that establish a terminology for the sector, define the minimum requirements and describe the test methods for the devices.

The possible introduction of future ISO standard is a major challenge for every stakeholder. The basic approach changes dramatically from the EN, focusing the requirements on physiological needs instead of product performances.

1.2 Quantitative Indicators of the Business Environment

The following list of quantitative indicators describes the business environment in order to provide adequate information to support actions of the CEN /TC:

The following list of quantitative indicators is estimation for the business environment
Market:

- Worldwide about (incl. EU) 3 billion €
- European Union about 1 billion €

Roughly two thirds of the market is covered by filtering devices, one third by devices independent from the ambient air, including devices for diving.

The annual rate of increase can be estimated to be about 2% in the EU.

The European market is shared by global companies, as well as SME (small and medium enterprises). Both are playing an important role not only in niche markets.

Revisions of EN standards and possible implementation of the future EN IOS Standards, as well as revision of the PPE directive might create additional costs for all stakeholders for necessary recertification, redesigning and training. This cost are not yet estimated

RPD are category III PPE (Personal Protective Equipment) and as such they shall obey to relevant Directive and primarily to 89/686/EC. This means that almost all RPD are made to EN standards. Other directives involved are mentioned later in the document.

2 BENEFITS EXPECTED FROM THE WORK OF THE CEN/TC

The mission of the CEN/TC 79 is to provide a European system of reference, which on the one hand, will allow the parties involved to attain a homogeneous level of safety within Europe and, on the other hand, will establish clearer competition conditions, taking in account ISO work program. This system of reference is found on the essential requirements of the annex II of the directive.
The documents developed by CEN/TC 79

- assist manufacturers to demonstrate fulfillment of the applicable Essential Requirements of the Personal Protective Directive and provide manufacturers, Notified Bodies and test houses with a clear route to CE marking;
- improve the ability to protect end users
- contribute to the elimination of trade barriers;
- provide agreed test methods;
- support methods for selection and use
- promote improvement in the quality of products on the market
- offer a larger and easier access to the market for the manufacturer
- provides an easy way to comply with the essential requirements of the directive and to show the compliance

Political and legal factors
For respiratory protective devices two EC Directives are relevant:

1. Council Directive 89/686/EEC of 21 December 1989 plus amendments 93/95/EEC, 93/68/EEC and 96/58/EEC concerning PPE, and

2. Council Directive 89/656/EEC of 30 November 1989 (plus Commission Communication for its implementation concerning the assessment of the safety aspects of PPE with a view of the choice and use thereof (89/C 328/02)) concerning the use by workers of PPE at the workplace.

The purpose of the first Directive is to eliminate barriers to trade and both to maintain or improve the level of protection of users.

The first Directive requests that all PPE meet the essential requirements as specified in Annex 2 of the Directive, where applicable, with regard to safety aspects, ergonomics and physiological parameters.

The second Directive contains employers´ obligations. Risk analysis and selection of the correct PPE are the most important ones.

Both Directives guarantee as much safety for the user as possible.

Harmonized standards as drafted by CEN/TC 79 provide a tool to demonstrate compliance with the essential requirements of the PPE Directive.

The standards developed by CEN/TC 79 build a framework for a harmonized regulatory process (testing and certification) within Europe.

The work of CEN/TC 79 was started under Mandates/Order vouchers: BC/CEN/07/88, BC/CEN/02/90 and BC/CEN/031/93/30.

Social factors
CEN/TC 79 regards the high level of safety of devices as a fundamental social factor. The acceptance of devices can also be increased by ergonomic design and convenient physiological parameters taking into account gender and ethnic peculiarities. Herewith the hazards to health are reduced, with consequently reduction of health care cost.

A basic principle is the awareness of the user that health determines his social and economic disposition, and that the use of PPE will help to protect his health.

Technical factors
The technical development of RPD is mainly characterized by mechanical, material, chemical and electronical knowledge. Reliability of products is essential. Good ergonomics and comfort increase the acceptance of RPD.

Economical factors
Competition is high in the market for RPD, not only in Europe but worldwide, resulting in a high pressure to suppliers of RPD to reduce prices. The application of CEN/TC 79 standards will avoid the danger that price reduction will result in reducing the quality level of the RPDs entering the market.

The economic value of the CEN/TC 79 standards is also of high importance for the using and manufacturing industry because of the risk minimizing effects relating to users health and safety. A defect of a device can damage user’s health or even life. Consequently, high compensations from the manufacturer or the insurer can arise.

International aspects
Standardisation activities on ISO level for RPD started in 2002 and made considerable progress since then. ISO/TC 94/SC 15 is responsible for RPD within ISO, including diving apparatus. In order not to split personal capacities, CEN/TC 79 decided in 2002 by resolution to focus on ISO work. In 2011 CEN/TC 79 started to work on the issue how to implement the upcoming results of the ISO work in Europe. Keeping in mind the major differences between the ISO approach (wearer related) and the CEN approach (product related) a smooth transition is necessary for all parties involved (users, manufacturers, test houses, Notified Bodies) is regarded to be necessary.

3 PARTICIPATION IN THE CEN/TC

All the CEN national members are entitled to nominate delegates to CEN Technical Committees, Sub-committees and experts to Working Groups, ensuring a balance of all interested parties.

Participation as observers of recognized European or international organizations is also possible under certain conditions. To participate in the activities of this CEN/TC, please contact the national standards organization in your country.

4 OBJECTIVES OF THE CEN/TC AND STRATEGIES FOR THEIR ACHIEVEMENT

4.1 Defined objectives of the CEN/TC

The objective of CEN/TC 79 is the development or improvement of standards related to respiratory protection. These are standards defining minimum performance requirements, test methods, selection and use and necessary supporting documents, e.g. for terms and definitions. The work done on ISO may help to hit this objective.

4.2 Identified strategies to achieve the CEN/TC.s defined objectives

Work done on ISO level shall not be duplicated at CEN level. This shall be achieved by the following strategy:

- Revision of existing EN standards only if this is necessary for safety reasons.
- Active involvement of CEN members on the work of ISO/TC 94/SC 15.
- Use of the knowledge gained from ISO/TC 94/SC 15 when updating EN standards or possibly adopt them as EN ISO standards in an appropriate time frame.
- Follow the indications of CEN-CENELEC Guide 17 (SME standardization guide) in writing standards.

Liaison and partner organisations:

SBS
SME Safety

TC cooperation:

CEN/TC 122
CEN/TC 158
CEN/TC 162
CEN/TC 23

Affiliate participation:

BAS

CEN/TC 79 co-operates also closely with ISO/TC 94/SC 15 “Respiratory protective devices”

Other liasons may be possible, whenever appropriate

4.3 Environmental aspects

The documents elaborated by CEN/TC 79 do not explicitly deal with such aspects, as these are not part of the Basic Health and Safety Requirements of the PPE Directive.
If coherence between health and safety requirements and environmental aspects is to be recognized, these aspects will be handled once they appear. However, in the area of Respiratory Protection safety aspects will always have priority over environmental aspects.

5 FACTORS AFFECTING COMPLETION AND IMPLEMENTATION OF THE CEN/TC 79 WORK PROGRAMME

RPD do not fall under the PPE Directive only, but other directives like PED or MDD, which need to be regarded as well. Writing the Standards in such a way, that they are in accordance or at least does not conflict with other directives may slow down the progress.

The envisioned revision of the PPE directive may also absorb working capacity of the committee members, because for formal reasons it might be necessary to revise all EN standards.