

Respirator Standardization and Regulation in Western Europe

Erik Bjarnov, Dantest
Birthe Arp-Hansen, Danish National Labor Inspection Services

Introduction

Initially we were asked to talk about standardization and regulation in **Denmark**, but **we** felt it was impossible to separate the Danish and the European **situation**. **Thus** we will present to you an overview of the standardization work currently going on in CEN, the current regulations in Scandinavia and the regulation that will be proposed shortly in the EC, the European Communities.

CEN

CEN, the **Comite Europeen de Normalisation**, is an organization of the national standardization organizations in 16 European countries covering essentially the whole of Western Europe. The EC countries together with the **five EFTA** countries, Norway, Sweden, Finland, **Switzerland** and Austria are the member states of CEN.

To become an European standard, an Euro **Norme** (EN), a proposed standard must be approved by a majority of the member states. The rules of CEN requires **EN's** to be implemented in all member states. Thus when a standard for a respiratory protective device has been finalized, this standard is valid all over Western Europe after a relatively short period of time.

CEN Standardization of Respiratory Protective Equipment

The CEN work on respiratory protective equipment began in 1974. The first **EN's** appeared in 1986. It seems a very long time to make a standard. However, looking back, much has been achieved in the time passed. It was a very ambitious project with many standards being worked on at the same time by the same persons. Also several of the countries had their own standards and test methods. Much time has been used to test new methods and compare them with the existing, and to

reach agreement on the philosophies behind each standard.

One of the philosophies is that only respiratory protective devices that really offer protection, should be standardized. This means that the device should be usable at workplace conditions that present a threat to health. In other words devices designed for nuisance levels only will not be standardized in CEN, since the lowest rated devices standardized will also be usable at nuisance level.

Another philosophy, which is still debated, is **components** testing versus testing of complete equipment. For the time being masks and filters are tested separately using "**worst case**" filter simulators in the face seal leakage testing. Other equipment, like turbo devices **incorporating** hoods, are tested as complete equipment.

It has been very difficult to keep the standardization and regulation aspects separated. The lay-out of a standard is shown in table 1. The title is fairly long, but descriptive. There are 7 to 8 clauses, of which the requirements are meant as minimum requirements, which means that equipment passing the tests is not necessarily the best available.

Table 1	
Lay out of a European Standard	
EN xyz	Respiratory Protective Devices (Actual Device)
	Requirements, Testing , Marking
Preamble	
1.	Scope and field of application
2.	References
3.	Definition and description
4.	Classification
5.	Requirements
6.	Testing
7.	Direction for use
8.	Marking

A great **effort** has been made to specify only measurable requirements. This task has been very **difficult** since it has meant that besides the tests of quality **control** type also a series of tests to simulate use of the device in "**real** life," i.e. at the **workplace**, should be designed. Tests yielding results that are independent of the test house performing the **test** are still sought.

TC 79 the technical committee for standardization of respiratory protective equipment met on October 2, 1987. At this meeting four standards were finalized from the technical point of view. The final editing only remains before they may be sent to CEN for preliminary voting with a fair chance of getting approval from a **majority**. The status of the CEN work is shown in tables 2 to 5. First the actual **EN's** where only one full **equipment** is included. Next the standards waiting for final voting. Then the standards somewhere on the way to preliminary voting and finally the standards that still are in the technical **subgroups** are shown.

Table 2

Existing European Standards 1987

- EN 132 Definitions
- EN 133 Classification
- EN 134 Terminology of piece parts
- EN 135 List of equivalent terms
- EN 137 Self contained open circuit compressed air breathing apparatus
- EN 148** Threads for **facepieces**. **Part 1:** Standard thread. **Part 2:** Centre thread.

Table 3

Proposed Standards ready for FINAL vote

- prEN 136 Full face masks
- prEN 140 Half masks and quarter masks
- prEN 141** Gas filters and combined filters
- prEN 142 Mouthpiece assemblies
- prEN 143 Particle filters
- prEN 144 Gas cylinder valves
- prEN 145 Self contained closed circuit compressed oxygen breathing apparatus
- prEN 146 Turbo particle filtering devices incorporating hoods and helmets
- prEN 147 Turbo particle filtering devices incorporating full face **masks**, half masks or quarter masks

Table 4

Standards ready for PRELIMINARY vote

- prEN 138 Fresh air hose breathing apparatus
- prEN 139 Compressed air line breathing Apparatus
- prEN 149 Filtering half masks against particles
- prEN 269 Power assisted fresh air hose breathing apparatus incorporating a hood.
- prEN 270 Compressed air line breathing apparatus incorporating a hood
- prEN 271 Compressed air line breathing apparatus for abrasive blasting

Table 5

Standards being prepared

- Gas filters against low boiling compounds.
- Filtering half masks against gases.
- Turbo gas filtering **devices** incorporating hoods or helmets.
- Turbo gas filtering devices incorporating full face **masks**, half masks or quarter masks.
- Gas cylinder valves. Side connectors.

At the meeting of the technical committee a work group was asked to perform a series of round robin tests to assure that one of the most difficult **tests**, the measurement of total inward leakage or face seal **leakage**, actually can be performed to the same result in the test houses. It is the general belief that this is possible. Thus the technical committee has decided to send the proposed standards for **half-** and quarter masks and for filtering **half-**masks to the final editing and translation. If it should turn out that this measurement is not specified sufficiently, there is still time to **revise** the proposal before it is sent to final vote.

In order to take advantage of all the European expertise gathered in the TC79, a subcommittee has been working on guidelines for the selection of the appropriate respiratory protective device to be used in a given situation. These guidelines are not meant to replace the regulations in each country, but are believed to be a help for the people responsible for workplace safety.

Regulation in Scandinavia

Although there is only one device, the self contained open circuit compressed air breathing apparatus, standardized in a European standard, **it does not** mean that the work has been purely theoretical. National standards or regulations have been based on the draft standards as well as the opposite, draft standards being based on national standards. Thus test houses and authorities have gained experience with the principles.

In Scandinavia (Denmark, Finland, Norway and Sweden) the labor inspection services, who are responsible for occupational health and **safety**, have a **system** of type approval of respiratory protective equipment. The **approvals** are based on test reports from independent test houses, where the tests and requirements are based on the newest available draft European standards at the time of approval. Also the executives are cooperating so that an approval in one country is the only proof needed to get approval in the other countries.

There is no legal requirement to use approved **equipment**. The requirement is that suitable equipment should be made available by the employer. The **system** of approved respirators has been made in order to give some guidance to equipment that really **offers** the user some protection. A list of approved personal **protective**

equipment is issued at regular **intervals**, and approved equipment may be marked with the safety star. This system has freed the executives from the difficult task of recommending equipment without favoring some producers, since all equipment may be approved if it has at least the minimum quality required.

Of course there is now approved equipment on the market that has been approved to different versions of the draft standards. Nobody is very happy about this situation, but bearing in mind that the protection factors found in a laboratory have little **resemblance** to the protection factors found at workplace studies, the differences between the equipment are regarded to be of minor importance for the time being.

With the European standards approaching the final state for almost all **r espiratory** equipment, the Scandinavian countries now work to establish a certification program for such equipment. This program is based on a quality assurance program performed by the producer combined with inspection and independent testing performed by accredited test houses. This means that besides a type approval testing according to the European standard, there will be regular testing of equipment actually marketed such that all tests of the type approval will be performed over a period of perhaps three years depending on the equipment in question.

Furthermore, with certified equipment available, the occupational health and safety executives hope to get the legal basis to require all equipment marketed and used to be certified. It is foreseen that the Scandinavian certification may be replaced by a **CEN** certification, when it is operative.

In Scandinavia there are strict rules for the use of respiratory protective devices. Before the use of such devices is at all considered, it shall be proven that the contaminants cannot be removed by other means. Unassisted filter respirators may only be used for three hours a day. Air supplied or power assisted (turbo) respirators may be used for the whole work shift with suitable breaks depending on the work load. The selection of type of equipment is based on a consideration of the total work situation where it is to be used. Guidelines are given, but a good deal of common sense must also be used in the selection process.

EC Activities

In the EC-commission two different general directories are working on **regulations**, that will also have impact on the area of personal protection.

These are Directorate Generale (DG) V for Health and Safety and DG III for Removal of Technical Barriers to Trade.

Four different technical committees have been formed. Two committees with technical experts work directly on the directive proposals. One smaller committee works with the annexes to the directive of DG V. This committee mainly consists of test experts. Finally a small **ad hoc** group seeks to coordinate the two directives and acts as advisor for the commission on the directives. The **ad hoc** group has representatives from **administration**, workers **unions**, employers organizations and technical experts.

The EC work progresses quickly and it is the aim to present the DG HI directive to the council by the end of this year (1987). One reason for this speed is the political decision, that **from** 1992 all barriers to trade within the EC shall be removed.

The DG V directive shall apply to the use of personal protective equipment at the workplace. The aim of this directive is to protect workers against risks to their safety and health whenever these risks cannot be avoided or sufficiently limited by the use of technical or organizational means of collective protection.

The directive tells when to use PPE's, that PPE's must be adequate and usable against the risks present and without risks to the user. Also several obligations are imposed on the employer, e.g. the **PPE's** shall be provided by the employer not by the worker.

The DG III directive concerns harmonization of regulations in the member states regarding personal protective equipment (PPE). A PPE is defined as a device designed to be carried or worn by one person as protection against one or more risks. The directive will be applied to **ALL PPE's** for use at work or privately.

The directive does not include **PPE's** for which

there is no national regulation or standards in any of the member states, nor PPE's that are covered by other EC regulation. The directive will contain a list of equipment **excepted** from the directive. The exceptions most likely will be military and diving equipment, parachutes, monitors, general working cloths, etc.

The directive states that it shall only be allowed to market or use PPE's of a type covered by the **definitions** if it is approved. On the other hand no member state may prohibit the marketing or use of approved PPE's although it is still the national rules that determine which type of approved PPE to use in a given situation.

The PPE **must** be labeled with an EC mark to show it is in accordance with the directive. Depending on the degree of "**danger**" the PPE shall protect against, there are three possible ways of getting the right to use the ED mark:

1. The manufacturer may declare the device to be in accordance with the requirements.
2. The device may be type tested at an accredited test institute.
3. There may be type testing as well as regular control testing by an accredited test institute.

It has **not** yet been decided which equipment may be marked by which procedure.

Finally the directive will define the essential requirements for all PPE's included in the directive. The information shall be sufficient to make a certification in accordance with the directive. Where there are standards for the equipment the directive will refer to these standards. For respiratory protective equipment in general there will be CEN standards available, at least within the time scale **of** four years.

As mentioned the DG III directive is planned to be finished by the end of this year, and the technical experts are actually meeting in **Bruxelles** these days in the last technical meeting foreseen for the directive. In other words it is too early to say exactly what the directive will look like. However we believe, that we have presented the general contents of the regulations to come.