

Review of Standardization and Certification in Germany and Future Europe*

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Abstract

The first part of this review is a description of the present situation in Germany concerning standardization, approval, selection, and use of respiratory protective devices. This system will be changed in 1992 like in other European countries. On January 1, 1993, the European system will be effective.

The review will describe the situation in Germany and the development of the European system. It describes the relevant EEC Directives on environmental protection and protection of persons both on and off the job. It also covers the EEC Directives on standardization. Special emphasis is on the EEC Directive for personal protective equipment and, mainly, respiratory protective devices.

The present status and the expectations for 1993 are described. This includes some special details of the EEC Directives, such as basic requirements and responsibilities of employers and employees, certification, and selection and use.

The present situation in Germany is that standards for general industry are developed and published by Deutsches Institut für Normung (DIN).¹

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These standards are voluntary standards as long as they are not listed in the annex to the Law on Technical Equipment. When covered by the law, in these cases the DIN standard is divided into general requirements and safety requirements.

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The Law on Technical Equipment applies to all consumer groups, but does not apply to such consumer groups as firefighters, miners, or civil defence. Equipment for these groups is partly covered by DIN standards, but there are numerous special specifications in addition to the DIN standards.

An example of this is the specification for respiratory protective devices to be used in mining.²

Richtlinien für den Bau und die Prüfung von Bergbau-Atemschutzgeräten



Deutscher Ausschuss für das Grubenrettungswesen

Equipment complying with the requirements in a DIN standard, can be identified by the GS mark (tested safety).



In addition to the mark shown immediately above, the test station is marked. Equipment that has been tested and granted the GS mark is published in a list that is revised annually. Because there are different standards, there is also a different marking system for equipment approved for mining or firefighting.

The rules for selection and use of respiratory protective devices are given at present in the "Atemschutz-Merkblatt" (a leaflet on respiratory protective devices).³ These rules were developed by the Industrial Injuries Insurance organization representing the employees. The edition currently in effect is dated October 1981, but will be revised using agreements reached in Europe. Just as there are different standards for mining, firefighting, civil defense, and other groups, the rules for selecting, using, and maintaining their equipment are different too (e.g., for mining).

This document explains the theory and the practical use of equipment. It also specifies a system for monitoring quality. The same applies to firefighting.⁴



The specification shown immediately above refers partly to DIN standards, but also to other firefighters' specifications. It also gives specifics for firefighting on use of equipment and activities for firefighters.

This survey could be extended considerably for other industries, but as will next be described, all this will be replaced in the near future by European regulations.

The Council Directive of 27 November 1980 (80/1107/EEC)⁵ presents the basic rules governing the "Protection of Workers from the Risks Related to Exposure to Chemical, Physical and Biological Agents at Work" and the assessment of those risks. This Directive applies not only to humans, but also to animals and the environment. It is effective for persons both on and off the job, for monitoring hazards and protection. The Directive can best be understood by using a table showing the meaning of the Directive, as below.

RISK- MANAGEMENT

DIRECTIONS OF PROTECTION	RISK	WORKER *
	RISK	WORKER *
	RISK	WORKER *
DIRECTIONS OF PROTECTION	RISK	WORKER *

* Worker also means animal and environment

This system applies not only to personal protective equipment, but to all risks. It indicates the four possible approaches to protect against a risk:

- The Basic Approach is to eliminate the risk.
- The two Primary Protection approaches consist of either confining the risk or protecting workers from the risk by technical and organizational means.
- The Secondary Protection approach must be applied in cases where the risk is unknown or cannot be defined; personal protective equipment is required.

This risk management procedure implies that the air quality and all risks are under surveillance. Work on this subject is done for example by CEN/TC 137, "Assessment of Workplace Exposure." Progress in this respect was slow until the Council Resolution of 7 May 1985 (85/C 136/01)⁶ which described a "New Approach to Technical Harmonization and Standards."

The reasons for being slow were that at that time all details for a specification or a requirement were given in EEC Directives, and the work of the European Committee for Standardization was slow. Based on this Council Resolution of 1985, known as "The New Approach," the EEC Directives only provide for basic requirements (a framework), while the details that permit assessment are given in European standards.

Respiratory protective devices (RPD) are a special category of personal protective equipment (PPE). Therefore, they are subject to the Council Directive of 21 December 1989 (89/686/EEC)⁷ on the "Approximation of the Laws of the Member States Relating to Personal Protective Equipment."

This Directive applies to all types of personal protective equipment. It contains basic information on certification and marking; it defines basic, general, and special requirements and describes the function of notified bodies for certification and testing.

There are some exceptions to Directive 89/686/EEC. The following is an exhaustive list of PPE classes not covered by the Directive:

- PPE designed and manufactured specifically for use by the armed forces or in the maintenance of law and order (helmets, shields, etc.).
- PPE for self-defense (aerosol canisters, personal deterrent weapons, etc.).
- PPE designed and manufactured for private use against
 - adverse atmospheric conditions (headgear, seasonal clothing, footwear, umbrellas, etc.)
 - damp and water (dishwashing gloves, etc.)
 - heat (gloves etc.)
- PPE intended for the protection or rescue of persons on vessels or aircraft, not worn all the time.

It is clear that the Directive covers firefighters, mining industry, civil defense as far as the personal protective equipment is not specific for one of these groups.

EEC agreed that the relevant standardization body in the meaning of the EEC Directives is:

C E N
European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Members of CEN are the national standardization bodies of the European Communities (EC) and the European Free Trade Association (EFTA).

For certification purposes, the Commission of EEC developed a system of modules. For PPE mainly three modules apply:

- EC Type—Examination
 - (Self-certification): statement about conformity by the manufacturer
- Checking of PPE manufactured
 - 'EC' quality control system for the final product: type testing plus auditing the manufacturer's quality system on the basis of ISO 9 000 (= EN 29 000)
 - System for ensuring EC quality of production by means of monitoring: type testing plus production surveillance by a third party on the basis of ISO 9 000 (= EN 29 000)

For respiratory protective devices self-certification is not permissible. Only the 'EC' quality control system for the final product and the system for ensuring EC quality of production is accepted.

Equipment that is in accordance with relevant European standards and is subject to the quality management required by the Directive is marked with the CE mark.



The CE mark will be complimented by a mark indicating the test station.

This CE mark will replace all equivalent signs (for example, the previously mentioned German GS-mark). The GS-mark may still exist in the future if there is a need to indicate that the quality of a product complies with a DIN standard. Manufacturers will probably not be permitted to use the German GS-mark to indicate that a product complies with a harmonized European standard or a European Directive.

The above mentioned Directive and standards apply to requirements and test procedures. For selection and use, the EEC Council published the Council Directive of 30 November 1989 on the "Minimum Health and Safety Requirements for the Use by Workers of Personal Protective Equipment at the Workplace" (third individual directive within the meaning of Article 16 (1) of Directive 89/391/EEC)(89/656/EEC).^{8,9}

This Directive describes in general terms the employer's obligation for informing and training workers, and all other details necessary to comply with the "right to know." This Directive also specifies the duties of the employees. A new detail in this Directive is that the employer is obliged to have a risk analysis of the workplace to determine the personal protective equipment required and, in addition, to assess whether the personal protective equipment procured is suitable for protecting safety and health at the workplace. Furthermore, this Directive requires the establishment of general rules for use on a national basis.

To support the assessment of safety aspects of the personal protective equipment, the Commission of the EEC published, under the date of 30 December 1989a, "Commission Communication, for the Implementation of Council directive 89/656/EEC of 30 November 1989, Concerning the Assessment of the Safety Aspects of Personal Protective Equipment with a View to the Choice and Use Thereof (89/C 328/02).¹⁰

This communication also provides a non-exhaustive list of risks to be covered, risks arising from the equipment, and risks arising from the use of the equipment. To permit an easy survey of the risks involved, a table with a matrix is part of this communication. The figure below shows a part of this matrix.

Specimen Risk Survey Table for the use of personal protective equipment

		RISKS											
		Physical				Chemical				Biological			
Parts of the body	Head												
	Upper limbs												
	Lower limbs												
	Various												

As described above, the detailed specifications that permit testing, certification, and marking of respiratory protective devices have to be developed by CEN. The responsibility to work on these European standards for respiratory protective devices is with the Technical Committee CEN/TC 79, with the structure as shown on the following page.

CEN/TC 79

Respiratory protective devices

- **SC 1**
Terminology, definitions, classification
and selection
- **SC 2**
Physiological requirements
- **SC 3**
Facepieces
- **SC 3/WG 1**
Respirator leakage
- **SC 3/4**
Power assisted filtering equipment
- **SC 4**
Filters and absorption devices
- **SC 5**
Fresh air hose and compressed air line
breathing apparatus
- **SC 6**
Self-contained breathing apparatus
- **SC 7**
Diving apparatus (SCUBA)

CEN/TC 79 cooperates with numerous other committees like CEN/TC 23 (pressure equipment), CEN/TC 158 (head protection), and CEN/TC 162 (protective clothing).

The work program of CEN/TC 79 consists at present of about 40 standards. The progress is such that these standards will be available for the target dates, except for a few standards which depend on international work and should be available in 1993 or 1994.

Once the European standards are accepted by the Technical Committee and by CEN Central Secretariat, they are subjected to a verification procedure using a checklist. This checklist is the CEN CHECKLIST FOR THE VERIFICATION OF THE COMPLIANCE OF THE MANDATED EUROPEAN STANDARDS WITH THE ESSENTIAL REQUIREMENTS OF THE EC DIRECTIVE ON THE DESIGN AND MANUFACTURE OF PERSONAL PROTECTIVE EQUIPMENT (89/686/CEE).

The above approach permits test stations and others to rely on the accepted European standards as meeting the basic, special, and specific requirements of the Directive. The European standards verified will be listed in an annex to Directive 89/686/EEC.

CEN/TC 79 also developed a CEN Report, "Guidelines for Selection and Use of Respiratory Protective Devices." This document will not be a European standard. It will be a CEN Report. Therefore, it will not be mandatory, but provides guidance for those countries and users who have not yet developed such guidelines or that have specific needs that cannot be applied throughout Europe.

Summary

The system as outlined above includes the expectations that the harmonized European standards will be available by June 30, 1992, to introduce the accepted European standards and withdraw any conflicting national standards by December 31, 1992, and having the system effective by January 1, 1993.

Abbreviations

CEN—European Committee for Standardization
Council—Council of the European Communities
Commission—Commission of the European Communities
DIN—Deutsches Institut für Normung (German Institute for Standardization)
EC—European Communities
EEC—European Economic Community
EN—European Standard
EFTA—European Free Trade Association
GS—geprüfte Sicherheit (tested safety)
PPE—personal protective equipment
RPD—respiratory protective device(s)
SC—sub-committee
TC—technical committee
WG—working group

References

1. *DIN Standards*, Beuth Verlag, Berlin, Germany.
2. Deutscher Ausschuss für das Grubenrettungswesen, Essen, Germany.
3. "Atenschutz-Merkblatt," Carl Heymanns Verlag, Luxemburgerstraße 449, 5000 Köln 41, Germany.
4. Feuerwehr-Dienstvorschrift 7, Deutscher Gemeindeverlag, Köln, Germany.
5. Council Directive 80/1107/EEC, *Official Journal of the European Communities*, Vol. 23, (3 December 1980) L 327, pp. 8-13.
6. Council Resolution 85/C 136/01, *Official Journal of the European Communities*, Vol. 28 (4 June 1985) C 136, pp. 1-9.
7. Council Directive 89/686/EEC, *Official Journal of the European Communities*, Vol. 32 (30 December 1989) L 399, pp. 18-38.
8. Council Directive 89/391/EEC, *Official Journal of the European Communities*, Vol. 32 (29 June 1989) L 183, pp. 1-8.
9. Council Directive 89/656/EEC, *Official Journal of the European Communities*, Vol. 32 (30 December 1989) L 393, pp. 18-28.
10. Commission Communication 89/C 328/02, *Official Journal of the European Communities*, Vol. 32 (30 December 1989) C 328, pp. 3-14.