CEN PPE Sector Forum

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Personal Protective Equipment – Recommendations for drafting and revising harmonised European PPE standards

Persönliche Schutzausrüstungen – Empfehlungen für die Abfassung und die Revision harmonisierten Europäischen PSA Normen

Equipement de protection individuelle – Recommandations pour la rédaction et la révision des normes européennes harmonisées sur les EPI

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Introduction

Harmonized European PPE standards are prepared under a mandate given to CEN/CENELEC by the European Commission and the European Free Trade Association (EFTA). They provide a means of demonstrating compliance with Essential Requirements of the New Approach Directive 89/686/EEC on the approximation of the laws of the Member States relating to Personal Protective Equipment (PPE).

Once the references of Harmonised Standards have been published in the Official Journal of the European Union compliance with the clauses of these standards provides – within the limits of the scope of the standards – a presumption of conformity with the corresponding Essential Requirements (ER) of the PPE Directive and associated EFTA regulations.

Harmonized Standards are powerful tools to help manufacturers and Notified Bodies in the certification process. The Annex ZA at the end of the standard provides the (only) link between the clauses of the standard and the corresponding ER of the PPE Directive and informs the user of the standard about the ER covered by the Harmonized Standard.

1. General

The recommendations given in this document apply as well to the development of new harmonized European standards as to the revision of existing ones.

To be fully usable Harmonized PPE Standards should cover all the ER that are relevant in the foreseeable conditions of use for which the PPE is intended. Standards writers should have this goal in mind when drafting or revising a standard. The question "What is the intended purpose of the PPE and what are the conditions of use and the hazards associated with that intended purpose?" should be a primordial discussion item in the development or revision of a PPE standard.

To answer this question, standards writers should make use of following tools (described in clauses 2 and 3), which enable them to draft standards that satisfy the requirements of the PPE Directive:

- A hazard analysis: to ascertain that all hazards related to the foreseeable conditions of use, for which the PPE is intended, are taken into account and to connect them with the corresponding ER of the PPE Directive

- An ER checklist: to verify whether all the applicable Essential Requirements have been covered and satisfied. The checklist is also used to draft one of the most important elements of a Harmonized Standard: the Annex ZA.

2. Hazard analysis

Before starting to draft or to revise a PPE product standard it is essential to know the hazards inherent to the intended purpose of that PPE and its conditions of use. Table 1 shows a non-exhaustive list of hazards that may be considered.

Table 1 Examples of hazards to be considered in a hazard analysis

Hazards related to:	Examples
The activity and the environment where the PPE is used	— being hit by falling objects or by projected objects — collision with obstacles; — slips; — cuts, bites, abrasion, etc; — burns due to heat and/or flames; — hypothermia or cold shock; — injuries due to dangerous substances; — acute or chronic eye-damage; — acute or chronic hearing damage; — user's presence not signalled; — etc.
Information problems	— user information missing, incomplete, wrong, ambiguous or misunderstood — etc.
Wearing the PPE	— physiological discomfort, e.g. heat strain (low, medium or high activity), limited evacuation of perspiration — hindrance of sensory perception, e.g. difficulties in identifying optical or acoustical warning signals; — adjustment systems not reliable e.g. not remaining in place for the foreseeable period of use; — presence of hazardous components; — rough surfaces, sharp edges, etc; — interference with activity-related movements, postures and gestures — problems to take PPE off rapidly in an emergency situation; — etc
Failure or loss of performance of the PPE or its components over time	— cleaning and/or decontamination effects; — loss of performance by influence of environmental factors (UV, temperature, humidity, etc), e.g. loss of mechanical strength or buoyancy — etc.
Wrong choice of materials, accessories and other elements	— closures (zippers, fasteners, buttons, etc) damaged after environmental exposure; — closures (zippers, fasteners, buttons, etc) open inadvertently when in use; — hardware penetrates the outer layer; — etc.

Once the hazard analysis finished, the ER check list can be developed in two stages:

- Selection of the applicable ER, based on the hazard analysis list
- Verification if the applicable ER are properly met by the standard.

It should be kept in mind that ER can not always be interpreted in the same way and should take into account the specific conditions of use of the PPE. The requirements of the standard should reflect this, e.g. short or long use time, exposure to high or low temperatures, necessity of adjustment and/or attachment systems or not, etc.

To consider an Essential Requirement as properly verified, the Harmonized Standard shall contain:

- A concrete and mandatory requirement, related to the risk, and
- Its associated test method or way of verification, and
- The criteria to decide on the acceptance or rejection of the test result

If one of these is lacking, the ER cannot be considered as duly verified.

An ER checklist should be drafted at the start of the development or revision process of a standard. This checklist should be updated at later stages of the drafting process. The checklist offers also a good tool for verifying the content of the Annex ZA.

It often shows that draft standards, for which no checklist had been established, are unable to demonstrate a satisfactory correlation with the applicable ER and consequently are refused by CEN/CENELEC consultants in their assessments.

3. The Annex ZA

The annex ZA gives an overview of the relation between the clauses of the standard and the ERs of the PPE Directive (Annex II). It is often assumed that a harmonized EN covers all applicable ERs, but this is not necessarily true. To achieve its goal a Harmonized Standard should cover all the applicable ER under the foreseeable conditions of use for which the PPE is intended and consequently the Annex ZA should refer to all these ER. When for any reason it is not possible to cover all the applicable ER or if some of the ER are only partially covered by the standard, this should also be clearly identified in the Annex ZA.

Most harmonized standards are product requirement standards, but test method standards may also have the status of a harmonized standard and contain an annex ZA. Their annex ZA will refer to their use in conjunction with a corresponding product standard.

All Harmonized European Standards shall contain an informative Annex ZA (BT Resolution 2/2003). This Annex ZA consists of:

- a standardized introductory wording explaining under which conditions Harmonized European Standards confer presumption of conformity to Directives
- a table giving the correspondence between the clauses of the Harmonized Standard and the Essential Requirements of the Directive.
    - first column: lists **all** ERs applicable to the PPE defined in the scope of the standard
    - second column: lists the corresponding clauses of the standard that cover the applicable ERs. If the standard does not address an ER, the corresponding cell in the second column should mention "not addressed by this standard"

— third column: further comments or remarks, e.g. that an ER has been addressed partially or that the ER can only met when the PPE is used in conjunction with other compatible items of PPE.

For EN ISO (CENELEC IEC) standards, the annex ZA will be part of the draft standard until formal vote stage and finally be included and published by CEN/CENELEC in the EN ISO standard (CENELEC/IEC standard) when the ISO/IEC standard is published.

Annex ZA should be drafted by the working group and due care should be taken when drafting it, given the paramount importance of this Annex. CEN/CENELEC Consultants may be requested to give advice. Anyway, before the start of the (parallel) formal vote, a CEN/CENELEC consultant will make a formal assessment of the candidate harmonized standard, which consists mainly of a thorough verification of the content of the Annex ZA. As a result of a negative assessment the formal vote procedure will be stopped and the complete standardization process delayed until a solution has been reached. In order to avoid such negative assessment, it is useful to discuss the annex with the CEN consultant at an early stage of the drafting process.

Annex ZA should be completed with the help of the checklist. When the harmonised standard contains separate clauses for requirements and for test methods, the annex ZA should only refer to the requirements clause. The provisions of the requirements clause should then refer to the relevant part of the test methods clause or to a separate test method standard. This avoids making Annex ZA too complex.

If the standard contains only a requirement or only a test method (or a reference to it), the ER is not verified. The corresponding ER should be left void in the Table of Annex ZA.

4. EN ISO (CENELEC IEC) standards

More and more European Harmonized Standards are adopted as EN ISO (CENELEC IEC) standards by endorsement of ISO/IEC standards. Care should be taken that these ISO/IEC standards meet the level of safety required by the European legislation. If requirements mandatory by European law are omitted or presented as optional in the ISO standard, the resulting EN ISO standard will be considered as incomplete for the purposes of presumption of conformity.

Candidate harmonised EN ISO standards should cover the same relevant Essential Requirements as harmonised EN standards do. They shall contain an annex ZA at the CD, DIS and FDIS stages. The annex ZA will not appear in the published ISO/IEC standard, but will be published separately by CEN/CENELEC in the EN ISO (CENELEC IEC) standard.

Working Groups should be aware that ISO/IEC standards may contain “options” that reflect market differences. The European Commission will not accept EN ISO (CENELEC IEC) standards containing such “options” as harmonized standards unless all options satisfy the corresponding ER with the same level of safety. The consequence would be that these standards will not be published as harmonized standards and hence will not provide presumption of conformity with the requirements of the Directive.

If a single international solution cannot be found for certain elements of the ISO/IEC standard at the time of drafting, other solutions should be envisaged. This can be done by lifting the contentious items out of the core ISO/IEC standard and bringing them to an ISO/IEC Technical Specification (ISO/IEC TS). The combination of the core EN ISO (CENELEC IEC) standard and of the separate ISO/IEC TS (to be adopted as an EN) can then be adopted as a harmonised European standard. Eventually also a separate EN can be developed on the basis of the ISO/IEC standard, but with modifications that satisfy the provisions of EU regulations.

5. Editorial aspects and structure

Although the main purpose of harmonized standards is to be a tool for demonstrating compliance with regulatory provisions, due attention should also be paid to editorial aspects of the standards, as this can be an enormous help to avoid discussions and misinterpretations after publication.

Standards should be written with the user of the standard in mind, in particular the user who is less acquainted with standards, e.g. in SMEs. The revision of a standard is a good opportunity to make such editorial improvements.

The wording used in a standard should be clear, precise and consistent and should be comprehensible to qualified persons who have not participated in its preparation. Sentences and paragraphs should be short and the lay-out should improve the readability of the standard. The structure of the standard should be consistent, e.g. if the same standard contains a requirement clause and a test method clause, the structure of both clauses should be mirrored, i.e. clause 4.1 (requirement) should correspond to clause 5.1 (test method), etc.

The content and structure of a set of standards should be clear and consistent without overlaps. Preferably a single reference product standard containing all the required specifications, either explicitly or by reference to other standards, should be developed for each type or group of PPE.

A combination of several types of PPE into an integral unit, e.g. gas-tight suits with integrated helmet, visor, gloves and boots according to EN 943-1 or -2, should preferably be addressed in the same standard. Special attention should be paid to the interfaces.

6. Major technical changes

Revised standards shall contain a list of significant technical changes, compared to the previous edition (BT resolution 1/2005). This list of changes shall be included in the Foreword (ISO/IEC approach) or as an informative annex (CEN/CENELEC approach). For EN ISO (CENELEC IEC) standards, the ISO/IEC approach prevails.

Editorial changes or updates of normative references need not to be mentioned, unless they have an impact on the technical content of the standard.

Standardization groups should be aware of the importance of this list of significant technical changes. This list may be of help to notified bodies in assessing the impact of the changes on their certification work. It also may be of help to manufacturers to give them guidance on modifications of their product or during any conformity assessment process.

7. Scope of a standard

The scope of a harmonized standard shall define unambiguously the subject of the standard (PPE for a given intended use) and the aspect(s) covered. It shall thereby indicate the limits of applicability of the standard, e.g. items not covered by the standard. Presumption of conformity is only given within the limits of the scope.

The scope shall not contain any requirement. Requirements shall be dealt with in specific clauses (usually clause 4)

8. Classes of protection and/or performance classes

According to the Directive, the existence of several classes of protection (and corresponding levels of performance) can only be justified by the corresponding existence of different levels of risk.

When drafting standards, the existence of different levels of the same risk should be examined. Classes of protection can be useful as they offer the possibility to use more comfortable PPE instead of PPE having an unnecessarily high level of protection.

The use of performance classes or levels for ranking products should be avoided, if no corresponding levels of risk can be given, since this suggests wrongly a fitness for use against different levels of risk.

The Directive always requires the optimal level of protection, i.e. the highest level of protection compatible with the nature of the activity performed.

9. Requirements and Test methods

Whenever possible, requirements and test methods should be representative of the hazard the PPE intends to cover.

Requirements and test methods are only then compulsory for those claiming compliance with a standard if they are in a “normative” section of the standard. Requirements and test methods shall therefore not be given in informative sections such as informative annexes or notes. This is particularly important when these requirements or test methods are intended to address Essential Requirements of the PPE Directive.

Requirements and test methods for different PPE covering the same type and/or level of hazard should be coherent. Unnecessary differences should be avoided.

When the related PPE includes electrical, electronic and programmable systems intended to perform safety functions, a specific clause referring to the requirements for their operating safety (dependability or functional safety) and the appropriate test methods shall be included.

Requirements shall be given in a concrete and mandatory way. The only allowed verbal forms to indicate requirements in standards are “shall” and "shall not".

To establish the requirement, the uncertainty of measurement should be considered. The precision of the test methods should allow distinguishing clearly between protection levels.

The test methods or ways of verification shall be included in full text or by reference to test methods standards.

To avoid later discrepancies, the test methods shall contain all necessary elements. The accuracy of test equipment and the precision of test procedures should be known and be realistic.

Tables 2 and 3 give guidance on elements that may be considered when drafting measurement requirements or test methods.

Table 2 – Examples of generic issues to be considered when formulating measurement requirements

Generic issues relating to the formulation of measurement requirements	Where relevant, proceed as follows
1. Do other documents already exist for general or related test methods for similar properties?	Consider existing documents and make reference to them if applicable. Avoid duplication of provisions
2. How precisely should the requirement be defined?	Define tolerances for all values other than minimum and maximum values
3. Can the test method be applied, with little or no difference or even verbatim, to more than one product or to a product type?	Formulate the test method as a document in its own right, then make reference to it in a suitable way (for example by supplements or amendments). Avoid duplication of provisions
4. Is it probable that other documents will also contain references to this test method?	See above
5. Does more than one adequate test method exist for the measurement task?	Define only one test method where possible. If for whatever reason, standardization must encompass more than one test method, state the reference test method
6. Is the required measurement apparatus not readily available?	In order to ensure that a comparable method can be performed by all parties, provide precise information on the measurement apparatus if at all possible, rather than referring to the product of a single instrument manufacturer
7. Is it necessary to standardize an item of test equipment which can also be used to test other products?	Produce a separate document in agreement with the committee responsible for such equipment

Table 3 – Examples of provisions to be considered in a test method standard (or a test method clause in a product standard)

Factor	Can this factor influence the test result?	If yes, provisions which may then be required in the standard
1. Test object	Condition of the test object, e.g. old, new, cold, warm, damp, dry, If applicable, type and condition of parts of the test object, e.g. old, new, sharp, blunt, dimensions	Pre-treatment, conditioning
2. Test arrangement	Measurement equipment e.g. accuracy of measurement, scanning rate, compliance with specifications in other standards, storage, evaluation e.g. dimensions, weight, sensitivity, compliance with specifications in standards, response time, alignment of sensors	Properties of the measurement equipment; if applicable, validation methods, and Properties, point of measurement, position and means of attachment of the sensors
	Further components of the test arrangement e.g. energy sources, testing bench, application of the loading to the test object, test finger, impact test bench, target panels, torso/dummy	Properties of these components (dimensions, drawings, weight, strength, etc.)
	Condition of the test equipment/work piece, if necessary e.g. old, new, concentration, cold, warm, damp, dry, hard, soft, standardized material, dimensions	Pre-treatment, conditioning
	Ambient conditions e.g. background noise, climate (temperature, atmospheric humidity), room dimensions Related to practice or simulated conditions Arrangement of the test object, e.g. direction of action, application of the loading, affixing	Dimensions, position/body posture of the test person, drawings
3. Performance of the test	Test procedure e.g. sequence, time, time of day	Test sequences, time intervals, number of repetitions
	Conditions of use/operation for the test object, e.g. speed, voltage	Related to practice or simulated conditions
	Number of objects to be tested	Number
4. Test subject	Experience, anthropometrics	Minimum/maximum requirements
5. Interpretation	Calculation method	Mean, median, minimum or maximum values

10. Ergonomics

Annex II of the PPE Directive contains several requirements related to ergonomics, comfort and usability. When drafting or revising a standard, these requirements should be considered.

The requirements and test methods specified in the standards should correspond to the best possible compromise between a high level of protection and the lowest possible level of constraint.

When practical test are specified, all the possible factors affecting the result should be considered by specifying:

- Number of PPE samples to be tested
- Device preparation

- Any conditioning prior to testing
- Number and selection of test subjects
- Activity sequence, including movements to be carried out
- Duration of each activity and intervals between activities, including the total time
- Number of times that each activity should be carried out
- Pass/fail criteria
- ...

Some of those parameters may be given in the requirement clause.

NOTE EN 13921 "Personal protective Equipment - Ergonomic principles", prepared by CEN/TC 122/WG9, gives guidelines on the specification of ergonomic requirements and test procedures

11. Innocuousness

A clause on innocuousness of materials should be included in PPE product standards. It should be clearly stated that PPE materials and parts should not contain, release or degrade to release any harmful substances.

Whenever possible, quantitative test methods and concrete limit values should be given. Care should be taken to ensure that these values are not in contradiction with values specified in national or European regulations.

In the case that the presence of harmful substances cannot be unambiguously stated, an example can be found in EN ISO 13688.

12. User information

The main clauses on user information are the clauses on "marking" and on "information to be supplied by the manufacturer".

The use of pictograms is preferred over the use of text because pictograms can be understood universally. Whenever possible, international pictograms (ISO 7000) should be used.

The clause related to the "Information supplied by the manufacturer" should be drafted considering all applicable items of ER 1.4 of Annex II of the PPE Directive. Other applicable ER should also be taken into account, when relevant (e.g. ER 1.3.3, 2.4, 2.8, 2.12, 3.1.2.2, 3.5, 3.6.2, 3.7.2, 3.8, 3.9.1, 3.9.2.2, 3.10). However, care should be taken that some of these ER contain real requirements and should not only be addressed in the user information but also in the requirement clauses of the standard.

The clause on user information should contain a sentence that emphasizes the use of easily comprehensible language in the information leaflet.

User information shall be in the official language of the country where the PPE will be put on the market. This is also applicable to the marking of the PPE when that marking contains text.

The “Guide for drafting the information to be supplied by manufacturers to the users in compliance with directive 89/686/EEC” may be used for guidance (document PPE N 108 rev.3 - see on CEN web page)

13. Useful links

ftp://ftp.cen.eu/BOSS/Reference_Documents/IR/CEN_CLC/IR3_E.pdf Internal Regulations Part 3: Rules for the structure and drafting of CEN-CENELEC Publications (ISO/IEC Directives – Part 2, modified)

http://boss.cen.eu/reference%20material/Guidancedoc/Pages/TechChangesRevEN.aspx Guidance - Identification of significant technical changes in revised European Standards

http://boss.cen.eu/reference%20material/Guidancedoc/Pages/OJ.aspx How to draft European Standards for citation in the Official Journal

http://www.cencenelec.eu/standards/Sectors/healthSafety/PersonalProtectiveEquipment/Pages/default.aspx PPE section on CEN web page.