CEN/TC 160
Protection against falls from height including working belts
Email of Secretary: thomas.hoegen_von@din.de
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Guide for the drafting or the revision of EN standards on PPE. Version 1.5

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Background

The attached guide has been prepared by A. Mayer, sector rapporteur PPE and J. Bahima, CEN Consultant.

PPE N 122 Version 1.5

CEN PPE Forum

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Guide for the drafting or the revision of EN standards on PPE

FOREWORD

The set of European standards on PPE developed in support to the PPE Directive 89/686/EEC has been published for many years. A majority of them have been already revised several times in order to make up for the first technical imperfections and deficiencies identified by the users of the standards (manufacturers, Notified Bodies, consumers associations, national authorities, etc.).

Nevertheless there is still a lot of possible and necessary improvements of their content and of their consistency.

The key issues to systematically be considered when starting a revision of an EN standard or the drafting of a new one, are considered in this document. When relevant they shall be taken into account in order to improve the global quality and coherence of the existing set of EN standards on PPE.

They globally aim in particular at :

1. better taking into account of all applicable Basic health and Safety requirements of the PPE Directive 89/686/EEC [1], [2]
2. better taking into account of the CEN rules laid down in the CEN Business Operations Support System (BOSS) [3]
3. better implementation of the decisions taken by the CEN Forum on PPE
4. improving the consistency of organisation of the set of PPE standards,
5. a better harmonisation of the content of the set of PPE standards,
6. improving the requirements related to efficacy and comfort of PPE for the benefit of end-users

WARNING

In the PPE directive 89/686/EEC the term Basic Health and safety Requirement is used (BHSR) .In other directives the wording Essential Health and safety Requirement (EHSR or ER) is adopted.

Any of them have to be considered as equivalent.

When the guide refers to mandatory requirements of the PPE Directive or of the CEN BOSS, the term “shall ” is used.

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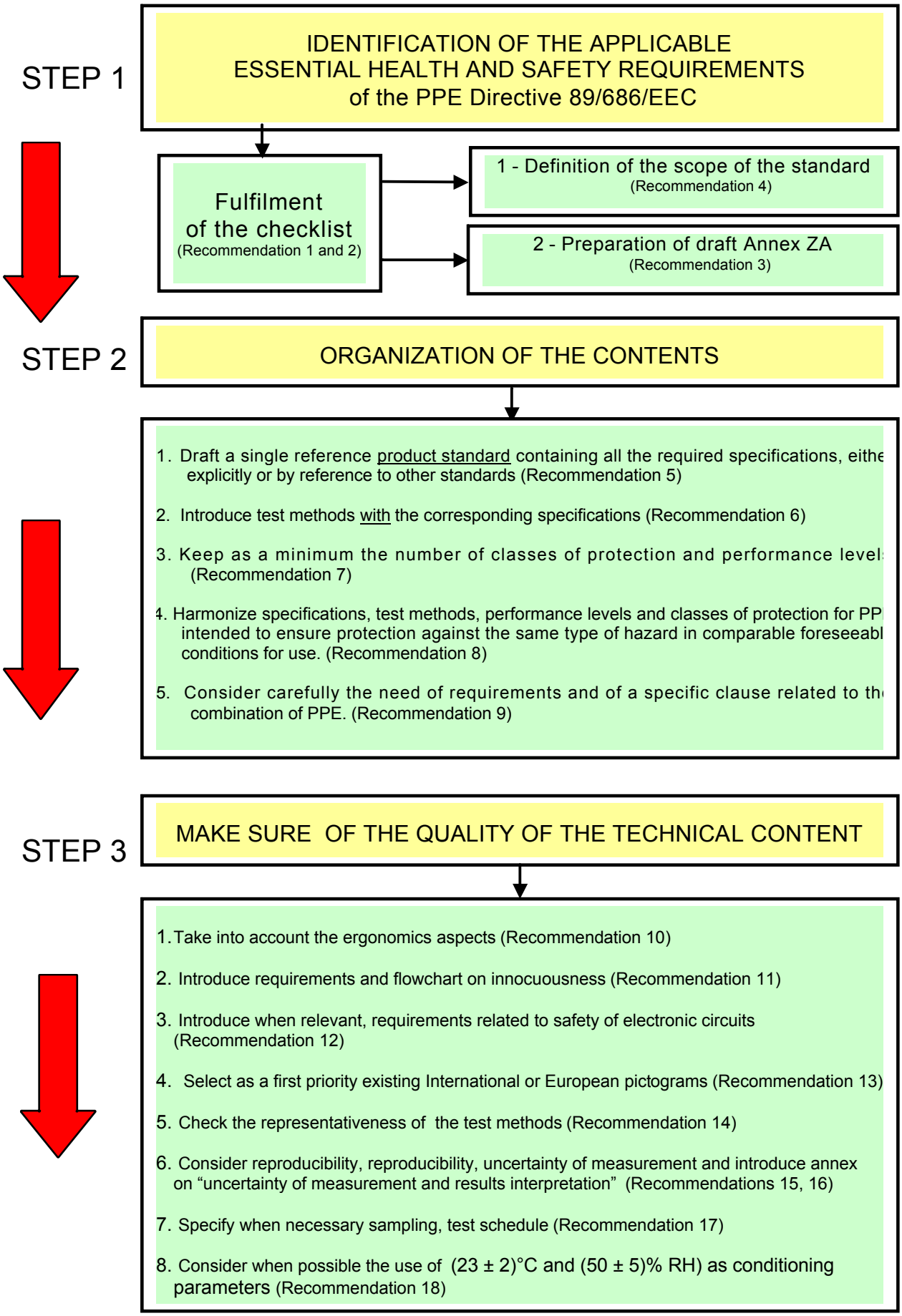

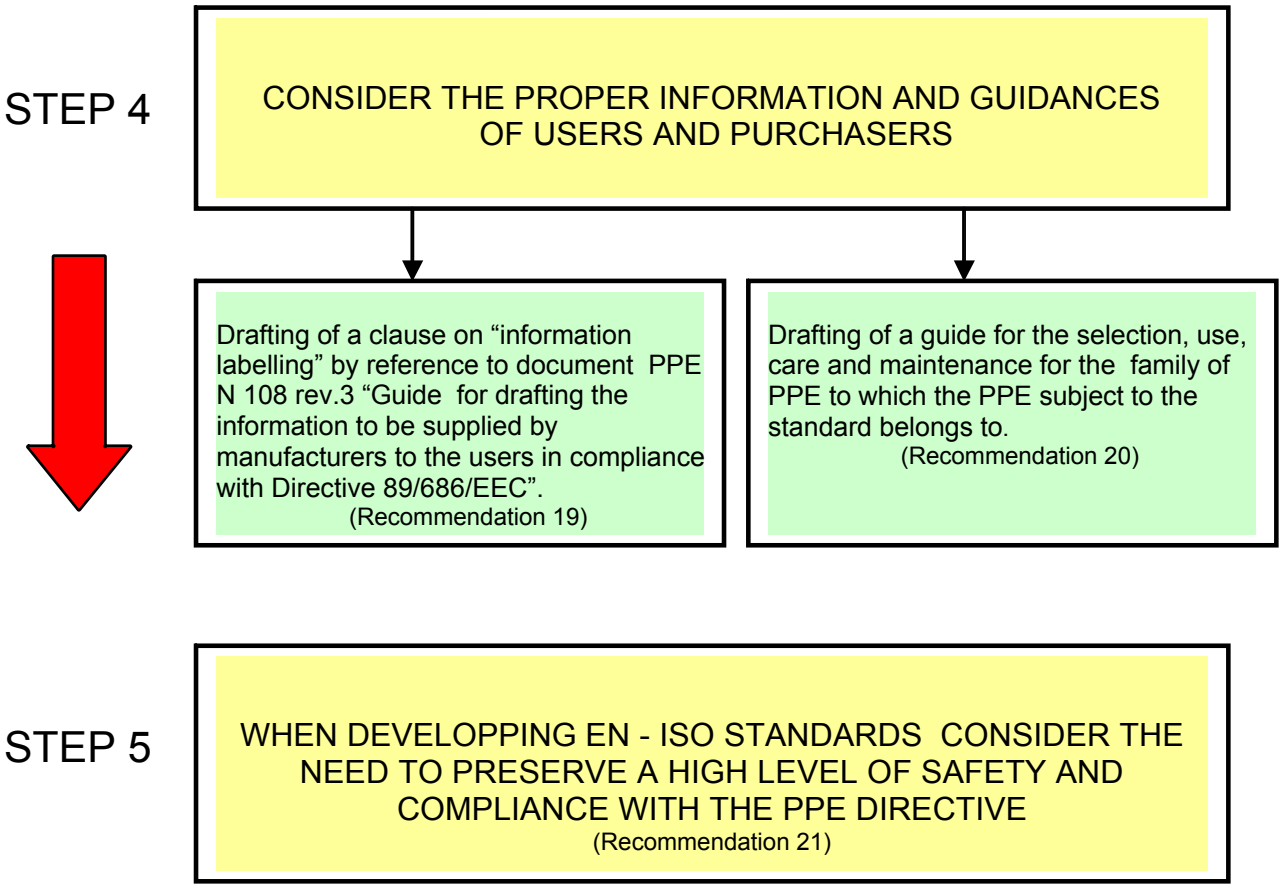
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PART A – The consistency of PPE standards regarding the Basic Health and safety Requirements (BHSRs) of the PPE Directive 89/686/EEC

A1. Risk analysis

A1. Coverage of all applicable BHSRs:

In the guide for the implementation of the PPE directive published by the EU Commission [4] it is clearly stated that:

If the manufacturer chooses to use harmonised standards to assess the conformity of his products to the PPE directive, he shall make sure that these standards cover all basic health and safety requirements applicable to his products. If the existing harmonised standards do not cover all applicable BHSRs he has, in addition to the application of these standards, to assess the conformity to the non covered BHSR by using other relevant technical specifications and test methods … Products may be placed on the market and put into service only if they are in compliance with all applicable basic requirements.

The identification by the standards users themselves of the basic requirements covered or not by a standard, has a triple legal, economic and social importance:

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- *To make clear and evident the exact coverage of the presumption of compliance* associated with a harmonised standard, in the interest of all parties involved: manufacturers, standardizers, notified bodies, users, consumers, market surveillance authorities, etc.,

- *to guarantee fairness of competition*, by preventing certain unscrupulous manufacturers and notified bodies from applying the standard without worrying about knowing whether it really does take into account all the essential requirements applicable to the product concerned,

- *within a context of growing internationalisation in standardisation, to preserve the specific European characteristic, namely a high level of safety,* emanating from Clause 95 of the treaty instituting the European Community.

RECOMMENDATION 1

In order to make easier and more comfortable for manufacturers and notified bodies the conformity assessment process, it is fundamental to develop, when possible, product standards covering all applicable BHSRs for the product.

If not possible , it is then necessary to identify clearly in a product standards the BHSRs covered, not or partially covered by the standard.

To meet this important objective two tools should be correctly used when drafting or revising a standard: the Check-list and the Annex ZA.

A2. The use of the check list:

In the CEN BOSS, the “Guidance for the drafting of 'European Standards to be cited in the Official Journal”, strongly advise Technical bodies drafting European Standards in support of New Approach Directives to use of the checklist during the drafting stage, documenting the relationship between the Essential Requirement(s) of those Directive(s) and the clauses of the draft. The model of the appropriate check-list to be used is given in Annex 1 of this document.

Before the revision process, the use of the check-list is also strongly recommended. It allows standardizers to identify gaps and deficiencies in standards and thus to initiate the required corrective actions, whilst manufacturers and notified bodies can list the essential requirements remaining to be additionally covered, trough "so to say expert examination", for full assessment of the compliance of their products.

Before the use of the checklist, the list of :

- hazards against which the PPE is intended to be used. (Guide to the implementation of directives based on the New Approach and the Global Approach).
- Factors which can affect the PPE efficiency in time

should be clearly established.

These hazards and factors to be considered are:

- *Associated to the intended use*: falls from a height, electrical shock, falling objects, chemical contaminant exposure, radiant heat, etc;
- *Associated to ergonomic and/or physiologic factors*: Constraints imposed, adaptation to user morphology, user hygiene or health, ventilation, design, etc;
- *Associated to possible materials failure:* tearing, withstand pressure, strength, corrosion, electronics etc
- *Associated to the environment* of the foreseeable conditions of use: rain, cold, temperature cycling, UV radiation, IR radiation, electromagnetic radiation, etc

It should also be kept in mind that only requirements referred to the PPE itself and related to the BHSRs shall be in the normative part of PPE standards. Any other requirement, not pertaining to the PPE conformity itself, but to the manufacturer, to the user or to any other party shall be put in informative annexes. (See BOSS - GD - Product Standards and conformity assessment).

RECOMMENDATION 2

All PPE TCs are instructed to verify the conformity of their standards (published or in progress) with the essential Requirements of the Directive on the design and manufacture of PPE by completing the checklist. Every document should be accompanied , at the earliest stage of development or revision of a standard, by a completed and updated checklist. However, the check-list will be not included in published PPE standards. (BTS 3 Resolution 9 and 12 /1991; confirmation by PPE Forum meeting December 2001).

A3 - The use of the compulsory Annex ZA:

According to the CEN rules (Guidance - How to draft 'European Standards for citation in the Official Journal' included in the CEN BOSS), each mandated standard shall contain for each EU New Approach Directive dealt with an informative annex Z about the relationship between the standard and the BHSRs of the relevant EU Directive.
This annex being always located at the end of the standard, it will normally be called " Annex ZA". However, if one or more European annexes exist after an adopted International Standard, the letter A will be replaced by the letter following the previous European annexes (e.g. if there is an Annex ZB, the annex about the relationship to an EU Directive becomes Annex ZC).

The draft Annex ZA should be established by the working group in charge of the drafting or revision of the standard at the earliest stage of the process and on the basis of the completed checklist. It should be then submitted for preliminary comments to the CEN consultant with the first draft and the checklist.

RECOMMENDATION 3

For each new Approach Directive of which the standard supports Essential Requirements, an informative annex Z.... shall be added as an integral part of the standard. (CEN BOSS - Guidance for the drafting of 'European Standards to be cited in the Official Journal [5]).
The models developed by the CEN PPE Forum by reference of the CEN/BT resolution and given in Annex II should be used.

A4 – Scope of an harmonized standard:

Remember that presumption of conformity is only given within the limits of the Scope (see heading of Annex ZA).

RECOMMENDATION 4

The Scope of an harmonized standard shall define without ambiguity the subject of the standard and the aspect(s) covered, thereby indicating the limits of applicability of the standard or particular parts of it. It shall not contain any requirement. (PNE Rules)

PART B - Consistency in the organization and content of standards:

B1 - Standards applicable to the same product :

According to the PPE directive 89/686/EEC, the reference(s) of the harmonized standard(s) used as a technical basis for EC conformity assessment , shall be mentioned in the EC declaration of conformity to be established and signed by the manufacturer or his authorized representative established in the Community.
In addition, EN standards, request to affix the reference and the date of standard on the PPE itself and/or to give them on the packaging and/or on a label.

If several standards are applicable to the same product they should all be mentioned.
The drafting of a unique standard (with several parts if needed) covering all BHSRs is always advisable and more comfortable for the manufacturers but also for the consumers and authorities.
This standard could be only a requirements standard making reference to all other relevant test/measurement standards.

RECOMMENDATION 5

Fragmenting standards governing the same component of PPE or the same type of PPE should be avoided when possible. In any case a single reference product standard containing all the required specifications, either explicitly or by reference to other standards, should exist for each type or group of PPE when applicable.

B2 – Test methods and specifications

For testing and certification by reference to standards, the knowledge of test/measurement method and of the corresponding requirements and pass/fail criteria are indispensable to be able to judge of the conformity of the product. The existence only of a test method without the corresponding requirement, or the existence of a requirement without the corresponding test method or without the pass/fail criteria is not consistent and will lead to discrepancies in the decisions taken. In these cases the corresponding BHSRs are considered as not verified by the standard. This is in contradiction with standardization approach, which is particular to diminish trade barriers and to promote common technical understanding.

RECOMMENDATION 6

Where a product standard includes or makes reference to a test method, the corresponding requirement(s) [acceptance limit value(s) or other specification(s)] should be given in a concrete and mandatory form.
Where a product standard includes requirement(s), the corresponding ways of verification should be included or made reference to in terms of clear and complete test/measurement method .

B3 – Performance levels and protection classes:

Different classes of protection can be useful, to offer where appropriate the possibility to use more comfortable PPE instead of PPE having an unnecessarily high level of protection.

In any case, if several classes of protection and or performance levels are used, the corresponding levels of risks and/or fields of application are to be clearly identified and given in the information to be supplied by manufacturer.
In other terms, it must be clear that the definition of different classes has to be always related to the different levels of risks existing in the foreseeable conditions of use and not related to the performance levels.

NB: Furthermore, when defining classes of protection or of performances levels, the uncertainty of measurements attached to the test results has to be taken into account to avoid difficulties of interpretation. It is recommended when the requirement for a class is given trough a lower and upper limit value, that the width of the class should be bigger than at least two times the estimated uncertainty.

RECOMMENDATION 7

The number of classes should be kept to a minimum in order to avoid difficulties and errors during the selection phase of the appropriate PPE by users and purchasers. In fact, the creation of several classes of protection can only be justified by the corresponding existence of different levels of risk and ergonomic factors, which can not be covered by a single class of PPE.

B4 – Specification in respect to comparable hazards:

Test methods and requirements adopted by TCs or WGs for different PPEs and covering the same type and/or level of a hazard are sometimes different.
These inconsistencies may create:

- a risk for the users when wearing an assembly of PPEs having different levels of protection
- a unnecessary high cost of the tests during the conformity assessment process

RECOMMENDATION 8

Where several type of PPE are intended to ensure protection against the same type of hazard in comparable foreseeable conditions for use, the relevant specifications, test methods, performance levels and classes of protection should be defined consistently. When the harmonization of both method/requirement is not possible, harmonization of the test method should at least be considered.

B5 – Combination of PPE (RES BTS4 19/1997)

A technical Committee Chairman receiving a request for standardisation work, having established that the equipment is a combined PPE (integral or non-integral) should then negotiate with other relevant technical committee Chairmen as to who has primary responsibility for the standardization work.

RECOMMENDATION 9

For combined integral PPE, the combined Standard should fully specify the main function and also the clauses of the relevant Standards for other functions for which the manufacturer may claim compliance. The manufacturer should also be required to draw attention to any limitations of use in the clause in the Standard headed: “Information to be supplied by the manufacturer”.

For combined non-integral PPE, the technical committee Chairman should attempt to achieve the situation that, where two or more items are attached to one another, at least one of which is PPE, they should individually be in accordance with the European Standards relevant to each item, where such exist, and continue to do so when worn as a combination. A clause related to the PPE interfacing should be introduced in the corresponding standard(s).

Attention should be drawn to any resulting compromises, for example, limitations of use, warnings or guidance notes. If it is necessary to draft a new standard for combined non-integral PPE, then the guidance for combined integral PPE should be followed.

PART C - Quality of the technical content of the Product standards:

C1 – Proper taking into account of ergonomics aspects:

At the design stage of the PPE ergonomic principles need to be applied to make PPE suited to its protection function under the foreseeable conditions of use.

When drafting or revising a standard, the following should be considered simultaneously:

- protection which must be highest possible according to the current state of the art;
- maximum reasonably “usability” to fit to the characteristics and to the environmental factors of the tasks to be performed by possible different users groups taking into account the tasks to be undertaken.

The specifications laid down in the standards should correspond to the best possible compromise between as high a level of protection as possible and the lowest possible level of constraint.

RECOMMENDATION 10

Requirements related to ergonomics (general, anthropometric, biomechanical, thermal, sensory …) to be introduced in the standards, together with their test method or way of verification should be specified. EN 13921 “Personal protective Equipment – ergonomic principles” elaborated by CEN/TC 122/WG9 gives guidelines for that purpose.

C2 – Innocuousness of the constituent materials:[7],[8],[9],[10]

In the foreseeable conditions of use PPE materials and parts, including any of their decomposition products, should not adversely affect user hygiene or health .They should not contain, release or degrade to release any harmful substances generally known to be toxic, carcinogenic, mutagenic, allergenic, teratogenic or otherwise harmful.
This health and safety requirement is mainly related to harmful substances that could release when PPE is in direct contact with the skin of the users (process which could be increased by perspiration, rubbing…) .

For the introduction of relevant test methods and specifications, particular attention should be paid to the presence of plasticizers, unreacted components, heavy metals, impurities and the chemical identity of pigments and dyes.

The specifications should be based on the exposure limit values of harmful substances, such as Cr(VI), Ni, Azo colorants etc… laid down in European or national regulations such as:

- Individual directives on the protection of workers from risks related to exposure to carcinogens (90/394/EEC,97/42/EC,1999/38/EC) chemical agents (98/24/EC,91/322/EC, 2000/39/EC), biological agents (2000/54/EC, 990/679/EC,95/30/EC,97/59/EC) and asbestos (83/477/EEC, 91/382/EEC, 2003/18/EC) at work within the meaning of Article 16 of Directive 89/391/EEC;

- Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations and the 29th amending directives;
  This directive is also applicable to PPE, and is in particular related to the nickel release(e.g. metallic spectacle frames), cadmium (components of PPE in plastics) and other chemical components that may come into contact with the skin.

When no specific regulation exist, it is advisable to refer to other documents such as studies, test reports, consumer test magazines, national and European eco-label criteria and so forth.

RECOMMENDATION 11

PPE Technical Committees are requested to include in each European standard, at the time of their revision or development of a new standard:

- *A clause relating to the innocuousness of materials – which can be based on the example of § 4.2. in EN 340 "Protective clothing -general requirements". It should be clearly stated that PPE materials and parts shall not contain, release or degrade to release any harmful substances generally known to be toxic, carcinogenic, mutagenic, allergenic, teratogenic or otherwise harmfu*l
- *A flow chart in an informative annex – which can follow the model given in the informative Annex B of EN 340 (ANNEX III)*
- *Whenever possible concrete limits should be given*

. Care should be taken to ensure that any given value do not come into contradiction with any other possibly existing value given in a regulation

C3 – PPE including electronic circuits

The level of protection of PPE including electronic circuits intended to perform safety functions, should be at least equivalent to that of standard PPE. Particular precautions have to be taken at design stage to prevent a component failure due, for example, to their sensitivity to certain environmental factors causing discomfort and even, in certain cases, real danger for the wearers. The PPE needs to remain safe and not lead to dangerous situations in cases of failure of or damage to the circuit or errors in the circuit logic. For example, the behaviour of such PPE in EMC “disturbed” environment, in hot, cold and humid climatic conditions must be thoroughly checked.

The methodology based on an analysis carried out on the basis of the EN 1050:1996 “Safety of machinery - Principles of risk assessment” under revision and EN SO 13849-1:2006 “Safety of machinery -- Safety-related parts of control systems -- Part 1: General principles for design“ standards could be a good basis to define appropriate additional specifications relative to functional safety to be introduce into the PPE standards.

RECOMMENDATION 12

When drafting or revising a standard related to PPE including electronic circuits intended to perform safety functions, a specific clause should be introduced and contain appropriate tests methods and requirements related to their operating safety (dependability).

C4 - Pictograms:

Whenever is necessary to give information related to health and safety, in particular on the field of use of PPE, harmonized pictograms should be used. These pictograms should be comprehensible so as to prevent ant misinterpretation.

RECOMMENDATION 13

When introducing in a standard the use of pictograms, the following procedure should be applied:

a) Use existing International or European pictograms when available.

b) If these pictograms are available but not practical for the intended or expected use, alterations may be proposed.

C5 – Validation of the representativity of test methods:

The test methods and the specifications developed to assess the performances of the PPE should be, as far as possible, representative of:

- The risks that the PPE is intended to protect the user against,
- All foreseeable conditions of use, which can affect the efficiency and comfort of the PPE.

In order to reduce as much as possible the discrepancies between the effective efficiency and comfort of the PPE in real condition of use and the results of the evaluation performed in laboratory, it is advisable to always correlate, as far as possible, the results obtain in laboratory with the reality of the conditions of use and of the risks. This evaluation could be carried out in particular with the help of social partners, consumer associations and OHS organizations.

This is of particular importance for the assessment of safety characteristics but also for the evaluation of the service life of PPE as requested in the PPE directive.

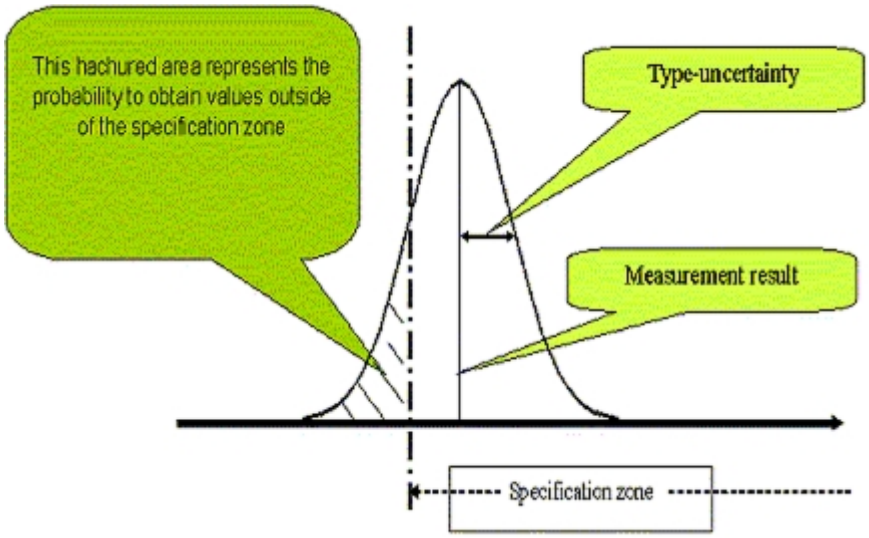
RECOMMENDATION 14

Before introducing or confirming a test method in a standard, it is advisable to validate its representativity by means of assessments carried out in real situation of use, PPE being worn by the operators while carrying out their normal tasks. This is of particular importance for test methods related to key health and safety characteristics.

C6 – Reproducibility, repeatability and Uncertainty of measurement

Repeatability is the variability of the measurements obtained by one person while measuring the same item repeatedly. This is also known as the inherent precision of the measurement or test equipment.
Reproducibility is the variability of the measurement system caused by differences in operator behavior. Mathematically, it is the variability of the average values obtained by several operators while measuring the same item.

It is of common knowledge that measurement results are never perfectly accurate. In practice the sources of systematic and random errors which can affect the results of measurement are numerous (even for the most careful operators).
To describe this lack of perfection, the term "uncertainty" is used. Although the concept of uncertainty may be related to a "doubt", in the real sense the knowledge of uncertainty implies increased confidence in the validity of results.
The figure below illustrates the decision difficulty when uncertainty could affect the compliance of a product to a specification limit (this figure illustrates the case of a Gaussian distribution, but the difficulty is the same in the case of all other kinds of distribution).



This margin of doubt should be quantified to be able to make a consistent decision. In fact a key consideration is the degree of risk associated with the decision making process.
Without knowledge of the accuracy (trueness and precision) of measurement methods and/or the uncertainty of measurement results, it may appear very easy to make decisions. But, in practice, these decisions may be incorrect and sometimes lead to serious consequences, if the measurement uncertainty is not taken into account.
For example, in the economical field, when rejecting instead of accepting a good product during a certification process or, conversely, when accepting a bad product by error. In the legal field, when returning a verdict of guilty instead of not guilty in case of market surveillance or of accident. In the human field, when falsely classifying dangerous products as safe. In the ethical field, when having overly optimistic or unduly pessimistic interpretation of results leading to a non - fair competition between manufacturers and between testing laboratories, etc.
So, it is vital to quantify the reliability of the measurement results to greatly reduce any disputes and adverse consequences of legal proceedings. This is of particular importance if we consider the growing number of cases of litigation in Europe and the liability problems of manufacturers in case of accidents.

RECOMMENDATION 15

When introducing or confirming a test method in a standard, permitting to obtain quantitative results, it must be included either values of precision (i.e. repeatability and reproducibility) or a process for uncertainty calculation.

The values of precision of the method should be obtained through inter-laboratory comparison tests, organized before the publication of the standard.

If the specifications introduced in existing standards take already into account the uncertainty of measurement, this should be clearly stated in the standards and the corresponding maximum acceptable uncertainty of measurement be précised for each test and measurement method.

C7 – Rules for the conformity assessment on the basis of test results and associated uncertainty of measurement

To judge the conformity of a product against the specifications laid down in a standard, test results and the associated uncertainty of measurement should be considered together. In order to avoid inconsistent decisions between testing laboratories, reference to harmonized decision criteria (acceptance and rejection) should be made in particular for key characteristics related to health and safety of users.

RECOMMENDATION 16

For each product standard the document "Uncertainty of measurement and results interpretation " given in the Annex IV of this guide should be introduced as an informative annex.

C8– Samples, test schedule and final result

The test results may depend on:

- the representativity of the sample
- the order in which the tests are carried out.

Another important point is how to get the final result. The rules to obtain this final result to be considered for a decision has to be clearly specified. In any case all samples have to comply the specifications. For key health and safety characteristics, the worst value should be considered as the final result.

RECOMMENDATION 17

Whenever possible and necessary, product standards and/or test standards should specify:

- that the samples should be representative of the PPE to be tested,
- the number of samples to be checked,
- *the required order of the individual tests to be carried out where relevant.*

It should be specified :

- *that all samples have to comply with the requirement,*
- *how to handle the individuals results*
- *how to determine the final result.*

C9– Conditioning

The use of harmonized conditioning temperature and humidity before and during the tests, facilitate the work of the laboratories and decrease the cost of the tests.
So it is advisable that all TCs trie in all PPE standards to adopt the same conditioning parameters. ISO 554 –1976 “Standard atmospheres for conditioning and/or testing - Specifications” may be used as a reference document.

RECOMMENDATION 18

Whenever possible and necessary, use the following parameters for conditioning before or during testing:

(23 ± 2)°C and (50 ± 5)% RH

PART D – Information and guidances to users and purchasers

D1 - Information to be supplied by manufacturers [5]

The information supplied by the manufacturer constitutes a fundamental element which is considered as an integral part of the PPE.

RECOMMENDATION 19

The clause often called in PPE standards “Information and labelling“, “Information supplied by the manufacturer” or “Instruction for use”, shall be established in conformity with the basic Health and Safety requirement 1.4, of the Annex II of the PPE Directive, but also, where relevant, with other applicable basic requirements of this directive.

A warning shall be introduced on the importance of the wording of that information which shall be based on a simple and easily comprehensible use of the language.

For example, the clauses “Marking” of the standards now frequently ask for the use of the following pictogram, instructing the user to see the information supplied by the manufacturer.

The document PPE N 108 rev.3 “Guide for drafting the information to be supplied by manufacturers to the users in compliance with directive 89/686/EEC”. [13] gives useful and detailed guidelines for the drafting of this clause.

In addition to the Basic Requirement 1.4, the other applicable Basic requirements of the PPE directive containing additional requirement related to the content of the information to be supplied by manufacturers are the following:

1.3.3 Compatibility of different classes or types of PPE designed for simultaneous use
2.4 PPE subject to ageing
2.8 PPE for use in very dangerous situations
2.12 PPE bearing one or more identification or recognition marks directly or indirectly relating to health and safety
3.1.2.2 Prevention of falls from a height
3.5 Protection against the harmful effects of noise
3.6.2 Complete PPE ready for use
3.7.2 Protection against heat and/or fire
3.8 Protection against electric shock
3.9.1 Non-ionizing radiation
3.9.2.2 Limited protection against external irradiation
3.10. Protection against dangerous substances and infective agents : 3.10.1 Respiratory protection 3.10.2 Protection against cutaneous and ocular contact.

D2 - Guides for the selection, use, care and maintenance of PPE

According to the directive 89/656/EEC on the use of PPE at workplaces, employers are requested to provide PPE appropriate to the risks to be prevented, and to existing conditions at the workplace .They should also take into account the ergonomic requirements and the worker's state of health. To make it easier, it is advisable to draft guidelines for the selection, use, care and maintenance for the different families of PPE giving in particular practical information on the link between the levels/classes of protection/performances and the corresponding risks.

RECOMMENDATION 20

Guidance documents should be developed of each category or sub category of PPE in support of the proper application of the content of the existing set of PPE product standards. The guidelines contained in these documents may not necessarily be exhaustive, but should highlight important aspects to which particular attention should be given.

These guidance documents, should at least, clearly precise for each level or classes of performance/protection introduced in the standards, the corresponding intended level of risks and/or the field of application of the PPE.

They should be based on the best practice for setting up and implementing a suitable PPE management programme. They should also provide a Europe-wide baseline for the selection, use, care and maintenance of PPE and not be conflicting with any national regulations in the same area.

When drafting or revising such guides it is recommended to adopt the following structure:
1 - Terms and definitions
2 - Hazards (to the head, legs, feet, eye and face …) and sources of hazards encountered in occupational (or sport/leisure) environment,
3 - Classification and main components of protectors,(general classification system, performance classification and corresponding field of use, marking)
4 – Risk assessment process (Recall the general principles of prevention: (a)avoiding risks; (b)evaluating the risks which cannot be avoided: (c)combating the risks at source; (d)adapting the work to the individual, especially as regards the design of work places, the choice of work equipment and the choice of working and production methods, with a view, in particular, to alleviating monotonous work and work at a predetermined work-rate and to reducing their effect on health. (e)adapting to technical progress; (f) replacing the dangerous by the non-dangerous or the less dangerous; (g)developing a coherent overall prevention policy which covers technology, organization of work, working conditions, social relationships and the influence of factors related to the working environment; (h)giving collective protective measures priority over individual protective measures; (i)giving appropriate instructions to the workers).
5 – PPE selection process (of safety helmets, shoes, respiratory protective devices…as relevant)
6 - Use, care and maintenance

PART E - Global relevance

Within the globalization context, one of the main challenges is to preserve the specific characteristic of the European standards, namely a high level of safety, emanating from Clause 95 of the treaty instituting the European Community.
Many EN standards on PPE are being transferred at ISO level, with the risk of a downgraded level of safety.
On that account, prior to adopting an ISO standard as a European harmonised standard in support to the PPE directive, one should check that all technical specifications of the ISO standard are in line with the EHSRs in order to avoid 'legal uncertainty'.
When deviations from EU regulations exist, they must be clearly identified, otherwise, economic logic may lead some manufacturers to choose to apply the less costly international standard and consequently put those manufacturers who comply with the obligations specified in the European directive in a difficult position.
Global Relevance is the characteristic of an ISO standard through which "it can be used/implemented as broadly as possible by affected industries and other stakeholders in markets around the world". Ideally, an ISO standard should represent a single international solution that applies to all countries and can be applied by all countries. At European level, the application of the Global Relevance approach is intended to lead to ISO standards which can be adopted as identical European standards. This is in line with the commitment of CEN to adopt common EN ISO standards whenever possible.
If a single international solution cannot be found for certain elements of the ISO standard at the time of drafting, the ISO policy allows an ISO/TC or SC to include 'options' in the standard in order to achieve its global relevance. These 'options' are intended to reflect market differences. However, such differences should not be permanent and so should be expected to disappear over time. If the elimination of market differences cannot be foreseen at the start of drafting, the ISO/TC or SC should not attempt to develop an ISO standard but should use another deliverable instead (such as the ISO Technical Specification).
The CEN guidance document [11] offers a sequence of 'Routes' for use by CEN technical bodies, and European experts active in ISO, in the application of the ISO policy. In accordance with the ISO policy, two of the Routes recognise that an (EN) ISO standard can contain a limited number of alternative (or additional) requirements in order for the product or service to overcome differences in the global market if these differences are believed not to be permanent. In order to avoid potential problems in the recognition of an EN ISO standard featuring options as a harmonized standard, it is requested to apply the following.

RECOMMENDATION 21

It shall be carefully considered that the European Commission will not recognise EN ISO standards containing options as harmonized standards providing a presumption of conformity unless ALL options comply with the essential requirements of the related Directive(s).
Unless there is absolute certainty during the DRAFTING of the ISO standard that ALL options do comply, it is recommended that Route C is considered as the first alternative to Route A if the EN ISO standard is intended to support a New Approach Directive.(See Annex V)

BIBLIOGRAPHY

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[2] Guide to the implementation of Community harmonization directives based on the New and the Global Approach – 2000- Luxembourg : Office for Official Publications of the European Communities - ISBN 92-828-7500-8

[3] CEN Business Operations Support System (BOSS) (http://www.cenorm.be/boss/index.htm)

[4] Guidelines on the application of the Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment. .2006

[5] CEN Guidelines for the drafting of the information to be supplied by manufacturers,2006.

[6] CEN Guidance - How to draft 'European Standards for citation in the Official Journal', BT Resolution 2/2003 "Relation between clauses of EN's and Essential Requirements of New Approach Directives (Annex Z), and BT Resolution 55/2004 " Wording and content of Annex Z for Amendments to Harmonised European Standards supporting EU Directives", CEN BOSS, April 2005

[7] Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work, Official Journal of the European Communities L 183, 29/06/1989, p. 0001 - 0008

[8] Council Directive 92/32/EEC of 30 April 1992 amending for the seventh time Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

[9] The consolidated COUNCIL DIRECTIVE (76/769/EEC) of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations

[10] European Parliament and Council Directive 94/27/EC of 30 June 1994 relating to restrictions on the marketing and use of certain dangerous substances and preparations.

[11] CEN Guidance on the implications of the ISO Global Relevance policy for CEN standardization, CEN BOSS

[12] Directive 94/27/EC of 30 June 1994 relating to restrictions on the marketing and use of certain dangerous substances and preparations.

[13] Document of the CEN PPE Forum. PPE N 108 rev.3 "Guide for drafting the information to be supplied by manufacturers to the users in compliance with directive 89/686/EEC", October 2006.

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung
Rue de stassart, 36 - 1050 BRUXELLES - Tél 32 2 550 08 63 - Fax 32 2 550 08 19

Annex I

PPE CHECKLIST

For the drafting and verification
of the mandated European standards
in compliance with Essential Health and Safety Requirements
of the EC Directive on the design and manufacture
of Personal Protective Equipment (89/686/EEC)

Work item : .....

Reference : .....

Status of the document : .....

Originator : CEN/TC/WG.....

-All PPE TCs are instructed to verify the conformity of their standards (published, in progress or under revision) with the essential Requirements of the Directive on the design and manufacture of PPE by completing the checklist. Every document sh ould be accompanied by a completed and updated checklist during all the drafting procedure including enquiry and formal vote. However ,the check-list will be not included in published PPE standards (BTS 3 Resolution 9 and 12 /1991 ; confirmation by PPE Forum meeting 4/5 December 2001).

-Those in charge of drafting must have read and analysed in detail before hand the content of the directive's essential requirements, as the checklist only gives the titles of these said requirements

BASIC HEALTH and SAFETY REQUIREMENTS (BHSR) (Council directive PPE 89/686/EEC)	Change ? (1)	Which clauses of the standard address the BHSR ?		OBSERVATIONS When an BHSR has not been taken into account, or has only partially been taken into account , please justify (3)
		Specifications	Test and measuring methods	
GENERAL REQUIREMENTS APPLICABLE TO ALL PPE				
1.1 Design principles 1.1.1 Ergonomics				
1.1.2 level and classes of protection				
1.1.1.1 highest level of protection possible				
1.1.1.2 classes of protection appropriate to different levels of risk				
1.2 Innocuousness of PPE 1.2.1 Absence of risks and other 'inherent' nuisance factors				
1.2.1.1 Suitable constituent materials				

(1) [1]If any change since the last edition of the check-list, please put a cross in the column
(2) If this requirement is not applicable put a cross in the column
(3) If corresponding specification and/or test method is(are) missing in this standard or in an other complementary standard, put BHSR not covered in this column. If the standard doesn't address all the requirements of the BHSR put BHSR partially covered, in this column

11

BASIC HEALTH and SAFETY REQUIREMENTS (BHSR) (Council directive PPE 89/686/EEC)	Change ? (1)	Which clauses of the standard address the BHSR ?		OBSERVATIONS When an BHSR has not been taken into account, or has only partially been taken into account , please justify (3)
		Specifications	Test and measuring methods	
1.2.1.2 Satisfactory surface condition of all PPE parts in contact with the user.				
1.2.1.3 Maximum permissible user impediment				
1.3 Comfort and efficiency				
1.3.1 Adaptation of PPE to user morphology				
1.3.1 Lightness and design strength				
1.3.2 Compatibility of different classes or types of PPE designed for simultaneous use				
1.4 Information supplied by the manufacturer				

(1) - If any change since the last edition of the check-list, please put a cross in the column
(2) If this requirement is not applicable put a cross in the column
(3) If corresponding specification and/or test method is(are) missing in this standard or in an other complementary standard, put BHSR not covered in this column. If the standard doesn't address all the requirements of the BHSR put BHSR partially covered, in this column

BASIC HEALTH and SAFETY REQUIREMENTS (BHSR) (Council directive PPE 89/686/EEC)	Change ? (1)	BHSR Non - Applicable ? (2)	Which clauses of the standard address the BHSR ?		OBSERVATIONS When an BHSR has not been taken into account, or has only partially been taken into account , please justify (3)
			Specifications	Test and measuring methods	
ADDITIONAL REQUIREMENTS COMMON TO SEVERAL CLASSES OR TYPES OF PPE					
2.1 PPE incorporating adjustment systems					
2.2 PPE "enclosing" the parts of the body to be protected					
2.3 PPE for the face, eyes and respiratory tracts					
2.4 PPE subject to ageing					
2.5 PPE which may be caught up during use					
2.6 PPE for use in explosive atmospheres					
2.7 PPE intended for emergency use or rapid installation and /or removal					

(1) If any change since the last edition of the check-list, please put a cross in the column
(2) If this requirement is not applicable put a cross in the column
(3) If corresponding specification and/or test method is(are) missing in this standard or in an other complementary standard, put BHSR not covered in this column. If the standard doesn't address all the requirements of the BHSR put BHSR partially covered, in this column

BASIC HEALTH and SAFETY REQUIREMENTS (BHSR) (Council directive PPE 89/686/EEC)	Change ? (1)	BHSR Non - Applicable ? (2)	Which clauses of the standard address the BHSR ?		OBSERVATIONS When an BHSR has not been taken into account, or has only partially been taken into account , please justify (3)
			Specifications	Test and measuring methods	
2.8 PPE for use in very dangerous situations					
2.9 PPE incorporating components which can be adjusted or removed by the user					
2.10 PPE for connection to another, external complementary device					
2.11 PPE incorporating a fluid circulation system					
2.12 PPE bearing one or more identification or recognition marks directly or indirectly elating to health and safety					
2.13 PE in the form of clothing capable of signalling the user's presence visually					
2.14 “Multi-risks” PPE					

(1) If any change since the last edition of the check-list, please put a cross in the column
(2) If this requirement is not applicable put a cross in the column
(3) If corresponding specification and/or test method is(are) missing in this standard or in an other complementary standard, put BHSR not covered in this column. If the standard doesn’t address all the requirements of the BHSR put BHSR partially covered, in this col

BASIC HEALTH and SAFETY REQUIREMENTS (BHSR) (Council directive PPE 89/686/EEC)	Change (1)	BHSR Non - Applicable (2)	Which clauses of the standard address the BHSR ?		OBSERVATIONS When an BHSR has not been taken into account, or has only partially been taken into account, please justify (3)
			Specifications	Test and measuring methods	
ADDITIONAL REQUIREMENTS COMMON TO SEVERAL CLASSES OR TYPES OF PPE					
3.1 Protection against mechanical impact					
3.1.1 Impact caused by falling or projecting objects and collision of parts of the body with obstacle					
3.1.2 Falls					
3.1.2.1 Prevention of falls due to slipping					
3.1.2.2 Prevention of falls from height					
3.1.3 Mechanical vibration					
3.2 Protection against (static) compression of part of the body					
3.3 Protection against physical injury (abrasion, perforation, cuts bites)					

(1) If any change since the last edition of the check-list, please put a cross in the column
(2) If this requirement is not applicable put a cross in the column
(3) If corresponding specification and/or test method is(are) missing in this standard or in an other complementary standard, put BHSR not covered in this column. If the standard doesn't address all the requirements of the BHSR put BHSR partially covered, in this column

BASIC HEALTH and SAFETY REQUIREMENTS (EHSR) (Council directive PPE 89/686/EEC)	Change ? (1)	BHSR Non - Applicable ? (2)	Which clauses of the standard address the BHSR ?		OBSERVATIONS When an BHSR has not been taken into account, or has only partially been taken into account, please justify (3)
			Specifications	Test and measuring methods	
ADDITIONAL REQUIREMENTS COMMON TO SEVERAL CLASSES OR TYPES OF PPE					
3.4 Prevention of drowning (lifejackets, armbands and lifesaving suits)					
3.4.1 Buoyancy aids	*				
3.5 Protection against the harmful effects of noise					
3.6 Protection against heat and/or fire					
3.6.1 PPE constituent materials and other components					
3.6.2 Complete PPE ready for use					
3.7 Protection against cold					
3.7.1 PPE constituent materials and other components					
3.7.2 Complete PPE ready for use					

(1) If any change since the last edition of the check-list, please put a cross in the column
(2) nIf this requirement is not applicable put a cross in the column
(3) If corresponding specification and/or test method is(are) missing in this standard or in an other complementary standard, put BHSR not covered in this column. If the standard doesn't address all the requirements of the BHSR put BHSR partially covered, in this column

BASIC HEALTH and SAFETY REQUIREMENTS (BHSR) (Council directive PPE 89/686/EEC)	Change ? (1)	BHSR Non - Applicable ? (2)	Which clauses of the standard address the BHSR ?		OBSERVATIONS When an BHSR has not been taken into account, or has only partially been taken into account, please justify (3)
			Specifications	Test and measuring methods	
3.8 Protection against electric shock					
3.9 Radiation protection					
3.9.1 Non-ionising radiation					
3.9.2 Ionising radiation 3.9.2.1 Protection against external					
3.9.2.2 Limited protection against external irradiation					
3.10 Protection against dangerous substances and infective agents					
3.10.1 Respiratory protection					
3.10.2 Protection against cutaneous and ocular contact					
3.11 Safety devices for diving equipment					

(1) If any change since the last edition of the check-list, please put a cross in the column
(2) If this requirement is not applicable put a cross in the column
(3) If corresponding specification and/or test method is(are) missing in this standard or in an other complementary standard, put BHSR not covered in this column. If the standard doesn't address all the requirements of the BHSR put BHSR partially covered,

Annex II

RECOMMENDATION for the DRAFTING of the ANNEX ZA In support of Directive 89/686/EEC

1. Foreword

In accordance with the Mandates given by the Commission to CEN, an harmonized standard should match all applicable Basic Health and Safety Requirements (BHSRs)[1] of the Directive.

However one must recognize that in practice the existing harmonized standard doesn't always address all applicable BHSRs.

The use of such an incomplete standard as a reference for CE conformity assessment induced some constraints for the manufacturers. As a matter of fact, the EU guide "How to apply the directive 89/686/EEC - PPE GUIDELINES" (See http://ec.europa.eu/enterprise/mechan_equipment/ppe/guide.htm) clearly states that:

If the manufacturer chooses to use European harmonised standards to assess the conformity of the PPE directive, he shall make sure that these standards cover all BHSRs applicable to his products under the foreseeable conditions of use. If the existing European harmonised standards do not cover all applicable BHSRs he has, in addition to the application of these standards, to assess the conformity to the BHSRs not covered by using other relevant technical specifications and test methods… PPE may be placed on the market and put into service only if they are in compliance with all applicable BHSRs.

The Annex ZA is a practical tool, enabling all stakeholders (manufacturers, standardizers, notified bodies, users, consumers, social partners, market surveillance authorities) to have a clear view on the coverage of the relevant Essential Requirement(s) by the harmonized standards.

Thereby, Annex ZA has to be considered one of the most important parts of the standard and be correctly presented and documented.

To be really informative, the Annex ZA should in particular:

- list the relevant addressed BHSRs and the corresponding clauses of the standard where technical solution(s) are proposed to assess the conformity of these BHSRs.
- identify the applicable BHSRs, not taken into consideration in the standard or not verified in the standard (e.g. not considered or not verified as consequence of lack of concrete requirement and/or lack of pass/fail criteria, and/or verification procedure in the standard or by reference to another standard.)
- identify the applicable BHSRs, only partially verified in the standard (e.g. when the standard doesn't address all the necessary requirements to consider the BHSR as fully verified)

2. The use of the check-list as a proper tool for filling in the Annex ZA:

According to the-CEN rules for the drafting of European Standards to be cited in the Official Journal' and in particular for the presentation of Annex ZA(Resolutions BT 2/2003 and BT 55/2004): technical bodies drafting European Standards in support of New Approach Directives are strongly advised to use a checklist during the drafting stage documenting the relationship between the Basic Requirements of the Directive(s) concerned and the clauses of the draft. (http://www.cenorm.be/boss/supporting/guidance+documents/gd032+-+relation+between+ens+and+er+of+nad/gd+-+relation+between+ens+and+ers.asp)

[1] The wording "Basic Health and safety requirement" (BHSR) is used in the PPE Directive 89/686/EEC, however the wordings "Essential Health and safety requirement" or "Essential requirements" are widely used. They all have the same meaning.

This check-list is a practical tool , to clearly identity all applicable BHSRs to a given PPE and the BHSRs addressed in the corresponding standard and then to properly fill in the Annex ZA.

3. General rules for filling in the Annexes ZA:

According the CEN BOSS rules Annexes Z relating to PPE Directive 89/686/EEC can be drafted in accordance with several formats.
However the “Format 1” merged with an adaptation of “Format 2” is the preferred format which can be used in all cases. It shows clearly the relationship between the Basic Requirements of the Directive 89/686/EEC and the clauses of the standard. Additionally it shows which Essential Requirements have not been considered in the standard
This format should be used for all PPE standards.

Table ZA – Correspondence between this European Standard and Directive 89/686/EEC

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ER) of Directive 89/686/EEC	Qualifying remarks/Notes
Give the references of the corresponding particular clause(s) or sub-clause(s) of the standard. (e.g. 4.5, 5.2.3) If no clause corresponds to the BHSR indicate: None	In this column list all applicable ERs to the corresponding PPE (e.g. 3.6.2 Complete PPE ready for use)	Possible remarks/notes: - ER only partially covered : e.g. standard doesn’t address all the necessary requirements to consider the BHSR as fully verified. - ER not covered : give the reasons e.g. Not addressed. No requirement and/or test methods (nor other complementary test method standard). -

3. Examples of application

3.1. Example Nr 1

This example aim at helping standardizers to practically establish the ZA Annex. To avoid any misinterpretation, it corresponds to a fictitious standard, but easily be transferred to any real standard.

Let us suppose a standard related to a hood with visor against heat and flames.

Looking at that fictitious standard we could observe the following :

- There are a number of applicable ERs that have not been dealt with:

- ER 1.1.1 ergonomics
- ER 1.1.2.1 Highest level of protection possible
- ER 1.2.1.1 Suitable constituant materials
- ER 1.2.1.2 Satisfactory surface condition of all PPE parts in contact with the user
- ER 1.2.1.3 Maximum permissible user impediment
- ER 2.3 PPE for face, eyes and respiratory tracts

- Some ERs, are not fully covered :

- ER 3.6.1 requirements related to hood exist but not for the visor
- ER 1.3.1 requirement stating that the hood shall remain in place for the foreseeable period of use, bearing in mind ambient factors and movements to be made is not considered.
- ER 1.4 no request for a specific warning in the clause related to the content of the “instructions for use” such as “the hood shall be always used with appropriate clothing protecting the body” nor for information dealing with the characteristics of appropriate spare parts to be used nor information related to visor.

According to the format proposed above Annex ZA should be established as follows.

ANNEX ZA (informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 89/686/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and European Free Trade Association, to provide a means of conforming to 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.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this standard confers, within the limits of the scope of this standard, a presumption of conformity with the relevant Essential Requirements of that Directive, except Essential Requirements 1.1.1; 1.1.2.1; 1.2.1.1; 1.2.1.2; 1.2.1.3 and 2.3, and associated EFTA regulations.

Table ZA – Correspondence between this European Standard and Directive 89/686/EEC

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 89/686/EEC	Qualifying remarks/Notes
None	1.1.1 ergonomics	No specifications nor test methods,
None	1.1.2.1 Highest level of protection possible	No specification nor test methods
None	1.2.1.1 Suitable constituent materials	No specifications nor test methods
None	1.2.1.2 Satisfactory surface condition of all PPE parts in contact with the user	No specifications nor test methods
None	1.2.1.3 Maximum permissible user impediment	No specifications nor test methods
4.1	1.2.1 Absence of risks and other inherent nuisance factors	
4.2	1.3.1 Adaptation of PPE to user morphology	Partially. No requirement indicating that the hood shall remain in place for the foreseeable period of use is given
5.2	1.4 Information supplied by the manufacturer	no request for a specific warning in the clause related to the content of the “instructions for use” such as “the hood shall be always used with appropriate clothing protecting the body” nor for information dealing with the characteristics of appropriate spare parts to be used.
6.1	1.3.2 Lightness and design strength	
6.2	1.3.2 Lightness and design strength	
6.3	1.3.2 Lightness and design strength	
None	2.3 PPE for face, eyes and respiratory tracts	No specification nor test method
6.4	Protection against heat and/or fire 3.6.1 PPE constituent materials and other components	Partially. No requirements for visor
6.5	Protection against heat and/or fire 3.6.1 PPE constituent materials and other components	Partially. No requirements for visor
6.6	Protection against heat and/or fire 3.6.2 Complete PPE ready for use	Partially. No requirements for visor
6.7	1.2.1 Absence of risks and other inherent nuisance factors	

7	2.12 PPE bearing identification marks relating to health and safety	
8	1.4 Information supplied by the manufacturer	Partially. No information on use and spare parts. No information on visor

WARNING: Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

3.2 . Example Nr 2

Let consider a standard related to a protective helmet against impacts where all applicable ERs are properly dealt with in the standard.

According to the format proposed above format 1 should be established as follows.

Relationship between this European Standard and the Essential Requirements of EU Directive 89/686/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and European Free Trade Association, to provide a means of conforming to 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.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this standard confers, within the limits of the scope of this standard, a presumption of conformity with all relevant Essential Requirements of that Directive and associated EFTA regulations.

Table ZA – Correspondence between this European Standard and Directive 89/686/EEC

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 89/686/EEC	Qualifying remarks/Notes
2.1.	1.1.1. Ergonomics	
2.2.	1.1.2.1.Highest level of protection possible	
2.3.	1.2.1. Absence of risks and other inherent nuisances factors	
2.4.	1.2.1.1. Suitable constituent materials	
2.5	1.2.1.2. Satisfactory surface condition for all PPE parts in contact with the user	
2.6.	1.2.1.3. Maximum permissible impediment	
2.7.	1.3.1. Adaptation to the user morphology	
2.8	1.3.2. Lightness and design strength	
4.1	1.2.1 Absence of risks and other inherent nuisance factors	
4.2	1.3.1 Adaptation of PPE to user morphology	
6.1	1.3.2 Lightness and design strength	
6.2	1.3.2 Lightness and design strength	
6.3	1.3.2 Lightness and design strength	
6.4	2.1. PPE incorporating adjustment systems	
6.5	2.2. PPE "enclosing" the parts of the body to be protected	
6.6	2.5 PPE which can be caught up during use	

6.7	1.2.1 Absence of risks and other inherent nuisance factors	
6.7.1	2.9 PPE incorporating components which can be adjusted or removed by the user	
6.8	3.1.1 Impact caused by falling or projecting objects and collision with an obstacle	
6.9	3.2 Protection against (static) compression of part of the body	
7	2.12 PPE bearing identification marks relating to health and safety	
8	1.4 Information supplied by the manufacturer	

Annex III

Annex III a - Extract of EN 340:2003 (E)

4 Basic health and ergonomic requirements

4.1 General

In the following paragraphs some basic health and ergonomic requirements are stated that are relevant for many types of protective clothing. For general ergonomic principles to be used in designing and specifying personal protective equipment see prEN 13921-1[2].

Protective clothing shall be designed and manufactured as follows.

4.2 Innocuousness

Protective clothing shall not adversely affect the health or hygiene of the user. Protective clothing shall be made of materials such as textiles, leather, rubbers, plastics that have been shown to be chemically suitable. The materials shall not in the foreseeable conditions of normal use release or degrade to release substances generally known to be toxic, carcinogenic, mutagenic, allergenic, toxic to reproduction or otherwise harmful. Information claiming that the product is innocuous shall be checked.

NOTE 1 - Information on the classification and identification of harmful substances can be found e.g. in [7, 8] of the Bibliography.

NOTE 2 - Guidance on how to consider acceptability of materials in protective clothing is given in informative annex B (flow chart).

NOTE 3 - Materials should be selected to minimise the environmental impact to the production and disposal of protective clothing.

NOTE 4 - The following list of documents is given for information and as examples of documents to be examined:

a Information supplied by the manufacturer could include a declaration confirming that the product does not contain any substances at levels that are known or suspected to adversely effect user hygiene or health,

b Materials specifications,

c Safety data sheets relating to the materials,

d Information relating to the suitability of the materials for use with food, in medical devices, or other relevant applications.

e Information relating to toxicological, allergenic, carcinogenic, toxic to reproduction or mutagenic investigations on the materials,

f Information relating to ecotoxicological and other environmental investigations on the materials,

The examination should determine whether the claim that the materials are suitable for use in the protective clothing or protective equipment is justified. Particular attention has to be paid to the presence of plasticisers, unreacted components, heavy metals, impurities and the chemical identity of pigments and dyes.

Materials of protective clothing shall comply with the following requirements:

a The chromium VI content in leather clothing shall comply with the requirements of EN 420.

b All metallic materials which could come into prolonged contact with the skin (e.g. studs, fittings) shall have an emission of nickel of less than 0,5 µg/cm² per week. The method of test shall be according to EN 1811.

c The pH value for protective clothing material shall be greater than 3,5 and less than 9,5. The test method for leather shall be according to EN ISO 4045 and for other materials according to EN 1413.

d The colour fastness to perspiration of protective clothing material to ensure user hygiene (e.g. no skin staining) shall be determined in accordance with EN ISO 105-A02 and shall be at least grade 4 of the Grey scale for the colour change of the specimen. The test shall be conducted in accordance with EN ISO 105-E04.

e Azo colorants which release carcinogenic amines listed in prEN 14362-1 shall not be detectable by the method in that standard.

Annex III b - Informative ANNEX B to EN 340

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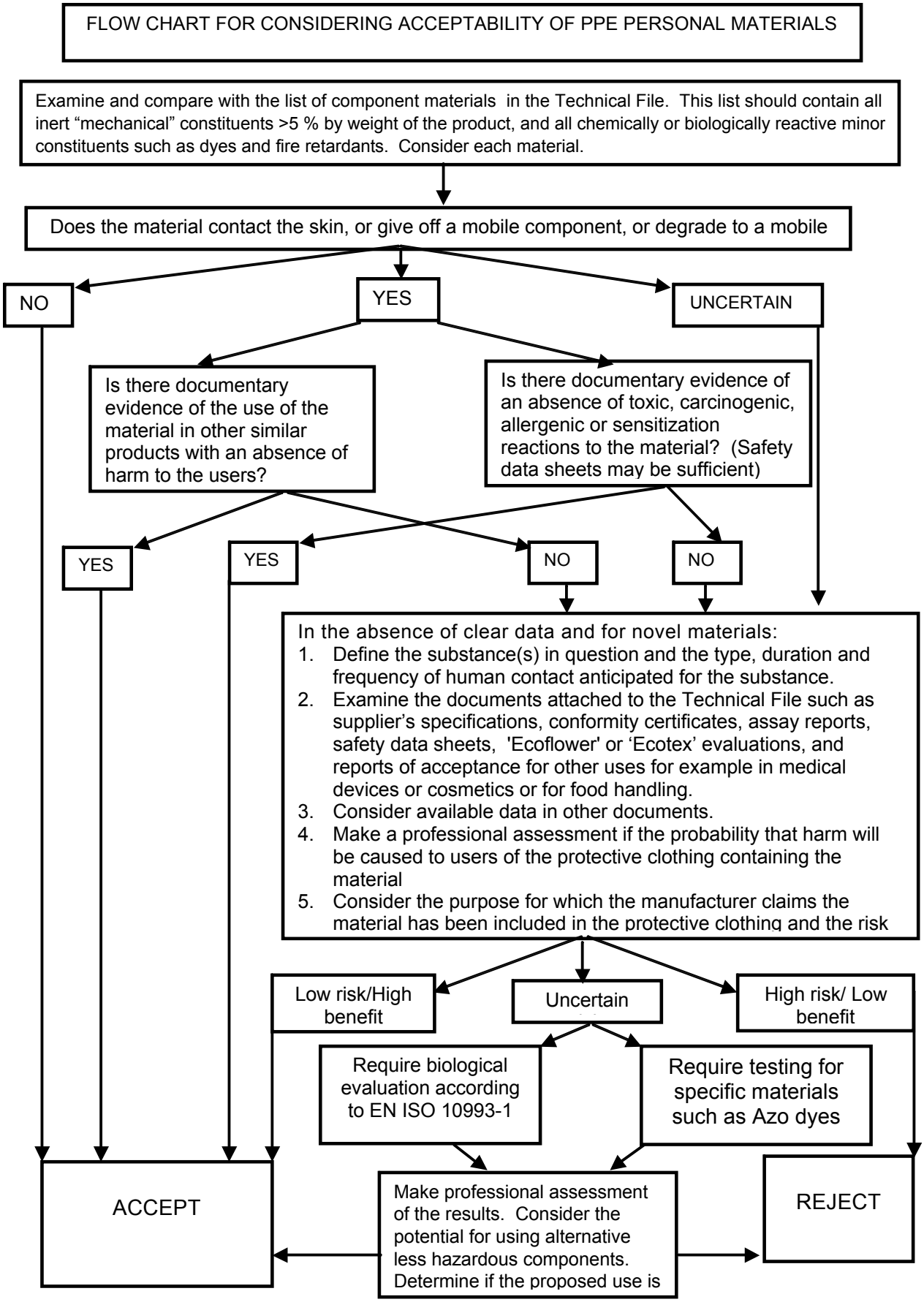

Annex IV

Informative Annex to PPE standards
Uncertainty of measurement and results interpretation

A.1 Test report and uncertainty of measurement:

The following protocol with regard to uncertainty of measurement shall be applied to test results where the non consistent decision could lead to health and safety risks for the end-users of the products. In order to ensure the safest conditions for the user, the result of the measurement including the uncertainty shall fall within the specification limit.

1 - If the test result plus/minus the uncertainty U of measurement limit falls completely inside or outside of the specification zone, then the result shall be deemed to be a straightforward pass or fail (Figures C.1 and C.2).

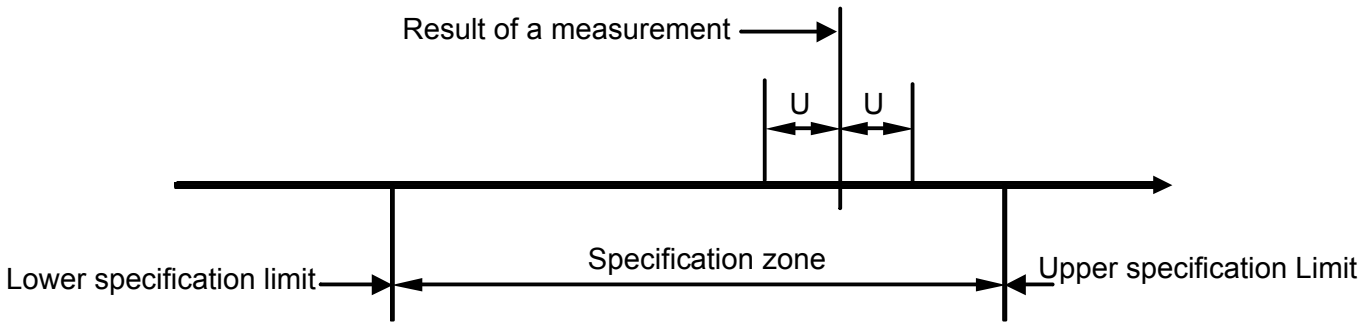

Figure C.1 — Result pass

Figure C.2 — Result fail

2 - If the test result plus/minus the uncertainty U of measurement, overlaps the specification zone, then the assessment of pass or fail shall be determined on the basis of safety, that is considering the safest conditions for the user of the PPE (Figure C.3).

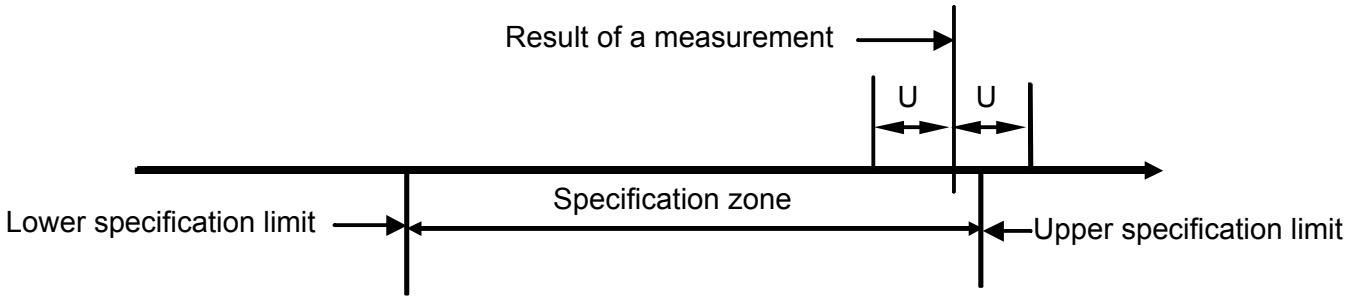

Figure C.3 — Result fail

Annex V

GLOBAL RELEVANCE

The Route A:

Single technical solution
Every effort shall be made to develop a globally relevant ISO standard representing a single technical solution in order for the EN ISO standard to be identical to the ISO standard in content and application.

The Route C:

Diverging requirements addressed through separate ISO Technical Specifications
In this case, the text of the ISO standard contains only core requirements that are applicable to all regions.
Diverging market requirements are dealt with in separate ISO Technical Specifications (ISO/TSs). One ISO/TS should address the particular requirements of the European market. In cases where the EN ISO standard is intended to support European legislation, the ISO/TS addressing the particular requirements of the European market should be adopted as an EN to complement the core EN ISO standard.
Note: the ISO/TSs should add few requirements to the core ISO standard. Hence the ISO standard must not be an “empty shell”, acting simply as a ‘bridge’ for the different ISO/TSs.