PPE GUIDELINES

GUIDELINES ON THE APPLICATION OF COUNCIL DIRECTIVE 89/686/EEC OF 21 DECEMBER 1989 ON THE APPROXIMATION OF THE LAWS OF THE MEMBER STATES RELATING TO PERSONAL PROTECTIVE EQUIPMENT

17 July 2006

NOTES

1. These guidelines are intended to be a manual for all parties directly or indirectly affected by Directive 89/686/EEC[1], commonly referred to as PPE ("Personal Protective Equipment) directive. Readers' attention is drawn to the fact that this guide is intended only to facilitate the application of Directive 89/686/EEC and it is the relevant national transposition of the text of the directive which is legally binding. However, this document does represent a reference for ensuring consistent application of the directive by all stakeholders. The guidelines are intended to help ensure the free movement of PPE in the Community territory[2] by consensus amongst Member States' government experts and other parties concerned.

2. These guidelines have been prepared by the relevant services of the Directorate General - Enterprise and Industry of the European Commission in collaboration with Member States, European industry, European standardisation and Notified Bodies.

3. The European Commission will undertake to maintain this guide. It is our goal to ensure that the information provided is both timely and accurate. If errors are brought to our attention, we will try to correct them. However the Commission accepts no responsibility or liability whatsoever with regard to the information in this guide.

This information is:

- of a general nature only and is not intended to address the specific circumstances of any particular individual or entity;
- not necessarily comprehensive, complete, accurate or up to date;
- sometimes refers to external information over which the Commission services have no control and for which the Commission assumes no responsibility;
- not professional or legal advice.

4. All references to the CE marking and EC declaration of conformity in this Guide relate only to Directive 89/686/EEC. To place PPE on the market in the Community territory all other relevant legislation must be applied.

5. Further guidance, especially concerning specific type of products, can be found on the Commissions website:

   http://ec.europa.eu/enterprise/mechan_equipment/ppe/index.htm

---

[1] Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment as amended by Directive 93/68/EEC, Directive 93/95/EEC and Directive 96/58/EC.

[2] According to the agreement related to the European Economic Area (EEA) (Council and Commission Decision 94/1/EC of 13 December 1993 (OJEC n° L 1 of 3 January 1994, p. 1) the territories of Liechtenstein, Iceland and Norway have to be considered, for the implementation of Directive 89/686/EEC, in the same right as of the Community territory. When this term, Community territory, is used in this guide, the same applies to the EEA territory. Likewise, solely in respect of this Directive, the responsibilities of the "Member States" can also be taken for the national authorities of these three territories.

INTRODUCTION

The objective of these guidelines is to clarify certain matters and procedures referred to in directive 89/686/EEC concerning Personal Protective Equipment (PPE). It provides a cross reference from the legal text of the directive to explanations by EU sectoral experts. The guidelines should be used in conjunction with the directive and with the European Commission's "Guide to the implementation of directives based on New Approach and Global Approach (Blue Guide)".

These guidelines are not only for the use of Member States' competent authorities, but also by the main economic operators concerned, such as manufacturers, their trade associations, bodies in charge of the preparation of standards as well as those entrusted with the conformity assessment procedures.

First and foremost, this document must ensure that, when correctly applied, the directive leads to the removal of obstacles and difficulties related to the free circulation (free movement) of goods within the European Community (see footnote 2). It should be noted that the statements in these guidelines refer only to the application of Directive 89/686/EEC unless otherwise indicated. All parties concerned should be aware of other requirements, which may also apply (see Article 5 (6)(a).

The PPE directive is a "New Approach" directive laying down Basic Health and Safety Requirements (BHSR) and leaving it to standards, primarily European harmonised standards, to give technical expression of the relevant requirements contained in the directive.

Directive 89/686/EEC is a total harmonisation directive, i.e. its provisions replace existing divergent national and European legislation which cover the same subjects as stipulated by directive 89/686/EEC.

"Use" Directives

The reader will want to be aware that where PPE is intended for use in a place of work, national and Community legislation intended to ensure the safety of employees will usually apply. Whereas "New Approach" Directives set the highest possible requirements given their overall objectives and hence do not allow for additional national provisions within scope, "Use" Directives (89/391/EEC[3], 89/656/EEC[4]) set minimum requirements. In effect this means that national authorities, following the agreement of other Member States by means of the notification procedure under Directive 98/34/EC, can put in place further requirements relating to "use" and selection so long as these do not constitute a barrier to trade.

[3] 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

[4] Council Directive 89/656/EEC of 30 November 1989 on the minimum health and safety requirements for the use by workers of personal protective equipment at the workplace (third individual directive within the meaning of Article 16 (1) of Directive 89/391/EEC)

Table of contents

Definitions

In general terms, the following definitions are considered acceptable.

Placing on the market – the first making available on the Community market of an individual product with a view to distribution and/or use, whether in return of payment or free of charge.

Putting into service – takes place at the moment of the first use within the Community by the end user.

Manufacturer – the natural or legal person, who:

- designs and/or manufactures a product covered by the Directive, or who has a PPE designed and/or manufactured with view to its placing on the market or for his own professional or private use, under his own name or trademark; or who:

- places a PPE on the market and/or puts it into service, under his own name or trademark.

The manufacturer bears responsibility for:

- undertaking an analysis to conclude if his product is subject to the PPE Directive and which requirements apply;

- design and construction of the PPE in accordance with the Basic Health and Safety Requirements (BHSR) laid down in the Directive;

- following the procedures for the assessment of the conformity of the product with the BHSR laid down in the Directive;

- providing marking and instructions for safe use, maintenance etc.

The manufacturer has sole and ultimate responsibility for the conformity of the PPE to this and other applicable directives. He is required to have a knowledge about the design and construction of the product to be able to declare such conformity in respect of all applicable provisions and requirements of the relevant directives.

Authorised representative – Any natural or legal person established within the Community who has received a mandate from the manufacturer to act on his behalf for specified tasks with regard to the latter's responsibilities under the Directive. The mandate should be written and should specify which obligations of the manufacturer can be conferred upon the authorised representative.

1.1 CHAPTER 1 SCOPE, PLACING ON THE MARKET AND FREE MOVEMENT

1.1.1 Article 1

1. This Directive applies to personal protective equipment, hereinafter referred to as PPE' .

It lays down the conditions governing its placing on the market and free movement within the Community and the basic safety requirements which PPE must satisfy in order to ensure the health protection and safety of users.

The PPE Directive applies to PPE intended for use in domestic, leisure and sports activities, as well as for professional use.

The objectives of the PPE Directive are:

- to provide the BHSRs which the PPE must satisfy to preserve the health and ensure the safety of intended users;
- to ensure free movement of PPE within the Community.

The Directive applies to PPE which is intended to be placed and/or put into service on the Community market **for the first time**. Consequently, the Directive applies to new PPE manufactured in the Member States, and to new and used PPE imported from outside of the Community.

The provisions of the Directive does not apply to the PPE intended to be placed on the market in a country outside the Community, or imported into the Community for re-export to a country outside.

2. For the purposes of this Directive, PPE shall mean any device or appliance designed to be worn or held by an individual for protection against one or more health and safety hazards.

This definition has proved readily understandable to equipment manufacturers and users alike, although some borderline cases still raise questions. Every term in the definition is important:

– PPE is *"worn"* in the sense that clothing, glasses, hearing protectors or fall arrest harnesses are worn. Indeed much PPE is clothing, be it garments, headgear, gloves or footwear. Other PPE is to be *"held"* in the hand, such as screens to protect the eyes and face during welding. The protection provided by PPE thus depends on an action by the person exposed to the hazard: the donning or holding of the equipment.

  Portable equipment which is neither worn nor held during use is not considered as PPE. So, for example, insulating mats or stools used by electricians for live working, or protective screens placed in the work stations are not regarded as PPE.

– PPE is worn or held *"by an individual"*. This is what distinguishes personal equipment from collective protective equipment. Significantly, the terms of the definition of PPE place it within the broad field of the protection of persons. The field of PPE is not limited to equipment used by employees or workers in general, but extends to areas unconnected with work, such as sports and leisure activities. Sunglasses, cycling or riding helmets, gardening gloves, shin-guards for footballers, harnesses for mountaineering, are all PPE.

– PPE is used *"for protection"* of the individual. Generally the equipment forms a shield between part of the body and the hazard for the protection of the individual against any type of risk: a shield of leather against rough surfaces which may graze the skin on hands, a shield of filtering glass against radiation which may injure the eyes, a shield of lead against X-rays which can damage body cells, and so on. This role of PPE as a shield is underlined by the pictograms chosen by PPE standards to symbolise protection against different hazards: a symbol representing the hazard is shown within a shield.

  On the other hand, equipment used by individuals to help to prevent risks, but which do not have a protective function, such as alarm devices e.g., gas detectors or oxygen depletion detectors, are not classed as PPE.

– PPE protects against *"one or more hazards"*. Risk is generally defined as the conjunction of two elements: a hazard, which is a phenomenon which may cause harm, and the probability of a person being exposed to that hazard. Since PPE is designed to protect against hazard, its function is to prevent the occurrence of harm to the exposed person. Consequently, when several risks exist simultaneously, the PPE has to protect against all the risks, not just against one of them.

  This is what differentiates PPE from equipment used after harm has occurred, such as rescue or first-aid equipment, which also tends to be used by third parties. Equipment used by a rescuer is not classed as PPE, unless used to protect the rescuer himself, for example, respiratory protective devices used by firemen when retrieving people from smoke-filled buildings.

  The hazards involved are those which may harm the equipment user. Equipment used to protect people other than the wearer, such as masks used to protect hospital patients, are not PPE. Likewise equipment for protecting goods, such as gloves worn to protect foodstuffs or electronic components are not PPE.

PPE shall also cover:

(a) a unit constituted by several devices or appliances which have been integrally combined by the manufacturer for the protection of an individual against one or more potentially simultaneous risks;

For example, a helmet coupled with a visor and/or hearing protection.

(b) a protective device or appliance combined, separably or inseparably, with personal non-protective equipment worn or held by an individual for the execution of a specific activity;

Some examples of this type of device are protectors against impacts included in motorcycle clothing or knee protectors included in trousers used for performing work whilst kneeling.

(c) interchangeable PPE components which are essential to its satisfactory functioning and used exclusively for such equipment.

There are many items which fall into this category, including filters for respiratory protective devices and screens for eye protectors.

3. Any system placed on the market in conjunction with PPE for its connection to another external, additional device shall be regarded as an integral part of that equipment even if the

system is not intended to be worn or held permanently by the user for the entire period of risk exposure.

An air line linking respiratory equipment to a compressor is such an example.

4. This Directive does not apply to:

- PPE covered by another directive designed to achieve the same objectives as this Directive with regard to placing on the market, free movement of goods and safety;

Marine Equipment Directive 96/98/CE[5] as amended by Directive 2002/75/EC relating to marine equipment states that PPE (listed in Annexes A1 and A2), if designed exclusively for use on board sea-going vessels, are excluded from the PPE directive and will be covered only by the Directive on marine equipment. The following equipment, if used as permanent equipment on board is excluded from the PPE Directive:

- life jackets;
- immersion suits;
- combinations of immersion suits with life jackets;
- breathing apparatus for firemen.

Directive 96/98/EC applies to **equipment for use on board any new European Union ship**, wherever the ship is situated at the time of construction, and to equipment placed on board existing EU ships, whether such equipment is being placed for the first time or is replacing used equipment already on board.

- the PPE classes specified in the list of excluded products in Annex I, independently of the reason for exclusion mentioned in the first indent.

See Annex 1 for an exhaustive list of products specifically excluded from the scope of the PPE Directive.

1.1.2 Article 2

1. Member States shall take all appropriate measures to ensure that the PPE referred to in Article 1 may be placed on the market and brought into service only if it preserves the health and ensures the safety of users without prejudice to the health or safety of other individuals, domestic animals or goods, when properly maintained and used for its intended purpose.

Article 2 defines market surveillance as an obligation for Member States.

The purpose of market surveillance is to ensure that the provisions of applicable directives are complied with across the Community. Article 2(1) obliges Member States to apply the Directive correctly[6] and to monitor its application. Market surveillance is also important for the interest of economic operators, as it helps to eliminate unfair competition.

[5] Directive 96/98/CE of December 20, 1996 relating to the marine equipment (OJ n° L 46 of February 17, 1997, p. 25).

[6] See http://ec.europa.eu/enterprise/mechan_equipment/ppe/transpos.htm for references of national measures transposing directive 89/686/EEC.

The national authorities conducting market surveillance have an obligation to take all appropriate measures to ensure that products, which do not comply with the provisions of the PPE Directive, are removed from the market.

Article 2 obliges Member States to take **"all appropriate measures"** with regard to PPE if it does not preserve the health and ensure the safety of users, irrespective of whether or not it complies with the Directive. These measures are implemented under the principle of "subsidiarity", that is, it is for the Member States themselves to decide the most appropriate action but such action needs to be both dissuasive and proportionate. Those foreseen in national legislation range from the issue of a compliance notice to (potential) gaol sentences and very high financial penalties.

On the application of any such measure restricting the free movement of a PPE the Member States must notify the action to the Commission services according to Article 7.

2. This Directive shall be without prejudice to the right of Member States to lay down in conformity with the Treaty any requirements which they consider necessary to ensure user protection, provided that this does not give rise to modifications to PPE which could result in its non-conformity with the provisions of this Directive.

Member States retain the right to lay down additional national provisions regarding **the use of PPE** which is intended to ensure the protection of workers or other intended users.

Directives 89/391/EEC and 89/656/EEC lay down minimum requirements for the health and safety of users under Article 137 of the EC Treaty. Member States are allowed to adopt or retain more stringent provisions, so long as they are compatible with the Treaty.

However, such measures must neither lead to the modification of a PPE designed and manufactured in accordance with the provisions of the applicable directives, nor influence the conditions for its placing on the Community market. This is evidently the case with the PPE Directive, which is a total harmonisation Directive under Article 95 of the Treaty.

National regulations (e.g. national exposure values) can lead to different rules for **selection and use** of PPE.

The PPE Directive does not lay down obligations for users. However, it must be remembered that according to directives based on Article 137 of the EC Treaty, employers have obligations as regards the use of work equipment at the workplace. An employer is considered to be any natural or legal person who has an employment relationship with a worker (that is any person employed by an employer), and has responsibility for the undertaking or establishment.

3. Member States shall not prevent the presentation at trade fairs, exhibitions and the like of PPE which is not in conformity with the provisions of this Directive, provided that an appropriate notice is displayed drawing attention to this fact and the prohibition on its acquisition and/or use for any purpose whatsoever until it has been brought into conformity by the manufacturer or his representative established in the Community.

Paragraph 3 concerns the showing at exhibitions of products which do not comply with the Directive. The display of PPE at a trade or retail show does not constitute "placing on the

market". However, if PPE is not in full conformity with the provisions of the Directive, this fact must be clearly advertised next to the PPE being exhibited.

1.1.3 Article 3

> The PPE referred to in Article 1 must satisfy the basic health and safety requirements laid down in Annex II.

Article 3 sets out the obligation of the manufacturer to design and produce PPE which satisfies the requirements at Annex II. The manufacturer must ensure that the BHSRs remain valid during the lifetime of the PPE.

The Directive provides "Basic Health and Safety Requirements**"** (BHSRs) instead of "Essential Health and Safety Requirements" which are more typical for other so-called "New Approach" directives. These, however are identical.

Only PPE complying with these BHSRs may be placed on the Community market and/or put into service. The manufacturer must provide information about the measures he has taken in order to ensure the conformity of the PPE to the BHSRs in his technical documentation which is further referred to in Article 8 and described in detail at Annex III.

BHSRs only deal with product characteristics aimed at ensuring the health and safety of intended users. They do not cover either environmental or social aspects.

These requirements are designed to ensure the optimal level of protection. They:

- arise from certain hazards associated with the product (for example physical and mechanical resistance, flammability, chemical, electrical or biological properties, hygiene, radioactivity, accuracy);

- refer to the product and/or its performance (for example provisions regarding materials, design, construction, manufacturing process, instructions drawn up by the manufacturer);

- lay down the principal protection objective(s) (for example by means of an illustrative list).

Or a combination of these three aspects.

1.1.4 Article 4

> 1. Member States may not prohibit, restrict or hinder the placing on the market of PPE or PPE components which comply with the provisions of this Directive and which bear the CE marking attesting their conformity to all the provisions of this Directive, including the certification procedures in Chapter II.

Article 4(1) seeks to ensure the free movement of PPE and PPE components[7] in the Community.

[7] Interchangeable components defined at Article 1(2)(c) which are essential to the safe functioning of the PPE

The CE marking is a declaration that all relevant conformity assessment procedures have been complied with and is a declaration to the national market surveillance authorities that this is the case.

2. Member States shall not prohibit, restrict or impede the placing on the market of PPE components which do not bear the CE marking and which are intended to be incorporated in PPE, provided that they are not essential to its satisfactory functioning.

Paragraph 2 authorises the free movement of PPE components, which, whilst they do not bear the CE marking, are meant to be built-into the PPE provided that they do not impact on the safe functioning of the PPE. Some examples of such components are:

- a torch intended to be built in the helmet -this device will not bear the CE marking unless it is covered by another Directive, for example ATEX (if the lamp is intended for use in a potentially explosive atmosphere);

- a belt for hanging tools that can be assembled on harnesses, **the latter** protecting against falls from a height.

1.1.5 Article 5

1. Member States shall regard as in conformity with the basic requirements referred to in Article 3 the PPE referred to in Article 8 (3) bearing the CE marking with respect to which the manufacturer is able to produce, on demand, the declaration of conformity referred to in Article 12.

Simple design PPE (Article 8 (3)) is regarded in conformity with the BHSRs if the CE marking is affixed and the manufacturer is able to present an EC declaration of conformity. The model for this EC declaration of conformity is at Annex VI to the Directive.

The PPE Directive does not foresee that the EC declaration of conformity is either attached to or needs to accompany the product itself. However, it is generally understood that this has to be presented on the demand of a market surveillance authority in a reasonable period of time in relation to the nature of the suspected non-compliance.

2. Member States shall presume that the PPE referred to in Article 8 (2) satisfies the basic requirements referred to in Article 3 if it bears the CE marking with respect to which the manufacturer is able to produce, on demand, not only the declaration referred to in Article 12 but also the certificate issued by the body of which notification has been given[8] in accordance with Article 9 attesting to their conformity to the relevant national standards, transposing the harmonized standards, assessed at the EC type examination level in accordance with the first indent of Article 10 (4) (a) and (b) .

Where a manufacturer has not applied or has only partly applied the harmonized standards or where there are no such standards the certificate issued by the body of which notification has been given must state the conformity to the basic requirements in accordance with the second indent of Article 10 (4) (a) and (b) .

[8] Also referred to as an “Approved”, “Notified”, or “Inspection” Body in the text of the Directive.

The application of European harmonised standards is voluntary, as is the case with all "New Approach" Directives. However, the application of a national standard that transposes a European harmonised standard, whose reference has been published, confers a presumption of conformity with the BHSRs of the PPE Directive that is covered by the standard.

European harmonised standards are European standards, which are adopted by European Standardisation Organisations (in this case CEN and CENELEC) prepared in accordance with the General Guidelines agreed between the Commission and the European standards organisations, and follow a mandate issued by the Commission after consultation with the Member States. The references of these are required to be published in all official EU languages in the OJEU[9] in order to provide for a presumption of conformity.

For PPE category II and III when the European harmonised standard(s) applied do(es) not cover all BHSRs the EC-type examination certificate issued by the Notified Body must state compliance to the BHSRs directly. If this is the case for "Simple" PPE, the manufacturer must be able to demonstrate the way the conformity is assured.

Article 5, paragraph 3 of the directive was deleted by the Directive 93/95/EEC.

4. The Commission shall publish the references of the harmonized standards in the Official Journal of the European Communities.

Member States shall publish the references of the national standards transposing the harmonized standards.

As noted above, European harmonised standards giving technical expression to the BHSRs at Annex II of Directive 89/686/EEC are developed by the following European standardisation bodies:

– European Committee for Standardisation (CEN)

– European Committee for Electrotechnical Standardisation (CENELEC)

Detailed information on the EU policy regarding (European harmonised) standards is available at:

http://ec.europa.eu/enterprise/standards_policy/index_en.htm

The list of European harmonised standards in the OJEU is regularly updated and is available at the following European Commission Internet address:

http://ec.europa.eu/enterprise/newapproach/standardization/harmstds/reflist/ppe.html

Information on standards is also available at the CENELEC and CEN web sites:

www.cenorm.be

www.cenelec.org

[9] The Official Journal of the European Communities (OJEC) was replaced by the Official Journal of the European Union (OJEU) following the entering into force of the Treaty of Nice.

A list of the national standardisation organizations is provided at:

CEN - http://www.cenorm.be/cenorm/members/members/index.asp

CENELEC - http://www.cenelec.org/Cenelec/About+CENELEC/Our+organization/CENELEC+Members/Default.htm

5. Member States shall ensure that by 30 June 1991 appropriate steps are taken to enable both sides of industry to have an influence at national level on the process of formulating the harmonized standards and keeping them under review.

This paragraph seeks to ensure that all stakeholders including employers, workers and consumers are represented in the standardisation process.

6. (a) Where the PPE is subject to other Directives concerning other aspects and which also provide for the affixing of the CE marking, the latter shall indicate that the PPE is also presumed to conform to the provisions of the other Directives.

Directives sometimes cover a wide range of products, phenomena and/or hazards.

As a result several directives may have to be taken into consideration for PPE, since the placing on the market and putting into service can only take place when the product complies with the provisions of all legislation applicable to it.

By the affixing of the CE marking and the declaration of conformity the manufacturer or his authorised representative declares that the PPE is in conformity with all the provisions which are applicable to them.

Manufacturers of PPE may need to consider the following Directives[10]:

- **Pressure Equipment Directive** 97/23/EC - applies to a limited range of equipment for holding gasses under pressure, for example breathing devices.

- **Electromagnetic Compatibility** directive 89/336/EEC[11] **- t**he EMC directive must also be applied to ensure that PPE with electrical/electronic devices does not cause electromagnetic disturbance and that its normal operation is not affected by such disturbances;

- **Radiocommunications and Telecommunications Terminal Equipment (RTTE)** directive 1999/5/EC. The RTTE directive must also be applied to ensure that PPE incorporating such device(s) is safe and does not disturb radio services or other equipment. The RTTE directive also covers EMC and safety aspects of such equipment.

- **Nickel Directive** 94/27/EC - restricting the release of nickel for those parts in direct and prolonged contact with the skin of the wearer;

[10] Please note that this list of examples is not exhaustive.
[11] This Directive is soon to be replaced by Directive 2004/108/EC

- **General Product Safety Directive**[12] 2001/95/EC - requires that producers only place on the market safe products destined for the consumer and entrustes Member States with the obligation to ensure that both producers and distributors comply with their obligations.
  For more information see Guidance Document on the Relationship between the General Product Safety Directive (GPSD) and certain sectoral Directives with Provisions on Product Safety;

  There are also a number of products which, whilst they may appear to fall within the scope of the PPE Directive, are dealt with by other directives because of their "specificity", as follows:

- **Toys** directive 88/378/EEC.

  Equipment designed to be worn by children to protect them against one or more risks falls within the scope of the PPE Directive e.g. bicycle or ski helmets, ski goggles etc. However, imitations of PPE (such as imitations of firemen's helmets, doctor's protective clothing) fall under the Toys Directive. Where there may be doubt as to the real intended use of such a product, it has been agreed with the Member States that such products should be supplied with a warning to the effect that they are toys and not PPE. Care does need to be taken by the manufacturer if it appears that imitation PPE might be reasonably assumed to protect against hazards. In such cases the manufacturer may not be able to derogate from his liability even with such a warning.

- **Medical Devices Directive** (MDD) 93/42/EEC.

  According to Article 1.6 of this Directive the MDD does not apply to PPE. The MDD applies to devices, other than medicines, used in health care. It aims at protecting the health and safety of patients, users of medical devices and other exposed persons. In order to decide whether the PPE Directive or the Medical Devices Directive should apply, the principal intended purpose of the device must be considered. For example, a mask to be used by a surgeon is a medical device as it protects the patient. On the other hand equipment worn by health care personnel to protect themselves against infectious agents falls under the PPE Directive. At present a proposal to amend the MDD is underway. It foresees the exclusion at Article 1 (6) being deleted and (at the same time) replaced by such provision enabling both Directives to apply parallel where necessary.

- **"ATEX"** directive 94/9/EC

  Equipment covered by the Personal Protective Equipment (PPE) directive 89/686/EEC is specifically excluded from Directive 94/9/EC. However, the manufacturer of PPE intended for use in potentially explosive atmospheres is required to consider BHSR 2.6. PPE intended for use in explosive atmospheres must be so designed and manufactured that it cannot be the source of an electric, electrostatic or impact-induced arc or spark likely to cause an explosive mixture to ignite.

  Following the Essential Health and Safety Requirements in Directive 94/9/EC would be one way to demonstrate compliance.

- **Marine Equipment Directive** 96/98/EC[13]

[12] For more information visit http://ec.europa.eu/consumers/cons_safe/prod_safe/gpsd/index_en.htm
[13] as amended by Directive 2002/75/EC

Equipment covered by the Marine Equipment Directive (MED) 96/98/EC is not designed to fulfil the role of PPE. Such safety equipment is subject to specific standards listed in Annex 1 of the MED and is for use only in emergency situations or during training.

(b) However, where one or more of these Directives allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate conformity to the provisions only of those Directives applied by the manufacturer. In this case, particulars of the Directives applied, as published in the Official Journal of the European Communities must be given in the documents, notices or instructions required by the Directives and accompanying such PPE.

1.1.6 Article 6

1. Should a Member State or the Commission consider that the harmonized standards referred to in Article 5 do not completely satisfy the relevant basic requirements referred to in Article 3, the Commission or the Member State concerned shall refer the matter to the committee created pursuant to Directive 83/ 189/ EEC, setting out its reasons.

The committee shall deliver an opinion without delay. In the light of the committee s opinion, the Commission shall notify Member States of whether or not it is necessary to withdraw the standards concerned from publications made pursuant to Article 5.

This Article provides the method for raising a **formal objection** with respect to European harmonised standards under the Directive.

If a Member State or the Commission considers that a European harmonised standard does not meet the BHSRs given expression by the standard, they are required to bring the matter before a special Committee originally set up under Directive 98/34/EC[14]. This Committee has the authority (amongst other matters) to approve standardisation mandates to the European standardisation bodies. It also has the right to inform them when the remit has not been satisfactorily fulfilled.

The 98/34/EC Committee gives its opinion on the **formal objection** raised and the Commission then decides whether it is necessary to withdraw the reference of the standard in the OJEU or to publish an opinion withdrawing the presumption of conformity from all or part of the standard.

2. The Standing Committee set up by Article 6 (2) of Directive 89/ 392/ EEC (1) may be apprised, in accordance with the procedure described below, of any matter to which the implementation and practical application of this Directive give rise.

The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft, within a time limit which the chairman may lay down according to the urgency of the matter, if necessary by taking a vote.

The opinion shall be recorded in the minutes; in addition, each Member State shall have the right to ask to have its position recorded in the minutes.

[14] Directive 83/189/EEC has been replaced and superseded by directive 98/34/EC as amended by Directive 98/48/EC

The Commission shall take the utmost account of the opinion delivered by the committee. It shall inform the committee of the manner in which its opinion has been taken into account.

The PPE Directive is managed at a European level by a PPE Experts Working Group, chaired by the European Commission, involving representatives of all stakeholders[15]. However, when necessary the Commission can call on the Standing Committee set up by Article 6 (2) of the Machinery Directive 89/392/EEC[16].

The latter Committee meets rarely and is restricted to representatives from the Member States only.

1.1.7 Article 7

1. If a Member State discovers that PPE bearing the CE marking and used in accordance with its intended purpose could compromise the safety of individuals, domestic animals or property, it shall take all necessary measures to remove that equipment from the market and prohibit the marketing or free movement thereof.
The Member State concerned shall immediately inform the Commission of such action, indicating the reasons for its decision and, in particular, stating whether non-conformity is due to:
(a) failure to comply with the basic requirements referred to in Article 3;

(b) the unsatisfactory application of the standards referred to in Article 5;

(c) a shortcoming in the standards referred to in Article 5.

The notification procedure referred to in Article 7 of the PPE directive (in practice referred to as the 'safeguard clause') is the procedure whereby any measure restricting the free movement of PPE bearing CE marking is notified to the European Commission.

This measure is used (but not wholly restricted to) when there are substantive grounds for doubt over the compliance of the PPE with the BHSRs and where it is deemed that equipment is liable to endanger persons, domestic animals or property.

In considering whether the safeguard clause should be triggered, Member States and the respective enforcement authorities consider whether the non-compliance is substantial or can be considered a non-substantial non-compliance to be resolved without recourse to the safeguard clause procedure. There is also general agreement that where the non-compliant PPE is only to be found on the territory of one Member State there is no need to take action at Community level and hence, notification under this Article is not required.

The safeguard clause is designed to allow the Commission to analyse the justification of any national measure restricting the free movement of CE marked PPE. Secondly, it provides a means to inform all national surveillance authorities about such PPE to have the necessary restriction extended to all Member States so as to ensure an equivalent level of protection throughout the Community.

[15] Member States, industry, standardisation and conformity assessment bodies and consumers.
[16] Now Directive 98/37/EC

For the safeguard clause to be applied, the non-conformity has to be established regarding a systematic failure in the design of the PPE.

2. The Commission shall initiate discussions with the parties concerned as soon as possible. If, after such consultation, the Commission decides that the action taken was justified, it shall immediately inform the Member State concerned and all the other Member States to that effect. If, after such consultation, the Commission decides that the action taken was not justified, it shall immediately inform the Member State concerned and the manufacturer or his authorized representative established in the Community to that effect. If the decision referred to in paragraph 1 is in response to a shortcoming in the standards, the Commission shall refer the matter to the Committee referred to in Article 6 (1) if the Member State concerned intends to adhere to its decision and shall initiate the procedure referred to in Article 6 (2) .

The "parties concerned" usually means all Member States of the EU, the manufacturer or his authorised representative established within the Community or, where neither are present on the Community territory, the person who placed the product on the Community market. It may also involve one or more notified bodies involved in the conformity assessment procedure.

Where the Commission finds that the measure adopted by the Member State is not justified, it asks that Member State to withdraw the relevant restrictive provisions and to take the appropriate action to immediately re-establish the free movement of the products in question on its territory. If a Member State refuses to follow the Commission's position the Commission has the right to proceed under Article 226[17] of the EC Treaty.

Where the Commission finds, following such consultation, that the measures are justified, it immediately informs the Member State which took the initiative and the other Member States[18]. This is usually communicated by means of a Commission Opinion.

3. If PPE which is not in conformity with the relevant requirements bears the CE marking the Member State concerned shall take the appropriate measures with regard to those responsible for affixing the mark and shall inform the Commission and the other Member States accordingly.

This procedure is not the same as the safeguard clause procedure described above (article 7, paragraph 1).

The non-conformity described here can be of an administrative or a technical nature.

For example, the affixing of marking and marks in addition to the CE marking is subject to certain restrictions. The market surveillance authority needs to ensure that these principles are respected and, where necessary, take appropriate action. Such action must evidently be taken with due respect to the principle of proportionality.

[17] Article 226 of the EC Treaty: If the Commission considers that a Member State has failed to fulfil an obligation under this Treaty, it shall deliver a reasoned opinion on the matter after giving the Member State concerned the opportunity to submit its observations.
If the Member State concerned does not comply with the opinion within the period laid down by the Commission, the latter may bring the matter before the Court of Justice.

[18] See footnote 2 concerning Norway, Iceland and Liechtenstein

A Member State must inform the Commission and the other Member States of its decision to restrict free movement due to incorrect affixing of the CE marking, and of its action against the person who has affixed the CE marking to a non-compliant PPE. No detailed evidence to justify the action is necessary, and no consultations regarding the national measures, as envisaged for the safeguard clause, take place. However, the Commission can take action under Article 226 of the EC Treaty should it consider necessary.

Member States do not have any obligation under the PPE Directive to inform about restrictions on PPE not in conformity and if not CE marked.

4. The Commission shall ensure that the Member States are kept informed of the progress and results of the procedure provided for in this Article.

According to paragraph 4 the Commission is required to inform the Member States on the details of ongoing procedures and results of safeguard notifications.

1.2 CHAPTER II - CERTIFICATION PROCEDURES

1.2.1 Article 8

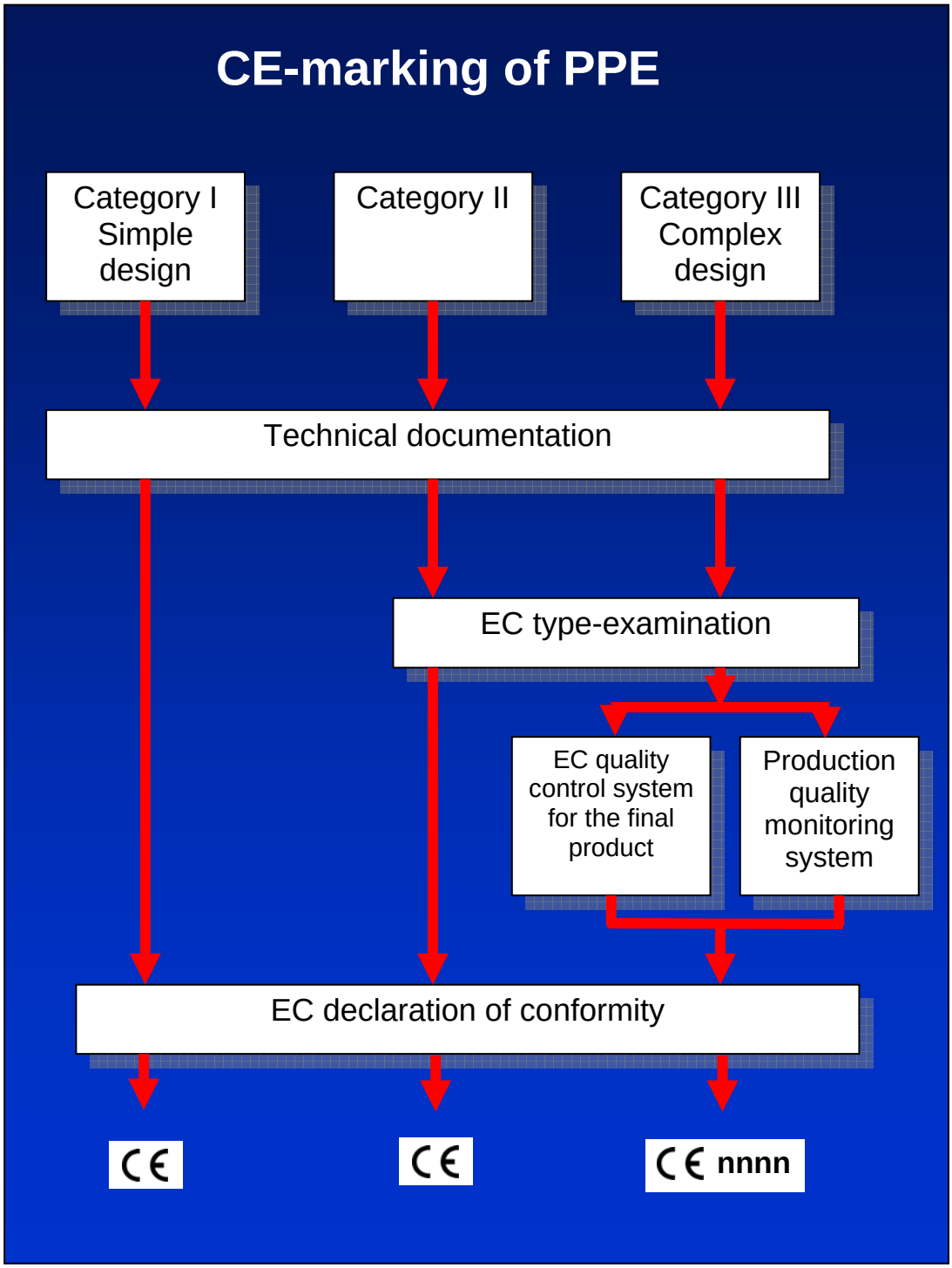
Article 8 brings together PPE covered by the Directive into three distinct groups and their relevant conformity assessment procedures. These are named in the Directive as “Simple design”, “Complex design” and neither of these, the last being a third Category. Whilst the Directive does not explicitly define these three groups as Categories, it is common practice to use the terms category I, II and III respectively.

The categories are:

- Category I (“simple design”): the PPE defined by the exhaustive list at Article 8(3). The manufacturer declares conformity by means of an EC declaration of conformity only;

- Category II (neither simple nor complex): PPE not defined by Article 8(3) & (4)(a) are subject to an EC-type examination by a Notified Body and an EC declaration of conformity is then produced;

- Category III (so-called “complex design”): the PPE defined by the exhaustive list at Article 8 (4)(a) are subjected to EC-type examination (see Article 8 (2)) and to one of the two Quality Assurance procedures as described at Article 11A and 11B. And an EC declaration of conformity is then produced.


CE-marking of PPE
Category I
Simple
design
Category II
Category III
Complex
design
Technical documentation
EC type-examination
EC quality
control system
for the final
product
Production
quality
monitoring
system
EC declaration of conformity
CE
CE
CE nnnn

The Guide on the categorisation of PPE (Appendix) clarifies the principles of categorisation as well as providing information on borderline cases and exclusions listed at Annex I of the Directive). This is the outcome of discussion with Member States.

1. Before placing a PPE model on the market, the manufacturer or his authorised representative established in the Community shall assemble the technical documentation referred to in Annex III so that this can, if necessary, be submitted to the competent authorities.

The manufacturer or his authorised representative established in the Community has the obligation to put together technical documentation whatever the category of PPE. The content of this documentation is prescribed at Annex III.

2. Prior to the series production of PPE other than those referred to in paragraph 3, the manufacturer or his authorized representative established in the Community shall submit a model for EC type-examination as referred to in Article 10.

The manufacturer, who can be located outside the Community, or an authorised representative, who must be located in the Community, are the only two entities that can make an application for an EC-type examination by a Notified Body.

Before serial production starts[19], the model of the PPE (type) has to be submitted for an EC-type examination. Exceptions are pre-prototypes and research prototypes.

Only one application per product can be made to a single Notified Body.

There have been a number of questions over the past years on how to apply the Directive to variants (including those adapted to the wearer) of a "model". In general, in such cases it is accepted that the following needs to be considered:

- A PPE is considered as a variant of a "model" PPE only if it differs on points that have no noticeable influence on the expected protective performances. In certain cases the variance may be differences relating in particular to marking, dimensions, sizing, shape, nature of constituent materials, colour, assembly methods, addition or removal of an accessory support, manufacturing processes, etc. However in other cases these differences will have an influence on the protective performance, therefore careful assessment has to be made by the manufacturer in collaboration with the Notified Body.
- It is the responsibility of the Notified Body, on its own authority, to evaluate in each case if a given PPE can be considered as a variant. In every case and for each of the variants identified, the applicant will provide the Notified Body with a detailed description indicating the differences in comparison with the reference model and the number of samples of the variants required for complementary checks and tests;

- PPE adapted to the wearer are those PPE that have to be adapted to a specific intended user to ensure perfect fit and functionality. This means that these PPE are unique pieces. Examples include orthopaedic shoes and mouth guards.

[19] The reader will want to be aware that the French text of the Directive is generally taken as the reference if uncertainty arises in translation. The French version of directive 89/686/EEC does not use the term "series" and as such it is generally recognised that any PPE, even if produced as a single unit, is required to be in compliance with the provisions of the Directive prior to its placing on the market and/ or putting into service.

- In the case of PPE adapted to the wearer, the manufacturer submits details of the construction process in the technical documentation together with the prototype. The Notified Body will need to assess these and the manufacturer will have to use the same construction process for each individual PPE produced according to this prototype;

- The Notified Body is free to decide whether it will grant extensions to existing EC-type examination certificates or if it prefers to issue a new EC-type examination certificate for the variant to be certified. This is only reasonable given that the Body issues its reports and certificates on its own authority and responsibility.

A typical example of a PPE where the above procedure might be relevant is protective glasses with corrective lenses.

3. EC type-examination shall not be required in the case of PPE models of simple design where the designer assumes the user can himself assess the level of protection provided against the minimal risks concerned the effects of which, when they are gradual, can be safely identified by the user in good time.

This category shall cover exclusively PPE intended to protect the wearer against:
- mechanical action whose effects are superficial (gardening gloves, thimbles, etc.),
- cleaning materials of weak action and easily reversible effects (gloves affording protection against diluted detergent solutions, etc.),
- risks encountered in the handling of hot components which do not expose the user to a temperature exceeding 50°C or to dangerous impacts (gloves, aprons for professional use, etc.),
- atmospheric agents of a neither exceptional nor extreme nature (headgear, seasonal clothing, footwear, etc.),
- minor impacts and vibrations which do not affect vital areas of the body and whose effects cannot cause irreversible lesions (light anti-scalping helmets, gloves, light footwear, etc.),
- sunlight (sunglasses).

This list is exhaustive and describes the PPE commonly referred to as “Category I”.

The manufacturer of PPE falling in the above Category has to establish his technical documentation.

If he does not have the required test facilities or expertise he can of course seek for such advice or facilities but he cannot request, for example, an EC-type examination. Even if third parties are involved in the conformity assessment process the manufacturer takes full responsibility for the compliance of the PPE.

Since the Directive has been applied a number of questions have arisen in order to clarify when PPE falls into this or the higher category.

It is clear that in all cases the manufacturer will need to assess the level of risk that the intended user will be protected against. Evidently if the risk is more severe than those listed the PPE must be considered as falling into a higher Category. This risk assessment is fundamental to the correct Categorisation of the PPE and hence the smooth application of the provisions of the Directive.

For example, the protection against sunlight is considered to be against indirect solar radiation. This is related to eye protectors and filters without corrective effect designed and manufactured exclusively to provide protection against indirect solar radiation (sunglasses).

However, if they are intended to provide additional protection such as against mechanical risks, splashes, molten metal, dust particles, they may be more correctly placed in a higher category. It is accepted that PPE for direct observation of the sun (e.g. sun eclipses) or against radiation from artificial light sources such as those used in solaria also belong to a higher category.

4. Production of PPE shall be subject:

a. according to the manufacturer's choice, to one of the two procedures referred to in Article 11 in the case of PPE of complex design intended to protect against mortal danger or against dangers that may seriously and irreversibly harm the health, the immediate effects of which the designer assumes the user cannot identify in sufficient time. This category shall cover exclusively:

- filtering respiratory devices for protection against solid and liquid aerosols or irritant, dangerous, toxic or radiotoxic gases;

- respiratory protection devices providing full insulation from the atmosphere, including those for use in diving;

- PPE providing only limited protection against chemical attack or against ionizing radiation;

- emergency equipment for use in high-temperature environments the effects of which are comparable to those of an air temperature of 100°C or more and which may or may not be characterized by the presence of infra-red radiation, flames or the projection of large amounts of molten material;

- emergency equipment for use in low-temperature environments the effects of which are comparable to those of an air temperature of -50°C or less;

- PPE to protect against falls from a height;

- PPE against electrical risks and dangerous voltages or that used as insulation in high-tension work.

This list of products is exhaustive and describes PPE commonly known as complex design (category III).

For “respiratory protection devices providing full insulation from the atmosphere” it is understood that the full insulation is only related to the respiratory system of the user, not to the full body of the user.

“PPE providing only limited protection against chemical attack or against ionizing radiation” needs to be understood that throughout the duration of the permeation, the chemical does not cross the material and provides 100% protection. However, the protection is limited in time. This means that this type of PPE can only be used for defined time periods as intended by the manufacturer and prescribed in the instructions for safe use.

The risks related to exposure to heat or cold are related to effects comparable with air temperature. Scientific literature describes that an air temperature of 100°C will result in second degree burn injuries in less than fifteen seconds, therefore the fifteen second time limit for second degree burn injuries is a good criterion to decide whether a PPE protecting against heat is category III PPE or not. In a similar way it is clear that the effects of –50° C are to be seen in calm air (wind speed of max. 5 km/h). These conditions can result in frostbite of the exposed surface in less than two minutes. In conditions where there is a lot of wind this effect can be reached at less extreme temperatures. Again this criterion (frostbite in less than two minutes) can be used to determine whether a PPE protecting against cold is category III or not.

It also needs to be clarified that emergency should understood in its broadest sense, since any risk of this nature may be regarded as an emergency. Examples of this type of PPE are garments designed to protect fire-fighters against the radiated heat or garments intended for use at iron melting installations.

PPE protecting against falls from a height are category III, if they designed to allow working at a height as well as to support the wearer in case of a fall. An example is equipment used by repair workers on pylons. Equipment to assist in (rock) climbing is another example. However, equipment allowing access or departure of a position at height and equipment specific to parachutes or paragliding are not considered as PPE since their primary function is not to protect the wearer but to allow the wearer to perform the desired action.

For PPE against electrical risks, it is commonly understood that voltages of less than 50V AC or 75V DC are not normally considered dangerous.

b. the EC declaration of conformity referred to in Article 12 for all PPE.

The EC declaration of conformity must be written taking into account the category of the PPE. (see annex VI).

The completion of the EC declaration of conformity and its signature is one of the last actions in any of the conformity assessment procedures, and can be completed in any of the official languages of the Community.

1.2.2 Article 9

1. Member States shall notify the Commission and the other Member States of the bodies which they have appointed to carry out the procedures referred to in Article 8 together with the specific tasks which these bodies have been appointed to carry out and the identification numbers assigned to them beforehand by the Commission.

The Commission shall publish in the Official Journal of the European Communities a list of the notified bodies and their identification numbers and the tasks for which they have been notified. The Commission shall ensure that this list is kept up to date.

Member States are solely responsible for the designation of Notified Bodies and their notification to the European Commission. National Authorities are also responsible for verifying at intervals that Notified Bodies fulfil the requirements in Annex V.

This notification includes the relevant field of competence for which that Body has been designated. Notified Bodies can be notified only for where a third party is required for the conformity assessment procedure(s) (PPE in category II or III). Member States are free to notify a Body at any time after the directive has been adopted.

The Commission obligation is to publish a list of Notified Bodies in the Official Journal of the European Union and to allocate an identification number to the Body. Each Body receives a single number irrespective of the number of directives for which it is notified.

A manufacturer always has the choice of contacting any Body with the appropriate scope of technical competence, which has been notified by a Member State. However the manufacturer may only make one application for an EC-type examination to a single Body.

Notified Bodies should not offer or provide consultancy services or advice to manufacturers in what refers to the design, construction, marketing or maintenance of PPE for which it is involved in the conformity assessment procedure.

The list of Notified Bodies in the field of PPE can be viewed at:
http://ec.europa.eu/enterprise/mechan_equipment/ppe/nb.htm
http://ec.europa.eu/enterprise/nando-is/home/index.cfm

2. Member States shall apply the criteria laid down in Annex V in assessing the bodies to be indicated in such notification. Bodies meeting the assessment criteria laid down in the relevant harmonized standards shall be presumed to fulfil those criteria.

The evaluation of the competence of Notified Bodies is the sole responsibility of the Member States. However they may only choose the bodies which comply with the minimum requirements in Annex V. The Body shall be technically competent and capable of carrying out the conformity assessment procedures in question and it shall have the necessary level of independence, impartiality and integrity.

3. A Member State shall withdraw its approval from such a body if it establishes that the latter no longer satisfies the criteria referred to in Annex V. It shall inform the Commission and the other Member States of its action forthwith.

Each Member State has the responsibility to ensure that the bodies which it has notified continue to meet the requirements at Annex V. Moreover, the Member State has the obligation to inform the Commission and the other Member States of any decision to withdraw the notification. This can be the case, for example, where the Notified Body no longer provides such conformity assessment services.

EC TYPE-EXAMINATION

1.2.3 Article 10

1. EC type-examination is the procedure whereby the approved inspection body establishes and certifies that the PPE model in question satisfies the relevant provisions of this Directive.

The responsibility of the Notified Body which carries out the EC-type examination is solely to ascertain whether or not the PPE model satisfies the requirements of the present Directive which are applicable to that type of PPE.

2. Application for EC type-examination shall be made by the manufacturer or his authorized representative to a single approved inspection body in respect of the model in question. The authorized representative shall be established in the Community.

As noted above only a single application for an EC-type examination can be made to a single Notified Body.

The Notified Body has no means of verifying that only one application has been submitted. For this reason most Notified Bodies require a sworn declaration whereby the manufacturer or his authorised representative in the Community attest, that he has only submitted one application.

3. The application shall comprise:

- the name and address of the manufacturer or his authorized representative and of the PPE production plant in question;

- the manufacturer s technical file referred to in Annex III.

It shall be accompanied by the appropriate number of specimens of the model to be approved.

The indication of the production plant, which must be included in the application, is of minor importance in the context of EC-type examination. However, this information is necessary to initiate supervision of the manufacture of Category III PPE (see Article 11). If the production plant is changed, the manufacturer should inform the Notified Body so that the technical file can be up-dated. The change of the production plant may have an effect on the control and test facilities.

The number of specimens accompanying the application is defined by agreement with the Body, which shall preferably be guided by the standards. If there is insufficient information in the relevant standards, recommendations may be available from the European Coordination Group of Notified Bodies.

The manufacturer’s technical file has to be included in the application the contents of which are defined in point 1 of Annex III. It is a key element for assessing the conformity of the product to the BHSRs which apply to it.

It may be useful for the purpose of the market surveillance to divide the technical file as follows:

The first part consisting of the essential technical data useful for assessing conformity, including:

- the name and address of the manufacturer and the identification of the product;

- a list of the European harmonised standards which have been followed and/or the solutions which have been adopted in order to meet the BHSRs;

- a description of the product;

- a draft for information supplied by the manufacturer.

  The information notice mentioned in Annex III (Information to be supplied by the manufacturer, Annex II, 1.4) forms part of the technical documentation to be prepared by the manufacturer, and there is no reference to it in the technical file. However, it is strongly advised that this be included in the technical file. In effect, the information notice is essential to provide information on the proposed conditions of use for the relevant PPE, restrictions on use, etc., in other words, how the PPE can be used and above all, the circumstances in which it should not be used. This information is therefore indispensable;

- a schematic plan of the product, where applicable.

The second part of the file is required particularly for Category III PPE (see Article 11B). It consists of a complete file containing all the test reports, information concerning the quality manual, plans, descriptions of the products and the manufacturing processes, the quality management system standards applied, etc.

If this division of the file is not undertaken by the manufacturer, the authorities could ask for the whole technical file since it would be difficult for the manufacturer to separate the information requested from the complete file in a timely manner.

4. The inspection body of which notification has been given shall conduct the EC type-examination in accordance with the under-mentioned procedures:

(a) Examination of the manufacturer's technical file

It shall examine the manufacturer's technical file to establish its suitability with respect to the harmonized standards referred to in Article 5.

Where a manufacturer has not applied, or has only partly applied, the harmonized standards or where there are no such standards, the body of which notification has been given must check the suitability of the technical specifications used by the manufacturer with respect to the basic requirements before examining the manufacturer's technical file to establish its suitability with respect to these technical specifications.

The aim of the legislator is that all the BHSRs applicable to the PPE are met, either by voluntary implementation of the European harmonised standards and/or by other means. During verification of the file, the Notified Body must verify that all the relevant applicable BHSRs to the PPE are met and referred to in the manufacturer's tehnical file.

(b) Examination of the model

When examining the model, the inspection body shall verify that it has been produced in accordance with the manufacturer's technical file and can be used in complete safety for its intended purpose.

It shall conduct the necessary examinations and tests to establish the conformity of the model with the harmonized standards.

Where a manufacturer has not applied or has only partly applied the harmonized standards or where there are no such standards the body of which notification has been given shall conduct the necessary examinations and tests to establish the conformity of the model with the technical specifications used by the manufacturer, subject to their being suitable with respect to these basic requirements.

The information to be supplied by the manufacturer must specify the intended use of the PPE and the risks covered. It is up to the manufacturer to indicate clearly the areas of use and the nature and scale of the risks to be covered. As already stated, it is important that the Body has access to the information given by the manufacturer in order to verify that the specifications indicated by the manufacturer really cover the BHSRs applicable to the PPE concerned.

Verification by the Notified Body of the effectiveness of the protection offered by the PPE assumes concrete knowledge of the dangerous situations inherent in its intended use as declared in the manufacturer's information, and of the acknowledged state of the art at that moment. Thus, the EC-type examination carried out by the Notified Body goes beyond simply applying the test resources specified in the relevant European harmonised standards and noting that the test results are in conformity with the levels of performance required by those standards. The fact that the transposed European harmonised standard is regarded as supporting the presumption of conformity does not relieve the manufacturer of his responsibility to design and manufacture PPE which meets the current state of the art, nor does it authorise the Notified Body to refuse to carry out an EC-type examination of a PPE which meets the current state of the art on the grounds that it would be different from the state of the art considered by the transposed European harmonised standard.

The BHSRs referred to in the third indent are those relevant requirements of the Directive which are applicable to the PPE in accordance with the foreseeable use. This paragraph allows the manufacturer to innovate by offering a PPE of radically new design, or having characteristics and levels of performance which offer a greater degree of safety than those envisioned in the European harmonised standards. It requires the Notified Body to demonstrate flexibility whilst at the same time, through its competence and expertise, ensuring that the PPE conforms to the regulations. The EC-type examination and testing of the PPE itself which follows examination of the file, is therefore the procedure which, enables the Notified Body to verify the conformity of the PPE with the provisions of the Directive.

5. If the model satisfies the relevant provisions, the inspection body shall draw up an EC type-examination certificate and shall notify the applicant to this effect. This certificate shall reproduce the findings of the examination, indicate any conditions attaching to its issue and incorporate the descriptions and drawings necessary for the identification of the approved model.

The Commission, the other approved inspection bodies and the other Member States may obtain a copy of the certificate and, in response to a reasoned request, a copy of the manufacturer s technical file and the reports of the examinations and tests conducted.

The file shall be held at the disposal of the competent authorities for 10 years following the placing of the PPE on the market.

If the PPE fulfils all the applicable BHSRs, the Notified Body must issue an EC-type examination certificate to the manufacturer. The issued certificate is only valid to the manufacturer whose name is on the product. If anyone else affixes his own brand labelling to

the product he becomes a manufacturer and shall make the application to the Notified Body for a new EC-type examination certificate.

The Notified Body may have made an agreement with the certificate holder that the certificate is granted for a limited period of time.

The fact that the EC-type examination certificate includes the descriptions and drawings necessary for identifying the model implies that the manufacturer's technical file includes this information and that the Body has verified it before including it in the certificate.

It is worth noting that a copy of the certificate can be obtained by the persons specified by the Directive without any conditions, whereas the technical file can only be obtained by means of a reasoned request, e.g. when there is a need to investigate accidents or on the grounds that information is being sought which is required for monitoring conformity to the BHSRs of the Directive.

The placing on the market referred to in the final sub-section of this paragraph is of course the final placing on the market of items which are in conformity with the model for which the certification has been granted. For example, if the PPE is in production for 5 years, the file must be archived for at least 15 years.

6. Any inspection body which refuses to issue an EC type-examination certificate shall inform the other approved inspection bodies of this fact. An inspection body withdrawing an EC type-examination certificate shall inform the Member State which approved it, to this effect. That Member State shall then inform the other Member States and the Commission, setting out the reasons for the decision.

Where the Notified Body selected by the manufacturer establishes that the model submitted does not conform to the BHSRs applicable to it, it must refuse to issue an EC-type examination certificate, the format not being specified. Before taking such a decision, which would severely penalise the manufacturer, the Notified Body notifies the manufacturer of its intention and the grounds thereof.

A refusal is not issued unless a definitive impasse is reached. To avoid any legal dispute with the manufacturer, this refusal must indicate the conclusions of the examination, specifying the essential requirements which have not been met. All other Notified Bodies must be informed of any decision to refuse certification, one aim being to prevent a second submission of the same PPE to another Notified Body. To avoid unnecessary distribution, the list of Notified Bodies who receive notification of a refusal could be restricted to those which have been notified for this particular type of PPE, using the lists published in the Official Journal of the European Union as a guide.

An EC-type examination certificate can only be withdrawn by the Notified Body which issued it. The decision to withdraw the certificate derives from the discovery of non-conformity to the model of the PPE concerned. Non-conformity may be due to an error by the Notified Body during the EC-type examination, either in the application of the Directive or in the conduct of the tests. It may also result from a modification, which the manufacturer has decided upon for whatever reason, which calls into question the conformity of specimens wrongly deemed to be in conformity to the model. The Body must inform the notifying authorities to which it is responsible of the grounds justifying its decision to withdraw an EC-type examination certificate and must be prepared to provide any clarification which may be

necessary. This will enable the notifying authority to inform the other Member States and the European Commission giving the reason for this decision as foreseen under this paragraph.

CHECKING OF PPE MANUFACTURED

1.2.4 Article 11

It should be recalled that the monitoring of manufactured PPE as defined in this Article relates only to Category III PPE referred to in Article 8, paragraph 4 (a), and that the manufacturer can choose between checks on the final product described in Article 11A and monitoring of production with supervision as described in Article 11B.

A. EC quality control system for the final product

1. A manufacturer shall take all steps necessary to ensure that the manufacturing process, including the final inspection of PPE and tests, ensures the homogeneity of production and the conformity of PPE with the type described in the EC type-approval certificate and with the relevant basic requirements of this Directive.

A manufacturer who has chosen the procedure involving checks on the final product must set up an internal system for monitoring production and must select a Notified Body that will be responsible for verifying the homogeneity of the production, the conformity with the certified type and with the BHSRs. Very often a manufacturer will apply the CE marking in an operation which is integrated into the manufacturing process. Since he cannot anticipate the decision of the Notified Body and since the identification number of that Body must appear in the marking, it is in the manufacturer's interest that the Body chosen for the final checks should be involved from the time the first items are produced.

Nevertheless, it should be highlighted that the EC-type examination certificate must be issued to the manufacturer that has applied for the quality control system laid down in this Article. This also applies to manufacturers that have own-brand label EC-type examination certificates.

A manufacturer cannot place on the market or bring into service any Category III PPE without having received the test report of the Notified Body which he has chosen for inspection of the final product indicating that the production is homogenous and the PPE is in accordance with the certified type.

2. A body of which notification has been given, chosen by a manufacturer, shall carry out the necessary checks. Those checks shall be carried out at random, normally at intervals of at least one year.

The manufacturer selects a Notified Body to carry out the necessary PPE checks. The manufacturer may select different Notified Bodies for different PPE manufactured on the same production equipment or for identical PPE manufactured at different, non-adjacent sites.

The Body carrying out these checks can be different from the one that has issued the EC-type examination certificate.

The term "random" implies that it is the Notified Body which decides the time, place and the nature of the checks and who is responsible for selecting the PPE to be checked.

The checks must be carried out at a minimum of one per year, starting from the date of initial certificate issue.

3. An adequate sample of PPE taken by the body of which notification has been given shall be examined and appropriate tests defined in the harmonized standards or necessary to show conformity to the basic requirements of this Directive shall be carried out to check the conformity of PPE.

The Notified Body has full latitude to define an “adequate sample”; it shall be guided by the European harmonised standards which define the tests, and in the absence of such standards it can make use of the work of the European Coordination Group of Notified Bodies or define test methods with the manufacturer which will enable it to judge the conformity of the PPE produced. In practice, the Body carries out checks on those properties of the PPE which effectively determine its suitability for its “safety” function, but is never required to repeat an EC-type examination.

Before the CE marking can be applied to PPE to be covered by this Article, the manufacturer, as a minimum, must have entered into an agreement with a Notified Body for the administration of this Article. The necessary checks shall include both A and B:

A.

Selection of product samples by the Notified Body, or an independent representative of the Body. Selection shall be made at a location agreed between the Notified Body and manufacturer.

The samples shall be randomly selected and be representative of the certified type. The samples shall be examined by the Notified Body to confirm that the manufactured PPE is as EC-type examined and remain in conformity with the standard or specification referenced on the corresponding valid EC-type examination certificate.

AND

B.

The Notified Body shall identify any instances of production not being homogeneous by one of the following:

(i). Once per year, carry out on-site review of company production and test records. Review to take place where at least the final assembly of PPE is carried out.

(ii). Once per year, carry out an on-site audit of the production control. This audit to take place where at least the final assembly of PPE is carried out.

(iii). Once per year, take sufficient samples to conduct statistical analysis of production homogeneity.

(iv). Select samples throughout the year, each sample smaller in size the in (iii), based upon production information supplied by the manufacturer, to assess production homogeneity.

If the results of the checks are satisfactory, the Body concludes that the manufactured PPE is in conformity.

4. Where a body is not the body that issued the relevant EC type-approval certificate it shall contact the body of which notification has been given in the event of difficulties in connection with the assessment of the conformity of samples.

Sharing of information between the Notified Bodies used by a manufacturer is confidential, and arises where there is difficulty in assessing the conformity of samples. The aim is to determine the causes of any discrepancy between the results obtained on the model and those obtained from sampling. It may be the result, for example, of a variation in the manufacturing process between the model and the test specimens, variability in the characteristics of the component materials, a discrepancy in the reference materials (between those used during the procedure described in Article 10 and those used during checks on the manufactured PPE) where the test method requires the use of such materials. It may also result from a difference between the test methods of the Notified Body selected for the Article 10 procedure and the Body selected for the Article 11A procedure.

5. The body of which notification has been given shall provide the manufacturer with a test report. If the report concludes that production is not homogeneous or that the PPE examined do not conform to the type described in the EC type-approval certificate or the relevant basic requirements, the body shall take measures appropriate to the nature of the fault or faults recorded and inform the Member State which gave notification thereof accordingly.

Following the inspection the Body gives the manufacturer an expert report from which it is possible to conclude, in view of the test results, whether or not there is any sign of non-homogeneity in the manufacturing process and whether or not the PPE examined conforms to the type described in the EC-type examination certificate.

In cases of non-homogeneity or non-conformity of PPE the Body is required to inform the Member State of the appropriate measures which it has taken on the basis of the nature of the defects found; these measures may be in the form of a further sampling, the introduction of corrective measures which may include halting production, or even informing the Notified Body that has issued the EC-type examination certificate of the defects found on the basis of which Body might consider to withdraw the relevant certificate.

6. The manufacturer must be able to present, on request, the report of the body of which notification has been given.

This report should be made available only to the market surveillance authorities who are responsible for implementing the Directive and/or monitoring the market and who request it. This report can be requested from the time the PPE is first placed on the market. Subsequent reports should be kept on file by both the manufacturer and the Body.

B. System for ensuring EC quality of production by means of monitoring

The EC quality system of the production adopted by the manufacturer guarantees that, the manufactured products are homogenous and in accordance with the certified type.

The Article 11B procedure may be satisfied if the quality assurance system specified in EN ISO 9001:2000, excluding the clauses mentioned in the foreword, are used.

The minimum requirements to be addressed by an 11B system and covered during assessments by Notified Bodies include the following:

- Quality policy / Responsibility authority / Management representative / Management review / Quality planning /

- Document control / Customer supplied product / Production control / Product identification /

- Inspection and testing / Inspection, measuring and test equipment / Inspection and test status /

- Control of nonconforming product / Corrective action /

- Handling, storage, packaging, preservation and delivery / Quality records / Internal quality audits /
- Training.

Generally the manual submitted in support of an application will be a policy document, which will outline the systems operated, and reference the on-site detailed procedures.

1. The system

(a) Under this procedure the manufacturer submits an application for the approval of his quality-control system to a body of which notification has been given, of his choice.

That application shall include:

- all the information relating to the category of PPE concerned, including, where appropriate, documentation relating to the model approved;
- documentation on the quality-control system;
- the undertaking to maintain the obligations arising from the quality-control system and to maintain its adequacy and efficiency.

The application for approval of the quality control system must contain all the information required –including the relevant EC-type examination certificate– to enable the selected Notified Body to assess the quality control system set up for the PPE referred to in Article 8 (4)(a) and described as Category III in the categorisation guide; the application should indicate the manufacturing location(s), as the assessment includes periodic audits on site. All of the elements necessary to fully comply with 11B need to be objectively witnessed on site during the assessment process. The term "category" used in this paragraph should be taken to mean the class or type of PPE within the meaning of Part 2 of Annex II. The application for approval of the quality control system must indicate the model(s) of PPE to be taken into consideration.

The third indent relating to the manufacturer's commitment sets out the obligations incumbent on him under the quality control system. These obligations are defined in the EN ISO 9001 as indicated above. This third indent requires the manufacturer to inform the selected Body of any changes he makes to this system, as and when they are introduced (see Article 11B, paragraph 1, sub-paragraph d).

(b) Under the quality-control system, each PPE shall be examined and the appropriate tests referred to in Section A paragraph 3 shall be carried out to check their conformity to the relevant basic requirements of this Directive.

The documentation on the quality-control system shall in particular include an adequate description of:

- the quality objectives, the organization chart, the responsibilities of executives and their powers in respect of product quality, the checks and tests which must be carried out after manufacture;

- the means to be employed to check the efficient operation of the quality-control system.

The phrase "each PPE" means "each type of PPE" and implies that the application may relate to several types of PPE. The text requires that the procedure in Article 11A, paragraph 3 be included in the quality control system. Given that the quality control system concerns the manufacturer's internal monitoring procedures, it should be understood here that the procedure in Article 11A, paragraph 3 is conducted by the manufacturer's internal monitoring service on a random sample.

The definition of the documentation to be submitted contained in this paragraph provides clarification of the manufacturer's obligations deriving from his quality control system. This system requires him to define the responsibilities of his management and his services, and the objectives of the system (in this case maintaining the conformity of the PPE produced with the certified type). The manufacturer needs to provide documents (amongst others) defining the system, purchases, and the identification and traceability of products entering the system are to be monitored. He must also define product parameters which cannot be checked on the final product, corrective measures and maintenance, storage, packing and delivery operations. The system may also indicate how to deal with complaints submitted to the after-sales service, organise internal audits and provide training. All these conditions are essential to ensure the effectiveness of the quality control system.[20]

(c) The body shall assess the quality-control system to determine whether it satisfies the provisions referred to in paragraph 1 (b). It shall assume that quality-control systems applying the relevant harmonized standard satisfy those provisions.

The body carrying out audits shall make all necessary objective evaluations of the components of the quality-control system and shall check in particular whether the system ensures conformity of PPE manufactured with the approved model.

The decision shall be communicated to the manufacturer. It shall include the conclusions of the check and the reasoned assessment decision.

The Notified Body is responsible for assessing the manufacturer's quality control system. The main obligation of the Notified Body is to satisfy itself that the manufacturer's quality control system fulfils the objectives which he has set himself, namely, for each type of PPE, to ensure the conformity of the PPE produced to the approved model, and to satisfy itself that the tests defined in Article 11.B.1.(b) have been conducted by the manufacturer according to the specified procedures and that the results were in conformity.

The assessment is done by means of an audit, which implies that the Notified Body has access to the elements identified in the QA system in order to satisfy itself that these conform

[20] For further information please read standard ISO EN 9001:2000

to the system being applied. If the Body has not requested any corrective measures, the approval of the system is valid for such a time as it is not modified. If the Notified Body requests corrective measures, it is free to verify their implementation at the end of the specified period and to approve the system if appropriate.

The audit team must include at least the following:
- experience and knowledge of the relevant quality system requirements (e.g. ISO 9001:2000) and the product technology concerned,
- knowledge of the EC-type examination certificate(s) which are applicable to the scope of the assessment
- access to and knowledge of the applicable Recommendation for Use sheets of the Coordination of Notified Bodies
- knowledge of the status of the standards applicable to the scope of the assessment (amendments, revisions, drafts, final drafts etc.)

The audit team can comprise a single person with the required knowledge skills etc. or a number of different people making up a team.

The decision which the Body notifies to the manufacturer must list the product groups and specifications applied included in the quality control system which have been taken into consideration in the assessment and must indicate the conclusions of the check.

(d) The manufacturer shall inform the body which approved the quality-control system of any plan to alter the quality-control system.

The body shall examine the proposed changes and decide whether the altered quality-control system satisfies the relevant provisions. It shall communicate its decision to the manufacturer. The communication shall include the conclusions of the check and the reasoned assessment decision.

Any proposal for a change in the system, however minimal, must be reported by the manufacturer to the Notified Body.

Any assessment following changes to a previously approved system must be limited to the relevant modifications.

If the modified system is judged to meet the requirements of the Directive, the notification containing the decision which is issued shall remain valid until the next modification.

2. Supervision

(a) The purpose of supervision is to ensure that a manufacturer correctly fulfils the obligations arising from the approved quality control system.

Supervision is the responsibility of the Notified Body. Its aim is to ensure that the objectives of the manufacturer's quality control system are achieved and are maintained over time.

(b) The manufacturer shall authorize the body to have access, for purposes of inspection, to PPE inspection, testing and storage sites and shall provide the body with all requisite information, in particular:

- documentation on the quality-control system;

- technical documentation;
- quality control manuals.

The purpose of the manufacturer's obligations as specified here is to enable the Body to carry out the inspection required in order to assess the conformity of the quality control system. The Notified Body is responsible for monitoring the production locations indicated in the manufacturer's application.

It should be recalled that:

- the contents of the documentation of the quality control system is defined by Article 11B, paragraph 1, sub-paragraph b;
- the contents of the technical documentation are specified in Annex III.

The quality manuals must be designed and kept permanently up to date by the manufacturer so that the objectives of the quality control system are attained. These manuals must make it possible to satisfy the quality control criteria of EN ISO 9001 with the permitted exclusions mentioned in the foreword or its equivalent.

(c) The body shall periodically carry out audits to ensure that the manufacturer is maintaining and applying the approved quality control system and shall provide the manufacturer with a copy of the audit report.

This Article does not specify the frequency of audit. By analogy with the Article 11A procedure one would expect there to be at least one audit a year. The Body is free to set the date for the audit. In addition, it is advisable to reassess the system every 3 years.

(d) In addition, the body may make unannounced visits to the manufacturer. In the course of such visits the body shall provide the manufacturer with a report of the visit and, if appropriate, with an audit report.

This procedure, which can be applied for example in the case of verification of the implementation of corrective measures requested during an audit, is additional to the normal procedure described in the preceding point and extends the access permission granted by the manufacturer (Article 11 B.2.(b)) to the Body.

(e) The manufacturer must be able to present, on request, the report of the body of which notification has been given.

This report should be made available only to the market surveillance authorities who are responsible for implementing the Directive and/or monitoring the market. This report may be requested from the time the product is first placed on the market.

EC DECLARATION OF PRODUCTION CONFORMITY

1.2.5 Article 12

The EC declaration of conformity is the procedure whereby the manufacturer or his authorized representative established within the Community:

1. draws up a declaration using the form laid down in Annex VI certifying that the PPE placed on the market are in conformity with the provisions of this Directive with a view to its submission to the competent authorities;

2. affixes the CE marking of conformity provided for by Article 13 to each PPE.

The EC declaration of conformity is the procedure by which the manufacturer, or his authorised representative established in the Community, declares using the form laid down in Annex VI that the PPE being placed on the market complies with all relevant provisions prescribed by the Directive. Although the written EC declaration of conformity does not accompany each individual PPE, it should be made available to market surveillance authorities on demand.

Signing the EC declaration of conformity authorises the manufacturer, or his authorised representative established in the Community, to affix the CE marking of conformity prescribed by Article 13 and Annex IV to each PPE. Once affixed to a PPE, the manufacturer or his authorised representative attests that the appropriate conformity assessment procedures have been completed in accordance with all the provisions of this Directive.

1.3 CHAPTER III - CE MARKING

1.3.1 Article 13

1. The CE conformity marking shall consist of the initials CE in the form shown in the specimen in Annex IV. In the event of the involvement of a notified body in the production control phase as indicated in Article 11, its identification number shall be added.

2. The CE marking must be affixed to each piece of manufactured PPE so as to be visible, legible and indelible throughout the expected life of the PPE; however, if this is not possible in view of the characteristics of the product, the CE marking may be affixed to the packaging.

3. The affixing of markings on the PPE which are likely to deceive third parties as to the meaning and form of the CE marking shall be prohibited. Any other marking may be affixed to the PPE or its packaging provided that the visibility and legibility of the CE marking is not thereby reduced.

4. Without prejudice to Article 7:

(a) where a Member State establishes that the CE marking has been affixed unduly, the manufacturer or his authorized representative established within the Community shall be obliged to make the product conform as regards the provisions concerning the CE marking and to end the infringement under the conditions imposed by the Member State;

(b) where non-conformity continues, the Member State must take all appropriate measures to restrict or prohibit the placing on the market of the product in question or to ensure that it is withdrawn
from the market in accordance with the procedures laid down in Article 7.

Personal Protective Equipment must, when placed on the market and/or put into service, bear the CE marking on the product or the packaging as required[21]. Following an amendment to the PPE Directive, it is no longer necessary to add the last two figures of the year in which the marking has been affixed. In case of category III PPE, listed in Article 8.4. (a) of the PPE Directive, the identification number of the Notified Body that intervened during the production control phase as indicated in article 11 must follow the CE marking.

The design of the CE marking is defined in Annex IV.

The CE marking shall, as a rule, be affixed to the product. However, in exceptional circumstances, the CE marking may not be placed on the product itself if conditions do not permit its affixing.

This would be justified where affixing it to the product was:

- virtually impossible,
- not achievable under reasonable technical and economic conditions,
- where the minimum dimensions of the CE marking could not be respected,
- where it could not be ensured that the CE marking was visibly, legibly and indelibly affixed.

In such cases, the CE marking has to be affixed to the smallest commercially available packaging intended for the end user.

The CE marking symbolises conformity to all provisions of the relevant directives. Therefore the affixing of other marks, such as the manufacturer's logo or a voluntary quality mark, which overlaps with and may be confused with the CE marking is prohibited.

Paragraph 4 refers to the responsibilities of the Member States with regard to surveillance of the market, in particular where the marking has been wrongly affixed. These measures are taken by the Member States without prejudice to the application of the safeguard clause.

1.4 **CHAPTER IV**

FINAL PROVISIONS

1.4.1 Article 14

Any decision taken in implementation of this Directive and leading to restrictions on the marketing of PPE shall be accompanied by a detailed explanation of the grounds on which it is based. The interested party shall be notified of the decision without delay and informed of the possibilities for appeal under the legislation in force in the Member State concerned and of the deadlines for lodging such appeals.

[21] Directive 93/68/EEC withdrew the requirement of adding the two last digits of the year in which the marking was affixed to the CE marking.

1.4.2 Article 15

The Commission shall take the necessary steps to ensure that data concerning all the relevant decisions in connection with the management of this Directive are made available.

1.4.3 Article 16

1. Before 31 December 1991, Member States shall adopt and publish the laws, regulations and administrative provisions necessary in order to comply with this Directive. They shall forthwith inform the Commission thereof.

They shall apply the measures in question with effect from 1 July 1992.

2. Furthermore, Member States shall allow, for the period until 30 June 1995, the placing on the market and putting into service on PPE in conformity with the national regulations in force in their territory on 30 June 1992.

3. Member States shall communicate to the Commission the texts of the provisions of national law which they adopt in the field governed by this Directive.

Article 16 sets out the timetable for the entry into force of the Directive.

- Adoption and publication of the national transpositions of the Directive: December 1991;

- Entry into force: 1 July 1992.

Member States were required to accept the placing on the market and putting into service of PPE which comply with the rules in force in their territory on the date of adoption of this Directive until 30 June 1995.

Member States transposed the Directive into national regulations and informed the Commission by sending a copy of the text of their provisions.[22]

1.4.4 Article 17

This Directive is addressed to the Member States.

New Approach directives are binding on Member States as to the result to be achieved but the choice of form and method of transposition is their own. However Member States must ensure that the most appropriate forms and methods of transposition are used to promote the effectiveness of the Directive so that the expected results namely, for the Personal Protective Equipment Directive, of freedom of movement and human health and safety, are achieved.

Under the Personal Protective Equipment Directive, the transposition measures are mandatory. A simple recommendation or administrative circular is not sufficient. Member

[22] See http://www.europa.eu.int/comm/enterprise/mechan_equipment/ppe/transpos.htm for references of national measures transposing directive 89/686/EEC.

States must not only repeal all contradictory national legislation but they must also ensure that more stringent measures than those foreseen by the directive are not introduced. Moreover Authorities must ascertain that the users of the legislation, e.g. manufacturers, are aware of their rights and obligations.

In certain cases, where the provisions of a directive are unconditional, the Court recognises the right of the private individual to avail himself of the provisions of a directive when this is in conflict with national legislation.

1.5 **ANNEX I**

EXHAUSTIVE LIST OF PPE CLASSES NOT COVERED BY THIS DIRECTIVE

1. PPE designed and manufactured specifically for use by the armed forces or in the maintenance of law and order (helmets, shields, etc.).

PPE designed and manufactured for military or police purposes means PPE designed exclusively for such purposes. It applies to all categories of PPE. However, PPE which can be used by military or police forces but is not specifically designed for their use is covered by the Directive. Firefighters are not considered as "armed or police forces"; the equipment they use are PPE with regard to the Directive.

Bullet-proof clothes or jackets for security guards are also not covered by the exclusion relating to the armed forces or forces of law and order and are Category II PPE.

It is permitted for a manufacturer to use the BHSRs of the Directive or relevant European harmonised standards when designing and manufacturing for military or police purposes but this PPE cannot bear the CE marking.

2. PPE for self-defence (aerosol canisters, personal deterrent weapons, etc.) .

3. PPE designed and manufactured for private use against:

- adverse atmospheric conditions (headgear, seasonal clothing, footwear, umbrellas, etc.);
- damp and water (dish-washing gloves, etc.);
- heat (gloves etc.);

PPE designed and manufactured <u>for private use</u> to provide protection against adverse atmospheric conditions, damp, water and heat does not fall under the scope of the Directive.

However PPE designed and manufactured <u>for professional use</u> to provide protection against weather conditions which are neither exceptional nor extreme **does** fall under the Directive.

4. PPE intended for the protection or rescue of persons on vessels or aircraft, not worn all the time.

This refers to PPE intended for the protection or rescue of persons on vessels or aircraft, not worn all the time i.e. emergency use. The terms "vessels and aircraft" refer exclusively to those carrying passengers and to seagoing vessels subject to the international conventions such as the International Maritime Organisation or International Civil Aviation Organisation.

.

5. Helmets and visors intended for users of two-or three-wheeled motor vehicles

1.6 **ANNEX II**

ESSENTIAL REQUIREMENTS OF HEALTH AND SAFETY

Basic Health and Safety Requirements (BHSRs) at Annex II are drafted to ensure the highest possible level of protection. In practice this means the best compromise between efficiency of protection, usability and comfort ***according to the generally acknowledged state of the art****. These requirements are to be applied in accordance with the foreseeable conditions of use. They either lay down the possible protection objectives and/ or refer to the performance of the product itself.*

Although no detailed manufacturing specifications are included in the BHSRs, their wording is aimed at being precise enough to create legally enforceable obligations, and at facilitating the drafting of mandates by the Commission to the European Standardisation Organisations in order to produce European harmonised standards.

BHSRs define the results to be attained, or the hazards to be dealt with, but do not specify or predict the technical solutions for doing so. They are also formulated so as to enable the assessment of conformity with those requirements, in the absence of European harmonised standards or in case the manufacturer chooses not to apply them.

This flexibility allows manufacturers to choose the most suitable way to meet the requirements. It also allows, for example, the materials and product design to be adapted to technological progress. Accordingly, so-called "New Approach" directives such as the PPE directive do not need regular adaptation to technical progress, since assessment of whether requirements have been met or not are based on the state of technical know-how at a given moment.

Annex II is divided into three sections:

- *General requirements applicable to all PPE;*
- *Additional requirements common to several classes or types of PPE;*
- *Additional requirements specific to particular risks.*

Therefore, in addition to the application of the general requirements, manufacturers need to clearly identify:

- *the hazards the PPE is intended to protect against in order to determine the additional BHSRs to be applied to the PPE;*
- *the foreseeable conditions of use and possible foreseeable misuse of their product.*

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 .

BHSRs set out in Annex II include all that is necessary to achieve the objective of the directive. PPE may be placed on the market and put into service only if they are in compliance with all applicable BHSRs. The guidance provided on this part of the directive has been carefully drafted to give the best possible advice to stakeholders. However, it should

always be kept in mind that as a "New Approach" Directive all technical solutions are available to the manufacturer in order to meet the relevant BHSRs to be applied to his product.

1. GENERAL REQUIREMENTS APPLICABLE TO ALL PPE

PPE must provide adequate protection against all risks encountered.

- To make sure that the protection offered by PPE is adequate against the risks encountered, the manufacturer needs to carry out a risk assessment[23] of the PPE in order to identify the intended level of protection and on the basis on the above analysis:

  - identify all applicable BHSRs;
  - design the characteristics of the components and constituent materials of PPE corresponding to these risks and additional factors such as environmental conditions, usability, tasks to be performed corresponding the foreseeable conditions of use.

1.1 Principles of design

1.1.1 Ergonomics

The PPE must be so designed and manufactured that in the foreseeable conditions of use for which it is intended the user can perform the risk-related activity normally whilst enjoying appropriate protection of the highest possible level.

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.

The operating requirements of PPE have to be evaluated simultaneously on the basis of the level of:

- 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.

1.1.2 Levels and classes of protection

1.1.2.1. Highest level of protection possible

The optimum level of protection to be taken into account in the design is that beyond which the constraints imposed by the wearing of the PPE would prevent its effective use during the period of exposure to the risk or normal performance of the activity.

This requirement introduces the principle of the best possible compromise between as high a level of protection as possible and the lowest possible level of constraint. (see 1.1.1). Nevertheless, for very specific applications, the safety of the wearer takes precedence. This is particularly the case, where according to the general recognised state of the art it is not possible to simultaneously ensure comfort and protection against high hazard levels (e.g. self rescue during an emergency situation, protection against ionising radiations, land mines removal…).

[23] This "risk assessment" should not be confused with the obligation of the employer to undertake a risk assessment with respect to ensuring that all potential hazards are either removed, reduced to a non-harmful degree or, where this is not possible, to provide the PPE to protect the employee.

Practical performance tests using test subjects can be performed to evaluate the acceptability of PPE and the feasibility of carrying out the intended activity.

1.1.2.2. Classes of protection appropriate to different levels of risk

Where differing foreseeable conditions of use are such that several levels of the same risk can be distinguished, appropriate classes of protection must be taken into account in the design of the PPE.

It is easier to indicate the nature of a risk than to quantify its level. Therefore it is difficult to define classes of protection appropriate to the levels of risks against which the PPE is intended to protect. This is why, in practice, classes of protection are generally defined by the levels of performance of one or several characteristics. These levels of performance are determined by conventional testing methods simulating the situations of risks as close as possible to the reality.

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 a number of various fields of application, in terms of both risk levels and ergonomic factors, which can not be covered by a single class of PPE.

On the other hand, 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.

Furthermore, when defining classes of protection the uncertainty of measurements attached to the test results need to be taken into account to avoid difficulties of interpretation. It is recommended that the width (the difference between the lower and upper limit value) of a protection class is clearly bigger than two times the estimated uncertainty.

1.2 Innocuousness of PPE

1.2.1 Absence of risks and other "inherent" factors of nuisance effect

PPE must be so designed and manufactured as to preclude risks and other nuisance factors under foreseeable conditions of use.

The use of PPE causes always some nuisance to the wearer. Those additional risks are not related to the risks against which they protect.

The following examples illustrate the inherent risks which can be generated by PPE:

- tight PPE preventing the evaporation of sweat and causing risk of hyperthermia, skin irritations, discomfort…;
- the slip of a harness or a safety helmet, resulting from bad design of the adjustment system;

- pockets of protective clothing allowing hot or cold products to be caught;
- PPE leading to difficulties in identifying optical or acoustical warning signals.
- the psycho-physiological constraints such as the increase of metabolic rate or fatigue.

1.2.1.1. Suitable constituent materials

PPE materials and parts, including any of their decomposition products, must not adversely affect user hygiene or health. The materials constitutive of PPE and their possible products breakdown should not have harmful effects on hygiene or health of the user.

The constituent materials cannot (in the foreseeable conditions of normal use), release or degrade to release substances generally known to be toxic, carcinogenic, mutagenic, allergenic, teratogenic or otherwise harmful.

The following list is examples of possible documents to demonstrate conformity to this requirement:

a) Information supplied by the manufacturer might 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 materials for use with food, in medical devices, or other relevant applications;
e) Test reports or other information relating to toxicological, allergenic, carcinogenic, toxic to reproduction or mutagenic investigations and measurements on the materials;
f) Information relating to eco-toxicological and other environmental investigations on the materials.

Particular attention should be paid to the presence of plasticizers, unreacted components, heavy metals, impurities and the chemical identity of pigments and dyes.

The exposure limit values of harmful substances, such as Cr(VI), Ni, Azo colorants etc. are often laid down in European or national regulations. In particular, the manufacturer may need to consider:

- Individual directives on the protection of workers from risks related to exposure to chemical, biological agents at work within the meaning of Article 16 of Directive 89/391/EEC;

- 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, annex I of this directive is an index of 8000 dangerous substances for which harmonised classification and labelling have been agreed at Community level There are currently fifteen classes of danger such as: toxic, harmful, corrosive, irritant, sensitising, carcinogenic, mutagenic, toxic for reproduction, etc considered in this directive;

- 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**.** This directive is also applicable to PPE, and is related to the nickel release from those parts of PPE containing Nickel that come into direct and prolonged contact with the skin. (E.g. metallic spectacle frames).

1.2.1.2. Satisfactory surface condition of all PPE parts in contact with the user

Any PPE part in contact or in potential contact with the user when such equipment is worn must be free of roughness, sharp edges, projections and the like which could cause excessive irritation or injuries.

The assessment of the characteristics of roughness, sharp edges etc. likely to cause injury can be based on objective tests and/or practical experience. Injuries may originate not only from the characteristics of the PPE but also from the activity of the user.

1.2.1.3. Maximum permissible user impediment

Any impediment caused by PPE to movements to be made, postures to be adopted and sensory perception must be minimized; nor must PPE cause movements which endanger the user or other persons.

Impediment to movement depends in particular on the PPE weight and design sizes have to take into account not only the morphology of intended users but also the dynamic movement required by their activity, the adjustment possibilities and on the characteristics of constituent materials. For example, the more the constituent materials are thick and rigid, the more likely they are to be impediment movements.

Impediment to sensory perception by the intended user can take many different forms. E.g. hearing protectors are intended to ensure the attenuation of noise which arrives at the intended user's ear but this requirement needs also to be considered alongside the need of the intended user to communicate with other operators and/or to hear warning signals.

Another example is fire-fighter clothing that needs to ensure protection against heat and flame. The protection may be of a lower level for minor part of the body in order for the intended user to be more quickly become aware of the danger and to escape more quickly.

With respect to sensory perception, it is necessary to seek the best possible compromise between safety and usability. For example, a glove needs to preserve the dexterity and tactile sensitivity of the intended wearer yet nevertheless ensure protection against risks which can be mechanical, chemical and/or thermal.

In order to assess the conformity of the PPE to this BHSR, objective test methods can be used to measure physical characteristics of the PPE having an effect on user impediment such as: sizes, rigidity, weight, field of vision ... When no objective method for the measurement of the level of impediment to movement exists, subjective trials can be performed, consisting in practical tests on a panel of test persons carrying out tasks simulating the possible foreseeable conditions of use.

1.3. Comfort and efficiency

1.3.1. Adaptation of PPE to the user morphology

PPE must be so designed and manufactured as to facilitate correct positioning on the user and to remain in place for the foreseeable period

of use, bearing in mind ambient factors, movements to be made and postures to be adopted. For this purpose, it must be possible to optimize PPE adaptation to user morphology by all appropriate means, such as adequate adjustment and attachment systems or the provision of an adequate size range.

PPE must be designed and manufactured in order to provide the highest possible comfort for each wearer, thus for different morphology types and for both sexes.

Many variables are necessary to describe morphology i.e. to define the shapes of the human body. Moreover, sizes of people and ethnical composition of the European population are likely to evolve (rapidly) in time. This should be carefully considered by referring to updated anthropometric databases while designing PPE. Where possible systems of adjustment are useful to adapt the PPE to each wearer to avoid custom-made products, which are not economically viable.

PPE needs to be equipped with elements capable of ensuring its remaining in place, taken into account all possible foreseeable factors, such as forces affecting the PPEs stability, movements to be made and postures to be adopted during the tasks, etc.

For example:

- Protective helmets need to be stable on the head of the wearer: a balanced weight distribution, an appropriate location of the centre of gravity and a nape strap are a few ways to do this. When necessary, and acceptable from a safety point of view, the helmet could also be equipped with a chin strap.
- Lifejackets need to remain in place when the user falls into water.

PPE must be so designed and manufactured as to facilitate correct positioning on the user. This could be evaluated by subjective tests, e.g. considering the opinion of wearers executing a conventional task. In certain cases, this facility of correct positioning can be evaluated by measuring technical properties specific to the risk to prevent, for example, the degree of tightness of the face piece of a respiratory protective device test subjects performing dynamic tasks.

Trials with test subjects or laboratory measurements could also be used to assess:

- Adjustability, the stability of adjustments;
- Consequences of displacement of the PPE, and the maximum tolerable displacement;
- Static and dynamic forces that might be exerted on the PPE in normal use, and during circumstances in which it is intended to provide protection.

1.3.2 Lightness and design strength

PPE must be as light as possible without prejudicing design strength and efficiency.
Apart from the specific additional requirements which they must satisfy in order to provide adequate protection against the risks in question (see 3), PPE must be capable of withstanding the effects of ambient phenomena inherent under the foreseeable conditions of use.

The manufacturer should design the PPE so that the best compromise between the weight and protection efficiency is realised. PPE can have adverse effects on the body by increasing muscle strain or energy consumption through increased or altered passive or dynamic loading. The weight (and its distribution) of PPE has to be considered in relation to the specific body part or parts likely to be affected. For example, additional mass on the head produces forces in the neck that have to be countered by the neck muscles and thus might have a negative influence on the wearer's health and safety. Heavy weights on the body or body parts increase energy consumption, especially when walking or running.

The efficiency of PPE can be affected by any number of environmental factors. These factors can lower the protection efficiency in time. The manufacturer should give enough information how environmental factors affect the protection level so that the user can assess the service life of the PPE. The manufacturer needs to include in the instructions for use the foreseeable environment and working conditions he has taken into account when designing the PPE in order to allow correct use and selection in any given situation.

For example, PPE integrating electronic components the behaviour in an EMC “disturbed” environment must be thoroughly checked. 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.

1.3.3 Compatibility of different classes or types of PPE designed for simultaneous use

If the same manufacturer markets several PPE models of different classes or types in order to ensure the simultaneous protection of adjacent parts of the body against combined risks, these must be compatible.

When different types of PPE from a manufacturer are intended to be worn simultaneously, the manufacturer will need to ensure that the safety function and comfort of each PPE are not compromised by the wearing of another PPE. For example an ear muff or a face shield is considered as compatible with a safety helmet, if the protective characteristics and the comfort of the hearing protector and of the face shield are not impaired by the simultaneous wearing of these PPE.

In all cases, the manufacturer will also need to draw the attention of intended users on any limitation of use or possible incompatibility.

See also requirement 2.14

1.4. Information supplied by the manufacturer

In addition to the name and address of the manufacturer and/or his authorized representative established in the Community, the notes that must be drawn up by the former and supplied when PPE is placed on the market must contain all relevant information on:

The information supplied by the manufacturer constitutes a fundamental element in order to judge the conformity of a PPE. **It is considered an integral part of the** PPE it refers to and shall be checked, in terms of content and understandability, by the Notified Body when undertaking an EC-type examination. The Notified Body shall verify that the equipment can be used in complete safety for its intended purpose. In order to do this, the Notified Body shall check that the claims of the manufacturer on the area and limits of protection of the product are in line with the technical specification used and with the relevant essential safety requirements

This document shall be established in conformity with this BHSR, but also, where relevant, with other applicable requirements, such as:

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

The manufacturer has the obligation to deliver the information in paper form to users with each unit of PPE put on the market.

For some types of PPE, such as ear-plugs or specific protective gloves which are sometimes sold in dispenser boxes, the instructions for use can be affixed to the boxes or be provided with each unit.

1.4 (a)

(a) storage, use, cleaning, maintenance, servicing and disinfection. Cleaning, maintenance or disinfectant products recommended by manufacturers must have no adverse effect on PPE or users when applied in accordance with the relevant instructions;

The storage instructions must specify the conditions, for example: to store only in its original packaging, in a dry atmosphere, at a maximum temperature of 60°C, away from light, etc.

The instructions for use have to give necessary information for putting on or taking off the PPE as well as how to make the necessary adjustments to the wearer's morphology.
The manufacturer cannot deviate from the obligation to define cleaning, maintenance and (if applicable) disinfection processes, since these are necessary to ensure the hygiene of the intended user of the PPE.

The instructions for cleaning, maintenance and disinfection must not only specify the products (or at least the criteria necessary to select them) but if relevant also the procedures to be applied. These procedures will specify the preliminary operations such as the disassembling of certain sensitive components, and the actual operations including the concentrations of cleaning product, the temperature, etc). The procedures will also mention any operation necessary to apply after cleaning or maintenance, to ensure that the PPE retain the optimum level of effectiveness. For example, the cleaning procedures include the conditions of drying for a PPE intended for heat and flame protection or the precautions to be taken with respect to the electrical risk if the PPE has electric or electronic components.

The conditions of disinfection depend on the type of PPE and the way in which it is carried/worn by the user. They can be less constraining if there is no direct contact of the PPE with the skin of the wearer, for example, the harnesses of fall arresting systems. On the other hand, they should be very prescriptive if there is direct and prolonged contact with the skin, for example, as is the case with respiratory protective devices or safety gloves.

The maintenance instructions must specify which are the operations the wearer can carry out himself, and how to do so (in particular giving precise information on spare parts), as well as when this requires the intervention of the manufacturer or a specialised person.

Any product specified by the manufacturer for the cleaning, maintenance or disinfection of the PPE will not be harmful for the PPE or its user. For instance, products that are recommended will be tested on carcinogenic or allergic reactions or they will not destroy the integrity of the material used in the PPE. The harmful effects on a potential user can be verified using safety data sheets of the products while the effects on the integrity of PPE can be checked applying the cleaning procedure before carrying out the test to determine the performance of the PPE.

1.4 (b) performance as recorded during technical tests to check the levels or classes of protection provided by the PPE in question;

The information shall mention the levels or classes of protection, determined by the manufacturer according to European harmonised standards or other relevant specifications and shall not duplicate the content of the test report.

1.4 (c) suitable PPE accessories and the characteristics of appropriate spare parts;

The manufacturer needs to indicate the accessories and spare parts compatible with the PPE in the instructions. The manufacturer is responsible for the design of these accessories and of their compatibility with the PPE. As a consequence he cannot assume any responsibility if a person uses those accessories other than those envisaged by him.

The characteristics of the spare parts mentioned in this requirement relate to the necessary information to their replacement and the limits for their use.

1.4 d) the classes of protection appropriate to different levels of risk and the corresponding limits of use;

For a class of protection claimed by the manufacturer, the instructions must specify the level of the risk covered and the corresponding limits of use. These are generally expressed by:

- the nature of the covered risk;
- the limitation of the parameters defining the risk (temperature, pressure, acoustic level, list of chemicals…);
- the limitation of the exposure duration to the risk.

These levels of the risks covered are sometimes difficult to know beforehand. In such cases they can be indicated by reference to the test conditions in which the examination of the type was undertaken.

1.4 (e) the obsolescence deadline or period of obsolescence of PPE or certain of its components;

Date of obsolescence is the date from which, the PPE becomes useless for its intended use or is no longer fit for its purpose, due, either to changes in its protective properties or to loss in functionality and it must be discarded or repaired. This date of obsolescence or period of obsolescence refers either to the self life, or to the useful life span, or to the time of use or to the ageing or to any other circumstance that may affect the PPE performances.
The manufacturer must provide all information necessary so that the user can determine a reasonable period of obsolescence. However the manufacturer is not obliged to affix the date of manufacture on the product or on the instructions for use.

This can be expressed by relevant information on how to identify the “end of life”, a limiting date of use or a maximum service time.

The service life of PPE depends on many factors such as the conditions of storage, use, cleaning, revision, maintenance where a manufacturer does not have control. The manufacturer has to provide any useful information so that the intended user can determine a reasonable time limitation. It can be a question of the evolution of a characteristic of use (for

example, an increase in respiratory resistance making the use painful) or of a characteristic of aspect and/or integrity (for example, striped or split eyepiece). It could also refer to the ageing of materials. For example, the appearance of cracks or discolouration on the surface of a thermoplastic safety helmet is an objective sign of ageing.

1.4 (f) the type of packaging suitable for transport;

This is related to the description of packing to be used for transport, for example, original packaging, tight packing etc., to keep the safety and usability characteristics of the PPE. The term "transport" is related not only to the transportation from the manufacturing place to other places but also to the protection of the PPE when not in use and moved.

1.4 (g) the significance of any markings (see 2.12).

Requirement 2.12 is related to the markings affixed on PPE concerning directly or indirectly the health or the safety of the intended user. There are other provisions of the directive which mention the affixing of markings with particular significance, thus for example requirements 2.4 (relating to the PPE subject to ageing), 3.5 (relating to hearing protectors), 3.9 (relating to eye protectors against the ionizing radiations), 3.10 (relating to respiratory protective devices).

In addition to these markings whose affixation is mandatory, other markings or pictograms can exist e.g. as defined in standards, providing useful information on field of use of the PPE and its level of performance. This shall be clearly explained in the instructions for use and can not lead to confusion with respect to the mandatory marking requirements (CE marking).

1.4 (h) where appropriate, the references of the directives applied in accordance with article 5 (6) (b);

This requirement refers to an Article concerning the application of Directives for which the CE marking is foreseen, the references detailed here are only so-called "New Approach" Directives that have been applied to the PPE.

In the information supplied by the manufacturer details have to be provided as to which directives the manufacturer has decided to apply.

1.4 (i) the name, address and identification number of the notified body involved in the design stage of the PPE.

The design stage includes all the operations of design and manufacture of the PPE which was subjected to EC-type examination. This requirement relates only to PPE of category II and III.

Using a Notified Body during the phase of design of PPE (the Body which makes the EC-type examination) does not discharge the manufacturer from his responsibilities, such as defined in the Articles of the directive.

These notes, which must be precise and comprehensible, must be provided at least in the official language(s) of the Member State of destination.

The manufacturer has the responsibility for the establishment of the original version of the instructions for use and of the validated versions in the languages of the Member States of the EU where he intends to place the PPE on the market.

This document has to be written in the language(s) of the Member States where the product is intended to be sold, the translation is made by the manufacturer and/or his authorized representative established in the Community under his responsibility, and must include his address.

Product information is one of the fundamental elements of any product and as such it has to be clear, concise, understandable and giving the appropriate information for the end users. It should be taken into account that the information supplied by the manufacturer may only be considered as effective, when it is perceived, understood, retained and appropriately used. Since the information supplied by the manufacturer provides the basis on which consumers can make a reasoned selection, it is also one of the means to increase the health and safety of the intended end user. High quality information minimises the risk of an incorrect selection and/or wrong use. The better the quality of information, the easier the selection and correct use of the PPE.

Further, CEN has elaborated a guide on information supplied by the manufacturer, which can be found at:

http://www.cenorm.be/cenorm/workarea/sectorfora/personal+protective+equipment/index.asp

2. ADDITIONAL REQUIREMENTS COMMON TO SEVERAL CLASSES OR TYPES OF PPE

2.1. PPE incorporating adjustment systems

If PPE incorporates adjustment systems, the latter must be so designed and manufactured as not to become incorrectly adjusted without the user's knowledge under the foreseeable conditions of use.

The manufacturer shall ensure by proper design that no unintentional changes of adjustment can influence the protection afforded by the PPE.

In the case of attachment units, this condition is met if, for example, they are inaccessible during conducting the task or, if they would be accessible, the system needs to be unlocked e.g. the simultaneous voluntary execution of two distinct movements.

2.2. PPE 'enclosing' the parts of the body to be protected

As far as possible, PPE 'enclosing' the parts of the body to be protected must be

sufficiently ventilated to limit perspiration resulting from use; if this is not the case, it must if possible be equipped with devices which absorb perspiration.

The main method that the body uses to keep a suitable temperature is sweat evaporation. Evidently, PPE has an influence on the conditions applying to the wearer affecting this physiological phenomenon.

As a result, the PPE has to be designed so as to allow a sufficient level of ventilation according to the task and foreseeable use conditions or the manufacture has to use breathable materials. In order to increase comfort, for example where protection against a toxic environment is required and hence the PPE has to be impermeable, sweat absorbing materials can evidently be chosen.

Where this BHSR is to be applied, the information supplied by the manufacturer needs to specify the necessary ventilation rate if the PPE is to be supplied with air ventilation. Useful information in respect of maintenance also has to be given, by specifying the cleaning and drying operations to be carried out after use.

This information has to be sufficient to make it possible for the employer to determine the maximum physiologically acceptable duration use of the PPE in accordance with directive 89/656/EEC.

2.3. PPE for the face, eyes and respiratory tracts

Any restriction of the user's field of vision or sight by PPE for the face, eyes or respiratory tract must be minimized.

The degree of optical neutrality of the vision systems of these PPE classes must be compatible with the type of relatively meticulous and/or prolonged activities of the user.

If necessary, they must be treated or provided with facilities to prevent moisture formation.

PPE models intended for users requiring sight correction must be compatible with the wearing of spectacles or contact lenses.

Any restriction to the natural field of vision of the intended user must be minimised in order to minimise risks or discomfort associated with either the intended tasks or environment.

In order to ensure the comfort of a user not requiring vision correction, safety oculars should not impair his vision. In other terms to be optically neutral by having refractive power as low as possible. Safety oculars with very low refractive powers are recommended for a permanent use or a meticulous work and the others only for intermittent or even for very short duration use.

Lenses provided with “anti-fogging” coating need to be designed to be so that this characteristic remains preventing moisture formation in all foreseeable conditions of use. If this is the case, information is to be given in the instruction for use, on how to clean the anti-fogging lenses to avoid degradation of the coating.

Devices integrated into PPE to reduce moisture have to be designed to prevent fogging whilst not downgrading the PPE protection level (e.g. ventilation holes in goggles).

Regarding integrated air ventilation, the air flow cannot create adverse health effects or nuisance (noise, comfort disturbing draught…).

If the PPE is intended to be put over corrective spectacles, the manufacturer needs take into account the normal dimensions of the spectacles to determine those for the PPE.

The manufacturer will want to be aware that, wherever possible, it is advisable to integrate the optical correction to PPE oculars or to provide a suitable mounting supporting the corrective spectacles.

2.4. PPE subject to ageing

If it is known that the design performances of new PPE may be significantly affected by ageing, the date of manufacture and/or, if possible, the date of obsolescence, must be indelibly inscribed on every PPE item or interchangeable component placed on the market in such a way as to preclude any misinterpretation; this information must also be indelibly inscribed on the packaging.

If a manufacturer is unable to give an undertaking with regard to the useful life of PPE, his notes must provide all the information necessary to enable the purchaser or user to establish a reasonable obsolescence date, bearing in mind the quality level of the model and the effective conditions of storage, use, cleaning, servicing and maintenance.

Where appreciable and rapid deterioration in PPE performance is likely to be caused by ageing resulting from the periodic use of a cleaning process recommended by the manufacturer, the latter must, if possible, affix a mark to each item of PPE placed on the market indicating the maximum number of cleaning operations that may be carried out before the equipment needs to be inspected or discarded; failing that, the manufacturer must give this information in his notes.

The ageing factors influencing the performance of the PPE that need to be taken into account are the effects of time, environment and use. The manufacturer will define in his technical file the ambient conditions as well as the foreseen use conditions taken into account when evaluating the effect of ageing on the PPE. It is understood that the date of expiry of the PPE corresponds with the decrease, by ageing effects, of the protective performance to the level that is not adequate against the risk.

The manufacturer needs to ensure that the storage will not change the PPE characteristics significantly.

The lifetime of the PPE, corresponding with the expiry date, is influenced by the use conditions of the PPE or the interchangeable components. The lifetime can be expressed in terms of time or of number of exposures. It is understood that the manufacturer cannot have full control over these conditions. Therefore the manufacturer will assist the user in determining the moment to dispose of the PPE with all relevant information on the foreseen use conditions as well as on all other factors influencing the lifetime (storage, cleaning, maintenance, etc. see also paragraph 1.4).

In the case that the prescribed cleaning process leads to a rapid and important deterioration of the PPE performance, the maximum number of cleaning cycles that can be performed without overhaul or disposal needs to be indicated.

For example:

- Certain protective clothing has a finish that will resist only a few wash cycles, but can be restored following the instruction of the manufacturer – in that case the maximum number indicated means the number of cleaning cycles between restoring the finishing or the maximum amount of re-treatments.

Certain materials used in protective clothing or gloves do not resist cleaning. In that case an indication that the product is only intended for a single use needs to be fixed to the PPE.

2.5. PPE which may be caught up during use

Where the foreseeable conditions of use include in particular the risk of the PPE being caught up by a moving object thereby creating a danger for the user, the PPE must possess an appropriate resistance threshold above which a constituent part will break and eliminate the danger.

The design of PPE shall be such that no risk of being caught can exist. If a residual risk of the PPE being caught remains, the product shall be so designed that that component has a suitable breaking resistance to avoid injuries due to PPE catching. This threshold depends on the characteristics of the components of PPE and their assembly. It must be designed by taking account the characteristics of part of the body to be injured and the severity of the possible health damage. The breaking force of the cord connecting ear plugs (for example) shall be much lower than the breaking force of a protective clothing.

In some cases it is difficult to confirm this requirement. In those cases the information supplied by the manufacturer shall clearly give warning to use these PPE in situations where this risk exists.

2.6. PPE for use in explosive atmospheres

PPE intended for use in explosive atmospheres must be so designed and manufactured that it cannot be the source of an electric, electrostatic or impact-induced arc or spark likely to cause an explosive mixture to ignite.

PPE intended to be used in an explosive environment, needs to:

- have anti-static properties which remain effective during all its service life when used and maintained correctly in accordance with the manufacturer instructions;
- be made of material which are known not to cause sparks e.g. by impact;
- strictly avoid PPE components likely to create sparks by shock or friction initiated by a PPE intended to be used in explosive atmosphere;
- not include unprotected electric components or parts which do not comply (where relevant) to directive 94/9/EC of 23 March 1994 on the approximation of the laws of the Member States concerning equipment and protective systems intended for used in potential explosive atmospheres.

2.7. PPE intended for emergency use or rapid installation and/or removal

These PPE classes must be so designed and manufactured as to minimize the time required for attachment and (or) removal.
Any integral systems permitting correct positioning on, or removal from, the user must be susceptible of rapid and easy operation.

The ease of donning and doffing of PPE intended for emergency use shall be as good as possible, taking into account the foreseeable emergency situations and the duration of the tasks. The verification of the required time can only be made by using test subjects in realistic simulated conditions.

In some cases it is important to be able to remove the PPE quickly to avoid or limit severe injuries: e.g. when hot or cold particles or liquids accidentally enter the PPE.

Instructions for use shall contain the information on quick donning and doffing of the PPE and advice for proper training of the users.

2.8. PPE for use in very dangerous situations

The information notes supplied by the manufacturer together with PPE for use in the very dangerous situations referred to in Article 8 (4) (a) must include, in particular, data intended for the exclusive use of competent trained individuals who are qualified to interpret them and ensure their application by the user.
They must also describe the procedure to be adopted in order to verify that PPE is correctly adjusted and functional when worn by the user.
If PPE incorporates an alarm which is activated in the absence of the level of protection normally provided, this must be so designed and accommodated as to be perceived by the user in the conditions of use for which the PPE is marketed.

PPE intended for this type of task is category III.

Where the manufacturer considers that the PPE can only be used by trained persons, further information needs to be provided, as follows:

- the details of the training of the "trainers" themselves so that the intended users;
- the correct donning and adjustment of the PPE to maximise its effectiveness;
- the correct procedure to verify the functionality of the PPE (e.g. content and periodicity of controls).

The warning device integrated in PPE needs to be designed so that it remains effective (e.g. visible and/or audible) in all foreseeable conditions of use and irrespective of the intended environmental variations (e.g. heat, cold, moisture, electromagnetic radiation, shocks…). This alarm device may, amongst other relevant factors, need to take into account the following:

- the sound environment;
- the wearing of hearing protectors (see requirement 3.5);
- the ambient illumination;
- the use of coloured optical filters against radiation.

Where, even with a warning device the manufacturer considers that the required level of protection cannot be assured, he will need to include a suitable warning in the instructions for use.

2.9. PPE incorporating components which can be adjusted or removed by the user

Any PPE components which can be adjusted or removed by the user for the purpose of replacement must be so designed and manufactured as to facilitate adjustment, attachment and removal without tools.

The instructions given by the manufacturer need to specify the adjustments and replacements that can be made by the user himself without tools and those which are to be done only by competent trained persons. In the first case the procedures to be followed to make them safely and easily without tools are to be included in the instructions for use.

2.10. PPE for connection to another, external complementary device

If PPE incorporates a system permitting connection to another, complementary, device, the attachment mechanism must be so designed and manufactured as to enable it to be mounted only on appropriate equipment.

As far as possible the design of PPE needs to prevent the incorrect connection. The information given by the manufacturer therefore has to describe how to ensure safe connection and where appropriate give adequate warnings to ensure that this is the case.

If PPE is designed so that several devices can be connected, for example to adapt it to different conditions of use, the information given by the manufacturer has to provide an exhaustive list of these devices and guidance on how to use them correctly.

For example, if the PPE is to be connected with breathable gas mixtures supply, the connector should be conceived so that it is impossible to connect it to non breathable gas supply, such as a nitrogen circuit.

2.11. PPE incorporating a fluid circulation system

If PPE incorporates a fluid circulation system, the latter must be so chosen, or designed, and incorporated as to permit adequate fluid renewal in the vicinity of the entire part of the body to be protected, irrespective of user gestures, posture or movement under the foreseeable conditions of use.

The most frequent use of these systems is in hot or cold environments or in situations when the user must be totally insulated from polluted atmospheres and it is necessary to maintain the body temperature within acceptable limits.

2.12. PPE bearing one or more identification or recognition marks directly or indirectly relating to health and safety

The identification or recognition marks directly or indirectly relating to health and safety affixed to these types or classes of PPE must preferably take the form of harmonized pictograms or ideograms and must remain perfectly legible throughout the foreseeable useful life of the PPE. In addition, these marks must be complete, precise and comprehensible so as to prevent any misinterpretation; in particular, when such marks incorporate words or sentences, the latter must appear in the official language(s) of the Member State where the equipment is to be used.
If PPE (or a PPE component) is too small to allow all or part of the necessary marking to be affixed, the relevant information must be mentioned on the packing and in the manufacturer's notes.

These marks cannot create confusion in respect of e.g. the risk covered or the category of PPE. Information given by the manufacturer has to specify the correct meaning of any pictogram (see requirement 1.4 g). They need be so designed to remain legible during the service life of the product, that means e.g. that the marking affixed on the PPE shall not be easily removable and/or damaged by e.g. scratching, cleaning or sun exposure.

These marks can only be considered as effective, when complete, precise and comprehensible, in other terms when it is properly perceived, understood, retained by the intended end user.

For the use of harmonised pictograms or ideograms the manufacturer may refer in particular to ISO 7000 “Graphical symbols for use on equipment-Index and synopsis.”

2.13. PPE in the form of clothing capable of signalling the user's presence visually

PPE in the form of clothing intended for foreseeable conditions of use in which the user's presence must be visibly and individually signalled must have one (or more) judiciously positioned means of or devices for emitting direct or reflected visible radiation of appropriate luminous intensity and photometric and colorimetric properties.

The intention of this requirement is to make the intended user of PPE visible especially when moving in an area where motor vehicles or other mobile machines are moving, in particular when the illumination is poor. Respect of this requirement allows for a better identification of the users of these PPE by the drivers but does not protect these users of PPE against the collision risks. The form of direct signalling or reflective material affixed to PPE needs to make it possible for the driver to recognize that it is a pedestrian and not a fixed obstacle.

Signalling devices or materials have to be so positioned on the clothing so that in the foreseeable conditions of use the signalling surfaces are not obstructed.

2.14. Multi-risk' PPE

All PPE designed to protect the user against several potentially simultaneous risks must be so designed and manufactured as to satisfy, in particular, the basic requirements specific to each of those risks (see 3).

3. ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS

3.1. Protection against mechanical impact

3.1.1. Impact caused by falling or projecting objects and collision of parts of the body with an obstacle

Suitable PPE for this type of risk must be sufficiently shock-absorbent to prevent injury resulting, in particular, from the crushing or penetration of the protected part, at least up to an impact-energy level above which the excessive dimensions or mass of the absorbing device would preclude effective use of the PPE for the foreseeable period of wear.

Impact tolerance criteria have been developed for different body regions usually derived from a combination of accident and casualty data.

The influence of impact is not only related to its energy level but also to other parameters such as the direction of the impact. The principle to find optimum level of protection is then to be applied at design stage.

3.1.2. Falls

3.1.2.1. Prevention of falls due to slipping

The outsoles for footwear designed to prevent slipping must be so designed, manufactured or equipped with added elements as to ensure satisfactory adhesion by grip and friction having regard to the nature or state of the surface.

There are several factors affecting the risk of slipping. One of most important influencing factors is the friction of the outsole of the footwear. The friction of the sole on the walking surface shall be in a suitable range of friction values. The properties of the walking surfaces corresponding to the foreseeable conditions of use shall be taken into account. The outsoles made from certain materials can also vary with the temperature or during the lifetime by wear and tear of the sole. For some use situations it is very difficult to design footwear having proper friction.

For footwear intended to be permanently used on very slippery ice surfaces, the manufacturer may equip the footwear with spikes or similar integrated additional elements. The manufacturer can also design specific removable PPE which shall be able to be attached easily, firmly and securely onto the footwear.

3.1.2.2. Prevention of falls from a height

PPE designed to prevent falls from a height or their effects must incorporate a body harness and an attachment system which can be connected to a reliable anchorage point. It must be designed so that under the foreseeable conditions of use the vertical drop of the user is minimized to prevent collision with obstacles and the braking force does not, however, attain the threshold value at which physical injury or the tearing or rupture of any PPE component which might cause the user to fall can be expected to occur.
It must also ensure that after braking the user is maintained in a correct position in which he may await help if necessary.

The manufacturer's notes must specify in particular all relevant information relating to:

- the characteristics required for the reliable anchorage point and the necessary minimum clearance below the user,
- the proper way of putting on the body harness and of connecting the attachment system to the reliable anchorage point.

PPE for the prevention against falls from a height shall be designed so that:

- the user is prevented from reaching any dangerous area where the risk of free fall exists (restraint equipment);

- or in case where the risk of free fall cannot be prevented, the PPE prevents the collision with obstacles or with the floor and minimise the risk of injury by dissipating the kinetic energy to the level which is not harmful to the user e.g. by leading-in the forces into the strong parts of the body or by the use of energy absorbing devices.

The manufacturer needs to list the components which can be used together in the fall arresting system and how to assemble them properly.

All of the components of all fall arrest systems and the assemblies need to be in conformity with the directive. The manufacturer has the responsibility to indicate the components which can be used together in the system and how to assemble them properly.

The design has to be so that in case of an accident, the victim can wait for rescue in a good position without excessive harmful effects.

3.1.3 Mechanical vibration

PPE designed to prevent the effects of mechanical vibrations must be capable of ensuring adequate attenuation of harmful vibration components for the part of the body at risk.

Under no circumstances must the effective value of the accelerations transmitted to the user by those vibrations exceed the limit values recommended in the light of the maximum foreseeable daily exposure of the part of the body at risk.

The directive regarding to the exposure of workers, 2002/44/EC, contains provisions aimed at avoiding or reducing risks arising from vibration. PPE can be part of the prevention programme. PPE against vibration can be difficult to use and therefore the directive recommends other prevention means. One recommendation of this directive is to provide suitable clothing to minimise the effect of mechanical vibration to those workers who are working in cold and damp conditions.

The efficiency of PPE against vibration needs to be evaluated by reference of the exposure action and limit values given in this directive.

3.2. Protection against (static) compression of part of the body

PPE designed to protect part of the body against (static) compressive stress must be sufficiently capable of attenuating its effects to prevent serious injury or chronic complaints.

3.3. Protection against physical injury (abrasion, perforation, cuts, bites)

PPE constituent materials and other components designed to protect all or part of the body against superficial injury caused by machinery, such as abrasion, perforation, cuts or bites, must be so chosen or designed and incorporated as to ensure that these PPE classes provide sufficient resistance to abrasion, perforation and gashing (see also 3.1) under the foreseeable conditions of use.

For "machinery" one should consider "mechanical actions". Therefore this requirement is applicable to all injuries independently from their origin.

This requirement is related to the real risks corresponding to the foreseeable conditions of use and to the physical safety of the user, and not to the quality of the product.
Resistance to abrasion, perforation and cut are important properties for many PPE as consequence that these risks are present in most of the tasks. In most cases they are caused by

- Abrasion: contact with abrasive surfaces or abrasive products, sandblasting.
- Perforation: contact with sharp pointed objects
- Cut: contact with sharp or toothed edges.

3.4. Prevention of drowning (lifejackets, armbands and lifesaving suits)

PPE designed to prevent drowning must be capable of returning to the surface as quickly as possible, without danger to his health, a user who may be exhausted or unconscious after falling into a liquid medium, and of keeping him afloat in a position which permits breathing while awaiting help.

PPE may be wholly or partially inherently buoyant or may be inflated either by gas which can be manually or automatically released or orally.

Under the foreseeable conditions of use:

- PPE must, without prejudice to its satisfactory operation, be capable of withstanding the effects of impact with the liquid medium and the environmental factors inherent in that medium,

- inflatable PPE must be capable of inflating rapidly and fully.
Where particular foreseeable conditions of use so require, certain types of PPE must also satisfy one or more of the following additional requirements:
- it must have all the inflation devices referred to in the second subparagraph, and/or a light or sound-signalling device,
- it must have a device for hitching and attaching the body so that the user may be lifted out of the liquid medium,
- it must be suitable for prolonged use throughout the period of activity exposing the user, possibly dressed, to the risk of falling into the liquid medium or requiring his immersion in it.

The PPE which meets this requirement protects the user against a risk of drowning. In general, it is considered that "liquid medium" refers to water.

Buoys and life jackets not carried permanently by people on board of aircrafts and ships are not subject to the PPE Directive (see Annex I) but to other specific directives (e.g. marine equipment directive 96/98/EC).

It should be noted that this type of PPE needs to protect against drowning even of the user is unconscious. Hence, the inflatation time of inflatable devices needs to be as short as possible to be able to save (in particular) an injured or unconscious person.
The luminous or sound signal device referred to must be able to perceived by the rescuers in all foreseeable conditions of use. Evidently, the reflective materials have to be effective when wet.

For prolonged use/ immersion, this PPE has to consider ergonomics requirements to be comfortable and usable during activities where the risk of a fall into water might exist.

3.4.1. Buoyancy aids

Clothing which will ensure an effective degree of buoyancy, depending on its foreseeable use, which is safe when worn and which affords positive support in water. In foreseeable conditions of use, this PPE must not restrict the user's freedom of movement but must enable him, in particular, to swim or take action to escape from danger or rescue other persons.

There has been a good deal of discussion over recent years over the borderline between different types of buoyancy aides. The general understanding is as follows:

- Arm rings are category II PPE which provide an aid to buoyancy;
- Floating seats are covered by the GPSD;
- Inflatable buoys are toys in terms the Toys Directive when they are to be used in shallow waters by children less than 14 years of age - In other cases, they are covered by the GPSD.

Buoyancy aids allow an unconscious user to be afloat but do not necessarily keep the head out of water, whereas the PPE intended for the prevention of drowning maintains the head out of water but may offer only very reduced mobility.

3.5. Protection against the harmful effects of noise

PPE designed to prevent the harmful effects of noise must be capable of attenuating the latter to such an extent that the equivalent sound levels perceived by the user do not under any circumstances exceed the daily limit values laid down by Council Directive 86/188/EEC of 12 May 1986 on the protection of workers from the risks related to exposure to noise at work (;).
All PPE must bear labelling indicating the noise attenuation level and the value of the comfort index provided by the PPE; should this not be possible, the labelling must be fixed to the packaging.

Directive 86/188/EEC has been replaced by directive 2003/10/EC on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (noise). Member states were required to transpose this new directive into national legislation before 15 February 2006.

The necessary attenuation foreseen here can be obtained by using earmuffs, earplugs or a combination of both.
Communication systems included in some hearing protectors are to be designed in order not to exceed the harmful noise "dose".
The ability to understand speech or to hear warning signals may be taken into account in the design of hearing protectors for certain applications.

For some users (such as musicians) it is essential to hear the sound of different frequencies correctly and therefore ear protectors need to have even sound attenuation characteristics throughout the whole frequency area.

If the earplugs are custom made, tests on prototypes and the instructions (for competent persons) on how to mould these plugs correctly need to be drawn up by the manufacturer and evaluated by the Notified Body.

The comfort index includes the effects of aspects related to the comfort for the user. These aspects can include pressure against the head, weight, type of materials, and so on. In the instructions for the user, the manufacturer includes clear information on how to use the hearing protector correctly so that the discomfort is minimised. For the time being it is not possible to determine comfort index, but the factors mentioned above should be taken into account in the design.

3.6. Protection against heat and/or fire

PPE designed to protect all or part of the body against the effects of heat and/or fire must possess thermal insulation capacity and mechanical strength appropriate to foreseeable conditions of use.

In most cases this type of PPE consists of several protective material layers, with the thermal insulation capacity which gives necessary protection.. The protection efficiency will depend not only on the insulation capacity but also on the proper coverage of the insulation of PPE. The size and model of the PPE has to be such that heat or flame is not able to harm the user through possible openings in the PPE and that the protection against heat and flame is not

lowered during the exposure. Therefore, PPE needs sufficient mechanical strength against abrasion, cuts and tearing.

3.6.1. PPE constituent materials and other components

Constituent materials and other components suitable for protection against radiant and convective heat must possess an appropriate coefficient of transmission of incident heat flux and be sufficiently incombustible to preclude any risk of spontaneous ignition under the foreseeable conditions of use.

Where the outside of these materials and components must be reflective, its reflective power must be appropriate to the intensity of the heat flux due to radiation in the infra-red range.
Materials and other components of equipment intended for brief use in high-temperature environments and of PPE which may be splashed by hot products such as large quantities of molten material must also possess sufficient thermal capacity to retain most of the stored heat until after the user has left the danger area and removed his PPE.

PPE materials and other components which may be splashed by large amounts of hot products must also possess sufficient mechanical-impact absorbency (see 3.1). PPE materials and other components which may accidentally come into contact with flame and those used in the manufacture of fire-fighting equipment must also possess a degree of non-flammability corresponding to the risk class associated with the foreseeable conditions of use. They must not melt when exposed to flames nor contribute to flame propagation.

This requirement applies to constituent materials and components and not to complete PPE.

The manufacturer needs to select materials, components or combinations of them so that in the foreseeable conditions of use:

- the heat flux transmitted to the wearer is under the tolerable exposure limit values;
- their flammability and/or melting do not create an additional burning risk for the PPE wearer.

In addition to the insulation properties, the reflective capacity of materials used is important in that it ought to be as high as possible without increasing other harmful factors like heat stress resulting from clothing materials impermeability.

The thermal capacity of materials, material combinations or components to be used in high temperature environments must be designed such that the PPE user will have, after exposure, enough time to leave the danger area and remove the PPE before the accumulated heat in the materials causes him any harm.

The mechanical resistance of PPE materials and other components, must, when necessary be adequate to meet the impact energy, nature and temperature of the splashes of hot products in order to provide sufficient protection to the user.

3.6.2. Complete PPE ready for use

Under the foreseeable conditions of use:

1. ***The quantity of heat transmitted by PPE to the user must be sufficiently low to prevent the heat accumulated during wear in the part of the body at risk from attaining, under any circumstances, the pain or health impairment threshold;***
2. ***PPE must if necessary prevent liquid or steam penetration and must not cause burns resulting from contact between its protective integument and the user.***
   If PPE incorporates refrigeration devices for the absorption of incident heat by means of liquid evaporation or solid sublimation, their design must be such that any volatile substances released are discharged beyond the outer protective integument and not towards the user.
   If PPE incorporates a breathing device, the latter must adequately fulfil the protective function assigned to it under the foreseeable conditions of use.
   The manufacturer's notes accompanying each PPE model intended for brief use in high-temperature environments must in particular provide all relevant data for the determination of the maximum permissible user exposure to the heat transmitted by the equipment when used in accordance with its intended purpose.

The manufacturer has to design the PPE such that in the foreseeable conditions of use:

- the accumulation of heat by the PPE while in use does not cause thermal stress, pain or harmful effects to the user;
- it prevents any penetration of liquid or steam liable to cause burns (e.g. by proper coverage of body parts to be protected);
- any part of the PPE which may be heated up to harmful temperature will not be in direct contact with the user.

PPE incorporating refrigeration devices for the absorption of incident heat must, where relevant, be designed such that in the foreseeable conditions of use, volatile substances released are discharged away from the user in order not to cause any additional harmful effect.
PPE against heat incorporating a breathing device, must be designed such that, in the foreseeable conditions of use, it fulfils the requirements applicable to respiratory protective devices: e.g. the air flow in ventilated suits must be high enough to protect against excessive heat load and contaminant inhalation.

With regards to PPE for brief use in high temperatures, the manufacturer must provide enough information so that the user can determine for each of his intended actions, the maximum effective protection time and/or the maximum acceptable use time from the physiological point of view.

3.7 Protection against cold

PPE designed to protect all or part of the body against the effects of cold must possess thermal insulating capacity and mechanical strength appropriate to the foreseeable conditions of use for which it is marketed.

PPE against cold is designed according to the foreseen risks and usually consists of several protective material layers. The protection efficiency of this type of PPE depends on the insulation capacity as well as proper coverage. The size and model of the PPE needs to, be such that cold does not directly harm the user through possible openings in the PPE.
PPE of this type also needs to have adequate mechanical strength against abrasion, cuts and tearing.

3.7.1. PPE constituent materials and other components

Constituent materials and other components suitable for protection against cold must possess a coefficient of transmission of incident thermal flux as low as required under the foreseeable conditions of use. Flexible materials and other components of PPE intended for use in a low-temperature environment must retain the degree of flexibility required for the necessary gestures and postures.

PPE materials and other components which may be splashed by large amounts of cold products must also possess sufficient mechanical-impact absorbency (see 3.1).

This requirement applies to constituent materials and components and not to complete PPE.

The manufacturer needs to select materials, components or a combination of them so that in the foreseeable conditions of use:

- the thermal flux transmitted through the PPE shall be as low as possible;
- the flexibility remains acceptable to insure comfort, usability and integrity of the products.

The mechanical resistance of materials of components, needs to be, where necessary, appropriate to the impact energy, nature and temperature of the splashes of cold products.

3.7.2. Complete PPE ready for use

1. ***The flux transmitted by PPE to the user must be sufficiently low to prevent the cold accumulated during wear at any point on the part of the body being protected, including the tips of fingers and toes in the case of hands or feet, from attaining, under any circumstances, the pain or health-impairment threshold;***
2. ***PPE must as far as possible prevent the penetration of such liquids as rain water and must not cause injuries resulting from contact between its cold protective integument and the user.***
   If PPE incorporates a breathing device, this must adequately fulfil the protective function assigned to it under the foreseeable conditions of use.

   The manufacturer's notes accompanying each PPE model intended for brief use in

low-temperature environments must provide all relevant data concerning the maximum permissible user exposure to the cold transmitted by the equipment

The manufacturer must design the PPE such that in the foreseeable conditions of use:

- the loss of body heat does not cause hypothermia, pain or harmful effects, in particular to the user's extremities (e.g. tips of fingers and toes);
- it prevents the penetration of liquids, such as rain water, likely to cause injuries(e.g. by proper coverage of body parts to be protected);
- any part of the PPE which might be cooled down to harmful temperature must not be in direct contact with the user.

PPE against cold incorporating a breathing device must be designed such that, in the foreseeable conditions of use, it will fulfil the requirements of a respiratory protective device: e.g. the temperature of breathable air flow is physiologically acceptable.

With regards to PPE for brief use in cold environments, the manufacturer must provide enough information so that the user can determine for each of his intended action, the maximum effective protection time and/or maximum acceptable use time from a physiological point of view.

3.8 Protection against electric shock

PPE designed to protect all or part of the body against the effects of electric current must be sufficiently insulated against the voltages to which the user is likely to be exposed under the most unfavourable foreseeable conditions.

To this end, the constituent materials and other components of these PPE classes must be so chosen or designed and incorporated as to ensure that the leakage current measured through the protective integument under test conditions at voltages correlated with those likely to be encountered in situ is minimized and, at all events, below a maximum conventional permissible value which correlates with the tolerance threshold.

Together with their packaging, PPE types intended exclusively for use during work or activities in electrical installations which are or may be under tension must bear markings indicating, in particular, their protection class and (or) corresponding operating voltage, their serial number and their date of manufacture; a space must also be provided outside the protective integument of such PPE for the subsequent inscription of the date of entry into service and those of the periodic tests or inspections to be periodic tests or inspections to be conducted.

The manufacturer's notes must indicate, in particular, the exclusive use for which these PPE types are intended and the nature and frequency of the dielectric tests to which they are to be subjected during their useful life.

To identify the "most unfavourable foreseeable conditions", the manufacturer will need to consider:

- the risk of direct contact to a live conductor;

- the possible harmful electrical parameters and threshold limit values;
- moistness of the skin;
- the effect, during normal use of the PPE, of contact with chemicals used such as solvents, of mechanical degradation/ageing and of climatic environmental factors

PPE marking intended for professional use to protect against electrical risks is intended to ensure their traceability and to give information on their scope of use and necessary periodic checking.

In addition to the electrical "main risk", other risks related to short-circuiting (such as thermal and mechanical risks) also need to be taken into account.

The manufacturer needs to clearly indicate the following in the instructions for use (amongst other information necessary to ensure safe use:

- maximum voltage for the class considered;
- storage;
- controls to be carried out (visual examination and gloves inflation) and their periodicity (in any case before each intended use);
- instructions for the maintenance of PPE.

Moreover, precautions of use, in particular aimed at preserving the electrical insulation properties of the PPE or against the risks of deterioration need to be indicated e.g. use of over-gloves to reduce the risk of punctures, cuts, abrasion, chemical attacks.

3.9 Protection against radiation

3.9.1 non-ionizing radiation

PPE designed to prevent acute or chronic eye-damage from sources of non-ionizing radiation must be capable of absorbing or reflecting the majority of the energy radiated in the harmful wavelengths without unduly affecting the transmission of the innocuous part of the visible spectrum, the perception of contrasts and the ability to distinguish colours where required by the foreseeable conditions of use.

To this end, protective glasses must be so designed and manufactured as to possess, for each harmful wave, a spectral transmission factor such that the radiant-energy illumination density capable of reaching the user's eye through the filter is minimized and, under no circumstances, exceeds the maximum permissible exposure value.

Furthermore, the glasses must not deteriorate or lose their properties as a result of the effects of radiation emitted under the foreseeable conditions of use and all marketed specimens must bear the protection-factor number corresponding to the spectral distribution curve of their transmission factor.

Glasses suitable for radiation sources of the same type must be classified in the ascending order of their protection factors and the manufacturer's notes must indicate, in particular, the transmission curves which make it possible to select the most appropriate PPE bearing in mind such inherent factors of the effective conditions of use as distance to source and the spectral distribution of the energy radiated at that distance.

The relevant protection-factor number must be marked on all specimens of filtering glasses by the manufacturer.

When designing PPE for protection for eye protection against non-ionising radiations, the manufacturer will, in particular, need to consider, the following:

- the spectral and additional characteristics of the radiation sources;
- the illumination of the environment;
- the distance of the wearer from the source(s);
- the need to allow colour recognition (e.g. warning signals or t° identification of materials at elevated temperatures)
- the effect of ageing and of radiations on the efficiency of the PPE exposed e.g. to sun, UV, IR radiations or laser sources. The transmission characteristics of the PPE shall remain at the requested level during all the service time of the products;
- the updated exposure limit values.

The exposure limit values of the eye to the non ionising radiations are laid down in scientific publications and national regulations to which the manufacturer can refer. In particular in:

- Directive 2004/40/EC of the EU Parliament and Council lays on the minimum health and safety requirements regarding the exposure of workers to the risks arising from exposure to magnetic fields (0 Hz to 300 GHz). It covers the microwaves and ultra high frequency waves (UHF) and the very high frequency rays (VHF) domains.
- The guidelines of the International Commission on Non-Ionizing Radiation Protection (ICNIRP) who regularly publish updated limiting exposure and recommend exposure limits values. A new directive, on the minimum health and safety requirements regarding the exposure of workers to the risks arising from exposure to optical radiation is currently under preparation.

Where this requirement refers to “radiation sources of the same type” it relates, for example, to those of the same nature (e.g. infra-red radiations) or of the same type of operations (e.g. radiations produced by arc and gas welding stations and associated processes).

This obliges the manufacturer to include the transmission curves in the instructions for use. The knowledge of the transmission curve is useful for the user only when the optical filter concerned cannot be characterised by a standardised scale or shade number.

In other cases, the supply of such curves is not of great use. They do not allow for the selection of appropriate filters without a computer for calculation and or the knowledge of other additional information such as the spectral irradiance or the spectral luminance of the radiant sources and of the spectral transmission values of the filters. Subject to these caveats, the transmission curves shall be made available to users on demand. The preferred option is that the manufacturer gives the standardised scale or shade number.

The manufacturer needs to give information on the scale or shade numbers of PPE and replaceable spare parts and of the corresponding field of use by means of informative markings on the PPE and in the instructions for use. When the PPE forms a single unit with non replaceable filters (e.g. laser eye protectors), the marking(s) can be placed on the frame.

3.9.2 Ionizing radiation

3.9.2.1 Protection against external radioactive contamination

PPE constituent materials and other components designed to protect all or part of the body against radioactive dust, gases, liquids or mixtures thereof must be so chosen or designed and incorporated as to ensure that this equipment effectively prevents the penetration of the contaminants under the foreseeable conditions of use.

Depending on the nature or condition of these contaminants, the necessary leak-tightness can be provided by the impermeability of the protective integument and/or by any other appropriate means, such as ventilation and pressurization systems designed to prevent the back-scattering of these contaminants.

Any decontamination measures to which PPE is subject must not prejudice its possible re-use during the foreseeable useful life of these classes of equipment.

The instructions for use need in particular to specify the procedure of decontamination which the PPE can withstand without significant degradation of its level of protection (in the case of re-usable PPE only).

3.9.2.2 Limited protection against external irradiation

PPE intended to provide complete user protection against external irradiation or, failing this, adequate attenuation thereof, must be designed to counter only weak electron (e.g. beta) or weak photon (e.g. X, gamma) radiation.
The constituent materials and other components of these PPE classes must be so chosen or designed and incorporated as to provide the degree of user protection required by the foreseeable conditions of use without leading to an increase in exposure time as a result of the impedance of user gestures, posture or movement (see 1.3.2).
PPE must bear a mark indicating the type and thickness of the constituent material(s) suitable for the foreseeable conditions of use.

PPE in conformity with this requirement constitute the ultimate recourse in the event of deterioration of the characteristics of the enclosures ensuring collective protection. The equivalent thickness of lead is given according to this limited energy so that the intended user is not exposed beyond the lawful exposure limit values.
Lead and heavy metals are used only to attenuate X or gamma rays. In the case of beta radiation, use of this type of protection should be avoided as the heavy metal will stop the beta radiation but will also cause a breaking x-ray called “Bremsstrahlung”. There is no specific protection against beta radiation other than equipment made of elastomers or polymers which help stop some of the radiation (the level of protection will depend on the material, its thickness and the energy of the radiation emitted).
The level of protection offered by a PPE is characterised by the determination of equivalent lead thickness of a lead sheet receiving the same rate of attenuation of the ionizing radiations. If the PPE comprises several components, each component and their assembly shall offer the requested level of protection whatever the posture taken by the user.

The thickness considered here can be expressed in term of lead equivalent thickness. The aim is to supply useful information to the user on the attenuation of the ionizing radiations offered by the PPE.
The lead equivalent thickness always has to be given with the energy of the radiation at which it has been verified.

3.10 Protection against dangerous substances and infective agents

3.10.1 Respiratory protection

PPE intended for the protection of the respiratory tract must make it possible to supply the user with breathable air when the latter is exposed to a polluted atmosphere and/or an atmosphere having inadequate oxygen concentration.

The breathable air supplied to the user by the PPE must be obtained by appropriate means, for example after filtration of the polluted air through the protective device or appliance or by a piped supply from an unpolluted source.

The constituent materials and other components of these PPE classes must be so chosen or designed and incorporated as to ensure appropriate user respiration and respiratory hygiene for the period of wear concerned under the foreseeable conditions of use.

The leak-tightness of the face-piece and the pressure drop on inspiration and, in the case of the filtering devices, purification capacity must be such as to keep contaminant penetration from a polluted atmosphere low enough not to be prejudicial to the health or hygiene of the user.

The PPE must bear the manufacturer's identification mark and details of the specific characteristics of that type of equipment which, in conjunction with the instructions for use, will enable a trained and qualified user to employ the PPE correctly.

The manufacturer's notes must also in the case of filtering devices, indicate the deadline for the storage of filters as new and kept in their original packaging.

It is advisable to design the PPE so that exposure to contaminants is clearly under the necessary limit values. Air supplied needs to be a suitable temperature and humidity so that the comfort of the intended user is not affected, it does not cause harmful effects or endanger the safe operation of the device.

Minimum oxygen concentration of the inhaled air has to be sufficient taking into account the demands of the tasks of the user. The amount of re-breathed exhalation air needs to be minimised to avoid the accumulation of carbon dioxide inside the mask. For very short periods of use, such as in escape apparatus, higher carbon dioxide concentrations may be accepted.

The filtration efficiency of the contaminants is dependent on the size, distribution and nature of the aerosols or gases and vapours as well as of the characteristics of the filtering element.

Filtration efficiency changes has to be considered in the design of the device and adequate instructions given.

The breathable gas supply in compressed air or oxygen breathing apparatus is to be ensured by proper design of the mechanical and operational strength and function. The risks caused by the wrong combination of the air supply systems of the breathing apparatus have to be eliminated as far as possible by design. If not possible, adequate information on safe combinations shall be given by the manufacturer.

The respiratory protective device cannot contain or release any substances which are known to be harmful. All of the materials used should be listed in the information for the user. The release of harmful filtering material from the filter has to be eliminated.

The design, adjustments and size range or overpressure inside the face-piece has to prevent face seal leakage as far as possible. The maximum breathing rate needs to be considered in the foreseeable use situation and the device designed that the breathing resistance is not too high. The foreseeable work load can also cause face-piece leakage due to higher under-pressure inside the mask. Moreover, the effect of the increase of the breathing resistance of particle filters during normal use of filtering face piece respirators should also be carefully considered. The magnitude of the penetration between the body of the mask and the face of the user is proportional to the square root of the resistance. Therefore, the higher the resistance of the filter, the greater the face penetration. This needs to be clearly explained in instructions for use accompanying particle filters and face masks.

The manufacturer is required to mark all respiratory protective devices, their components and important spare parts so that it is clear to which device these belong to. These markings also have to be described in the instructions for use.

All filters have to be marked with relevant pictograms and information on the deadline for the storage of the filters when kept sealed in their original packaging.

The essential requirement 2.3 applies to all respiratory protective devices. This requirement foresees the use of anti fogging products or lenses when necessary. This is essential for full face masks intended for use in very polluted and foggy atmospheres where it is not possible to remove the apparatus in order to clean it.

3.10.2 Protection against cutaneous and ocular contact

PPE intended to prevent the surface contact of all or part of the body with dangerous substances and infective agents must be capable of preventing the penetration or diffusion of such substances through the protective integument under the foreseeable conditions of use for which the PPE is placed on the market.

To this end, the constituent materials and other components of these PPE classes must be so chosen, or designed and incorporated as to ensure, as far as possible, complete leak-tightness, which will allow where necessary prolonged daily use or, failing this, limited leak-tightness necessitating a restriction of the period of wear.

Where, by virtue of their nature and the foreseeable conditions of their use, certain dangerous substances or infective agents possess high penetrative power which limits the duration of the protection provided by the PPE in question, the latter must be subjected to standard tests with a view to their classification on the basis of efficiency. PPE which is considered to be in conformity with the test specifications must bear a mark indicating, in particular, the names or, failing this, the codes of the substances used in the tests and the corresponding standard period of protection.

The manufacturer's notes must also contain, in particular, an explanation of the codes (if necessary), a detailed description of the standard tests and all appropriate information for the determination of the maximum permissible period of wear under the different foreseeable conditions of use.

The protective part of this PPE will prevent adequately direct contact of the harmful substance (chemicals, biological agents, …) with the skin or eyes.
PPE protecting against dangerous substances needs to have penetration and permeation properties suitable according to the risk and tasks for which they are designed. This will be the case at least during the use time indicated in the instruction for use. In practice all materials have limited protection over time and thus relevant information and warnings are needed in the instructions for use.

It is not possible to test the protection efficiency against all (mixtures of) substances in all ambient conditions. Therefore tests with representative chemicals will give an indication to the user. In the instructions for use these test substances are to be clearly mentioned so that the end user can select suitable PPE for his tasks. The meaning of these results (e.g. breakthrough time) need to be explained to make it clear for them user. On that basis the user will be able to evaluate the protection and protection time in his/her own working situation.

3.11 Safety devices for diving equipment

1. Breathing equipment

The breathing equipment must make it possible to supply the user with a breathable gaseous mixture, under foreseeable conditions of use and taking account in particular of the maximum depth of immersion.

2. Where the foreseeable conditions of use so require, the equipment must comprise:

(a) a suit which protects the user against the pressure resulting from the depth of immersion (see 3.2) and/or against cold (see 3.7);

(b)an alarm designed to give the user prompt warning of an approaching failure in the supply of breathable gaseous mixture (see 2.8);

(c)a life-saving suit enabling the user to return to the surface (see 3.4.1).

The term "diving equipment" is restricted to equipment used for the diving in a sub aqueous (i.e. water) medium.

Respiratory tracts are subjected to the effect of the pressure. Breathing apparatus must therefore be provided with a system automatically ordering the regulation of the feeding system in a breathable gas mixture.

Whether in a sub aqueous medium or pressurised dry medium, the user is always exposed to pressure. The flexible combinations used in practice cannot ensure a protection against the pressure within the meaning of requirement 3.2. This requirement, with regard to the pressure, imposes only that the combinations will not induce new risks arising from the equipment itself. The warning device forms integral part of the breathing apparatus aimed to article 3.11, first subparagraph.

The life saving suit which allows for the rapid escape of the diver should not be confused with the diving suit. This rescue equipment (called a “buoyancy compensator”) is worn independently and over the diving suit which provides the diver with means for controlling buoyancy, for holding him in a head-up position at the surface even if he is unconscious and in cases of emergency for returning at the surface.

1.7 **ANNEX III**

TECHNICAL DOCUMENTATION SUPPLIED BY THE MANUFACTURER

The documentation referred to in Article 8 (1) must comprise all relevant data on the means used by the manufacturer to ensure that a PPE complies with the basic requirements relating to it.

In the case of PPE models referred to in Article 8 (2), the documentation must comprise in particular:

1. the manufacturer's technical file consisting of:

(a) overall and detailed plans of the PPE accompanied, where appropriate, by calculation notes and the results of prototype tests in so far as necessary for the verification of compliance with the basic requirements;

(b) an exhaustive list of the basic safety requirements and of the harmonized standards or other technical specifications referred to in Articles 3 and 5, taken into account in the design of the model;

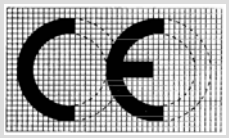
2. a description of the control and test facilities to be used in the manufacturer's plant to check compliance of production PPE with the harmonized standards or other technical specifications and to maintain quality level;

3. a copy of the information notice referred to in Annex II, 1.4.

When establishing the technical documentation, the manufacturer or his authorised representative must take account of the category of PPE, in particular the definition of the means of control and tests necessary.

It should be noted that there is no on-site assessment of the test equipment of the manufacturer under the conformity assessment procedure as described in Article 10. However, the description of the test equipment as well as the instructions for use are important for the assessment of the conformity of PPE with the requirements of the directive. Therefore, they have to be considered to be a part of the technical file.

The text does not specify the archival life of technical documentation. However, it is generally understood that this period is ten years from the date the PPE was last placed on the market.

1.8	**ANNEX IV**
	CE CONFORMITY MARKING AND INFORMATION
	- The CE conformity marking shall consist of the initials 'CE' taking the following form:
	
	- If the CE marking is reduced or enlarged the proportions given in the above graduated drawing must be respected.
	- The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm. This minimum dimension may be waived for small-scale PPE.

The CE marking symbolises the conformity of the PPE with all the provisions of the directive (i.e. a declaration of conformity) and that it has been subject to the appropriate conformity assessment procedures.

It must be affixed before a PPE is placed on the Community market. However, it may be affixed in a third country if the PPE is manufactured there.

Where a PPE is subject to several directives, which all provide for the affixing of the CE marking, it indicates that the product is presumed to conform to the provisions of all these directives.

Equipment which is not covered by the directive cannot be CE marked indicating conformance with its provisions. However, this evidently does not preclude CE marking to products covered by other so-called "New Approach" Directives.

The CE marking must be affixed visibly, legibly and indelibly to the PPE. However, where this is not possible it must be affixed to the packaging (smallest unit intended for end-user).

In case of PPE of category III, the CE marking shall include the identification number of the Notified Body carrying out the quality control after Art. 11 A or B. The CE marking and the identification number should have the same size.

CE marking is the only marking which symbolises conformity with the provisions of the directives. Additional markings and marks are possible, provided that they fulfil a different function from that of the CE marking, are not liable to cause confusion with it, and do not reduce its legibility and visibility.

1.9 **ANNEX V**

CONDITIONS TO BE FULFILLED BY THE BODIES OF WHICH NOTIFICATION HAS BEEN GIVEN

(Article 9 (2))

The bodies designated by the Member States must fulfil the following minimum conditions:

1. ***availability of personnel and of the necessary means and equipment;***
2. ***technical competence and professional integrity of personnel;***
3. ***independence, in carrying out the tests, preparing the reports, issuing the certificates and performing the surveillance provided for in the Directive, of staff and technical personnel in relation to all circles, groups or persons directly or indirectly concerned with PPE;***
4. ***maintenance of professional secrecy by personnel;***
5. ***subscription of a civil liability insurance unless that liability is covered by the State under national law.***

Fulfilment of the conditions under 1 and 2 shall be verified at intervals by the competent authorities of the Member States.

Member States are responsible for the notification of bodies which comply with the above **minimum** requirements. The assessment of the Body seeking notification determines if it is technically competent and capable of carrying out the conformity assessment procedures in question, and if it can demonstrate the necessary level of independence, impartiality and integrity.

The EN 45000 and EN ISO/IEC 17000 series of standards are important instruments to help in establishing conformity with the requirements of the PPE Directive. Accreditation according to these standards supports the technical part of notification and, although it is not mandatory at Community level, it remains an important and privileged instrument for evaluating the competence, impartiality and integrity of the bodies to be notified.

To be eligible a Body must be a legal entity established on the territory of the Member State concerned and to come under its jurisdiction.

To guarantee independence and impartiality a Body must be a fully independent third-party Body and must not be the manufacturer, designer or supplier of the PPE under assessment. Notified Bodies may, on their own responsibility, accept measurement results from a manufacturer's laboratory.

There is no guidance document at the European level which indicates the financial value of liability insurance. It should generally correspond to the level of activities of the Notified Body in the field of PPE. The insurance should in particular cover cases where the Notified Body may be obliged to withdraw certificates.

A Notified Body can have part of its work carried out by another Body/laboratory (subcontracting) on the basis of established and regularly monitored competence. Subcontracting does not entail the delegation of powers or responsibilities. Therefore, the Notified Body remains responsible for all of its activities and issued documents.

None of the minimum criteria provides for an explicit requirement for the Notified Body to establish and maintain a quality system although the conduct of conformity assessment and the issue of certificates and reports must in itself be subject to a review process. It needs to establish appropriate and documented procedures of quality control in order to ensure continual compliance, as required.

Council Decision 93/465/EEC contains a general obligation for Notified Bodies to participate, or ensure proper representation, in the co-ordination and co-operation activities of Notified Bodies at a European level. Since 1992 there has existed the Horizontal Committee of the European Co-ordination and Co-operation of Notified Bodies in the field of PPE (HCNB) and its Vertical Groups (VGs) dealing with the different types of PPE. Contact address of HCNB:

http://ec.europa.eu/enterprise/mechan_equipment/ppe/nb.htm

In general the “Recommendation for Use” sheets of the HCNB and its VGs should be applied by all Notified Bodies.

In addition, to provide for technical competence Notified Bodies are obliged to either participate directly or be represented in European standardisation or otherwise ensure that they keep themselves informed of the standardisation and its development.

Member States are not obliged under Community law to notify all bodies demonstrating technical competence.

Member States are responsible for ensuring that Notified Bodies maintain their competence at all times and are capable of carrying out the work for which they are notified. It is up to the Member States to choose the means and methods for this. The competence of the Notified Body shall be subject to surveillance, which is carried out at regular intervals and follows the practice established by the national accreditation organisation.

Member States may decide to notify a Body for a limited period of time, and to renew the notification subsequently.

1.10 **ANNEX VI**

MODEL EC DECLARATION OF CONFORMITY

The manufacturer or his authorized representative established in Community ([1]):
.....
.....

declares that the new PPE described hereafter ([2])
.....
.....

is in conformity with the provisions of Council Directive 89/686/CEE and, where such is the case, with the national standard transposing harmonized standard No ..... (for the PPE referred to in article 8 (3))

is identical to the PPE which is the subject of EC certificate of conformity No ..... issued by ([3])([4])**.....**
.....

is subject to the procedure set out in article 11 point A or point B ([4]) of Directive 89/686/CEE under the supervision of the notified body([3])
.....
.....

Done at ....., on .....

.....
Signature ([5])

([1]) Business name and full address; authorized representatives must also give the business name and address of the manufacturer.

([2]) Description of the PPE (make, type, serial number, etc.).

([3]) Name and address of the approved body.

([4]) Delete whichever is inapplicable.

([5]) Name and position of the person empowered to sign n behalf of the manufacturer or his authorized representative

The EC declaration of conformity must be drawn up by the manufacturer or the authorised representative established within the Community in one of the official languages of the Community when the PPE is placed on the market. The EC declaration of conformity is issued under the sole responsibility of the manufacturer or authorised representative established within the Community.

The EC declaration of conformity must be made available to the surveillance authority upon request. Its essential objective is to enable public authorities to ensure that PPE placed on the

market conform to the BHSRs of the Directive. It is not required that PPE are accompanied by the EC declaration of conformity.

It is generally recognised that the market surveillance authority of a Member State can request a translation of the EC declaration of conformity into its official language.

For category I PPE, the EC declaration of conformity must ensure that the PPE satisfies the BHSR s of the Directive.

For category II and III PPE, the EC declaration of conformity must additionally ensure that the PPE is in conformity with the type/model for which an EC-type examination certificate has been issued. The name, address and identification number of the Notified Body which issued the certificate are to be included in the EC declaration of conformity.

For category III PPE, the address and identification number of the Notified Body involved in the quality control for the final product set out in Article 11 A+B of the directive must also be included in addition to the above.

The EC declaration of conformity must be made available to the market surveillance authority upon request. It is generally recognised that the market surveillance authority of a Member State can request a translation of the EC declaration of conformity into its official language. It is not required the PPE is accompanied by the EC declaration of conformity.

The EC declaration of conformity must be kept for at least ten years from the last date of manufacture of the PPE.

Remark:

Annex VI contains in its 3rd paragraph a printing error. The reference to article 8(3) is wrongly cited. In fact the reference must read: “(for the PPE referred to in article 8(2))”

1.11 APPENDIX GUIDE FOR THE CATEGORISATION OF PERSONAL PROTECTIVE EQUIPMENT (PPE)[24]

24 It should be stressed that when establishing the proper category for PPE, the level of risk it provides protection against evidently needs to be considered.

Summary of the provisions of Directive 89/686/EEC concerning categorisation of PPE, according to the level of risk the intended user is protected against. (more explanation about this can be found in the guidance document on the PPE Directive)

1. definition of PPE (article 1.2)

   PPE shall mean any device or appliance designed to be worn or held by an individual for protection against one or more health and safety hazards.

   PPE shall also cover:

   1.1. a unit constituted by several devices or appliances which have been integrally combined by the manufacturer for the protection of an individual against one or more potentially simultaneous risks (article 1.2 (a))

   1.2. a protective device or appliance combined, separably or inseparably, with personal non-protective equipment worn or held by an individual for the execution of a specific activity (article 1.2 (b))

   1.3. interchangeable PPE components which are essential to its satisfactory functioning and used exclusively for such equipment (article 1.2. (c))

   1.4. any system placed on the market in conjunction with PPE for its connection to another external, additional device shall be regarded as an integral part of that equipment even if the system is not intended to be worn or held permanently by the user for the entire period of risk exposure (article 1.3)

2. equipment excluded from the scope of the PPE Directive, referred to in this document as category 0

   2.0. PPE covered by another Directive designed to achieve the same objectives as this Directive with regard to placing on the market, free movement of goods and safety (article 1.4 first indent)

   2.1. PPE designed and manufactured specifically for use by armed forces or in the maintenance of law and order (helmets, shields, etc.) (annex I item 1)

   2.2. PPE for self-defence (aerosol canisters, personal deterrent weapons, etc.) (annex I item 2)

   2.3. PPE designed and manufactured for private use against :

   - Adverse atmospheric conditions (headgear, seasonal clothing, footwear, umbrellas, etc.)
   - Damp and water (dish-washing gloves, etc.)
   - Heat (gloves, etc.) (annex I item 3)

   2.4. PPE intended for the protection or rescue of persons on vessels or aircraft, not worn all the time (annex I item 4)

   2.5. Helmets and visors intended for users of two- or three-wheeled motor vehicles (annex I item 5, added by Directive 93/95/EEC)

3. categorisation

3.1. PPE classified as category I (article 8.3)
PPE of simple design where the designer assumes the user can himself assess the level of protection provided against the minimal risks concerned the effects of which, when they are gradual, can be safely identified by the user in good time.

This category shall cover exclusively PPE intended to protect the user against:

3.1.1. mechanical action whose effects are superficial (gardening gloves, thimbles, etc.)
3.1.2. cleaning materials of weak action and easily reversible effects (gloves affording protection against diluted detergent solutions, etc.)
3.1.3. risks encountered in the handling of hot components which do not expose the user to a temperature exceeding 50°C or to dangerous impacts (gloves, aprons for professional use, etc.)
3.1.4. atmospheric agents of a neither exceptional nor extreme nature (headgear, seasonal clothing, footwear, etc.)
3.1.5. minor impacts and vibrations which do not affect vital areas of the body and whose effects cannot cause irreversible lesions (light anti-scalping helmets, gloves, light footwear, etc.)
3.1.6. sunlight (sunglasses)

3.2. PPE classified as category II (article 8.2)

This category shall cover all PPE not mentioned under items 3.1. or 3.2.

3.3. PPE classified as category III (article 8.4)
PPE of complex design intended to protect against mortal danger or against dangers that may seriously and irreversibly harm the health, the immediate effects of which the designer assumes the user cannot identify in sufficient time.

This category shall cover exclusively:

3.3.1. filtering respiratory devices for protection against solid and liquid aerosols or irritant, dangerous, toxic or radiotoxic gases
3.3.2. respiratory protection devices providing full insulation from the atmosphere, including those for use in diving
3.3.3. PPE providing only limited protection against chemical attack or against ionizing radiation
3.3.4. emergency equipment for use in high-temperature environments the effects of which are comparable to those of an air temperature of 100°C or more and which may or may not be characterized by the presence of infra-red radiation, flames or the projection of large amounts of molten material
3.3.5. emergency equipment for use in low-temperature environments the effects of which are comparable to those of an air temperature of –50°C or less
3.3.6. PPE to protect against falls from a height
3.3.7. PPE against electrical risks and dangerous voltages or that used as insulation in high-tension work

PART 1 : per type of PPE

Type of PPE		Certification category	Reason
1.	**equipment for hearing protection**		
1.1	All equipment protecting hearing (weather worn in or over the ear)	II	3.2.

Type of PPE		Certification category	Reason
2.	**equipment for eye protection**		
2.1	All eye protectors and filters	II	3.2.
Except:			
2.2	Eye protectors and filters designed and manufactured for use in high-temperature environments the effects of which are comparable to those of an air temperature of 100°C or more and which may or may not be characterised by the presence of infra-red radiation, flames or the projection of large amounts of molten material	III	3.3.4.
2.3	Eye protectors and filters designed and manufactured to provide protection against ionising radiation	III	3.3.3.
2.4	Eye protectors and filters designed and manufactured to provide protection against electrical risks	III	3.3.7.
2.5	Swimming and/or diving goggles and masks	I	3.1.1.
2.6	Eye protectors and filters designed and manufactured exclusively to provide protection against sunlight, sun glasses (not corrective) for private and professional use. This includes cases where glasses are tinted after manufacturing or any other assembly after manufacturing (e.g. assembly of sunlight protective lenses in a non CE marked frame)	I	3.1.6.
2.7	Ski goggles of all types, except corrective spectacles	I	3.1.6.
2.8	Corrective spectacles including corrective sunglasses *note* : where corrective spectacles provide protection other than protection against sunlight (e.g. against impact, abrasive projections, etc.), they are classified as personal protective equipment of the category corresponding to the hazard in question solely in respect of their protective features	0	Medical use
2.9	Visors incorporated into helmets designed and manufactured for use with two- or three-wheeled motor vehicles	0	2.5.

Type of PPE		Certification category	Reason
3.	**equipment for protection against falls from a height**		
3.1	All protective equipment designed and manufactured to provide protection against falls from a height, for private or professional use (working at heights, falling off boats, mountaineering, rock climbing, speleology, etc.). This category also includes equipment for working at a height and with support (harnesses, thigh straps, belts, etc.) *Note* : this equipment includes harnesses (thigh straps, shoulder belts, etc.) and all accessories intended for attaching a person to a structure, with the exception of anchorage points forming an integral part of the structure or rock face. ▪ For example: for professional use: lanyards, mobile fall arresters, karabiners, energy absorbers, connectors, anchor points, etc. ▪ for mountaineering, rock climbing, and speleology: connectors (simple ropes), ropes for abseiling (double ropes), slings, climbing karabiners, rope clamps, chocks, pitons, ice pitons, gripping devices for use on artificial climbing walls, etc.	III	3.3.6.
Except:			
3.2	Anchorage points forming an integral part of the structure or rock face	0	Definition PPE
3.3	Equipment for accessing or leaving positions at a height (winch seats, descenders not fitted with a built-in speed-regulating system, etc.)	0	Definition PPE
3.4	Equipment for climbing, rock climbing, speleology etc. (ice-axes, hammers, descenders not fitted with a built-in speed-regulating system, rope-climbing equipment, etc.)	0	Definition PPE
3.5	Support equipment (harnesses, etc.) designed and manufactured for use with parachutes, paragliders, hanggliders, etc. and which cannot be used for purposes other than those for which they were designed.	0	Definition PPE
3.6	Emergency parachutes	0	2.4.

Type of PPE		Certification category	Reason
4.	**equipment for head protection**		
4.1	All helmets, including sports helmets	II	3.2.
Except:			
4.2	Helmets designed and manufactured for use in high-temperature environments the effects of which are comparable to those of an air temperature of 100°C or more and which may or may not be characterised by the presence of infra-red radiation, flames or the projection of large amounts of molten material.	III	3.3.4.
4.3	Helmets designed and manufactured to provide protection against electrical risks	III	3.3.7.
4.4	Light headgear designed and manufactured to provide scalp protection	I	3.1.5.
4.5	Helmets designed and manufactured for riders of 2- or 3- wheeled motor vehicles, including racing helmets	0	2.5.
4.6	Helmets designed and manufactured specifically for use by the armed forces or in the maintenance of law and order	0	2.1.

Type of PPE		Certification category	Reason
5.	**equipment for part or whole face protection**		
5.1	All equipment	II	3.2.
Except:			
5.2	Equipment designed and manufactured for use in high-temperature environments the effects of which are comparable to those of an air temperature of 100°C or more and which may or may not be characterised by the presence of infra-red radiation, flames or the projection of large amounts of molten material	III	3.3.4.
5.3	Equipment designed and manufactured for use in low-temperature environments the effects of which are comparable to those of an air temperature of –50°C or less	III	3.3.5.
5.4	Equipment designed and manufactured to provide protection against electrical risks	III	3.3.7.
5.5	Visors designed and manufactured for incorporation into helmets used by riders of 2- or 3-wheeled motor vehicles, including racing visors	0	2.5.

Type of PPE		Certification category	Reason
6.	**Protective clothing**		
6.1	All items of clothing and/or accessories (whether or not detachable) designed and manufactured to provide specific protection remark : o this category includes also protective clothing used for sports activities such as diving suits, protective clothes for waterskiing, etc. o this category also includes bullet-proof clothing used by other than the armed forces (for instance security guards)	II	3.2.
Except:			
6.2	Clothing and/or accessories (whether or not detachable) designed and manufactured to provide protection against electrical risks	III	3.3.7.
6.3	Clothing and/or accessories (whether or not detachable) designed and manufactured for use in high-temperature environments the effects of which are comparable to those of an air temperature of 100°C or more and which may or may not be characterised by the presence of infra-red radiation, flames or the projection of large amounts of molten material	III	3.3.4.
6.4	Clothing and/or accessories (whether or not detachable) designed and manufactured for use in low-temperature environments the effects of which are comparable to those of an air temperature of –50°C or less	III	3.3.5.
6.5	Clothing and/or accessories (whether or not detachable) designed and manufactured to provide only limited protection against chemical attack or against ionising radiation *Note* : the manufacturer shall indicate the products against which protection is provided, and the time for which such protection lasts.	III	3.3.3.
6.6	Clothing and/or accessories (whether or not detachable) designed and manufactured to provide complete insulation from the atmosphere	III	Equivalent to 3.3.2.
6.7	Clothing and/or accessories (whether or not detachable) designed and manufactured to provide protection against weather conditions which are neither exceptional nor extreme, for professional use	I	3.1.4.
6.8	Clothing and/or accessories (whether or not detachable) designed and manufactured to provide protection against mechanical action the effects of which are superficial	I	3.1.1.

6.9	Clothing and/or accessories (whether or not detachable) designed and manufactured to provide protection against risks arising from handling hot components which do not expose the user to a temperature of over 50°C or to dangerous impacts	I	3.1.3.
6.10	Clothing and/or accessories (whether or not detachable) designed and manufactured specifically for use by the armed forces or in the maintenance of law and order, including bullet-proof clothing or jackets, clothing protecting against biological contamination or ionising radiation *remark* : the given examples of garments used by others than armed forces or maintenance of law and order, are PPE and in category II	0	2.1.
6.11	Clothing and/or accessories (whether or not detachable) designed and manufactured to provide protection against weather conditions which are neither exceptional nor extreme, for private use	0	2.3.
6.12	Ordinary clothing and/or accessories (whether or not detachable) or sports clothing and/or accessories (not providing specific protection), including uniforms	0	2.3.
6.13	Motorcyclists' garments and additional protection. o If only protection against climatic conditions : see 6.11 o If additional protection claimed (e.g. impact protectors for limb or back, pads for elbow or shoulders, protection from cuts and abrasion, …)	0 depends on protection included	2.3.

Type of PPE		Certification category	Reason
7.	**Respiratory protective equipment**		
7.1	All respiratory protective equipment (however described) designed and manufactured to provide protection against solid aerosols, liquid aerosols or gases; All respiratory protective equipment designed and manufactured to provide full insulation from the atmosphere; all respiratory protective equipment designed and manufactured for use in diving	III	3.3.1. and 3.3.2.
Except:			
7.2	All respiratory protective equipment designed and manufactured specifically for use by the armed forces or in the maintenance of law and order	0	2.1.
7.3	Surgical masks *Note :* where such masks are intended to protect the wearer against microbial and viral infections, etc. they are in certification category III (personal protection rather than medical use)	0	Medical use

Type of PPE		Certification category	Reason
8.	**equipment for leg and/or foot and anti-slip protection**		
8.1	All equipment and/or accessories (whether or not detachable) designed and manufactured specifically to protect the foot and/or the leg and to provide anti-slip protection *Note* : Protection against static electricity is included in this category since this equipment is used in environments with potential risk of explosion.	II	3.2.
Except:			
8.2	Equipment and/or accessories (whether or not detachable) designed and manufactured to provide protection against electrical risks for work involving dangerous voltages, or used to provide insulation against high voltages	III	3.3.7.
8.3	Equipment and/or accessories (whether or not detachable) designed and manufactured for use in high-temperature environments the effects of which are comparable to those of an air temperature of 100°C or more and which may or may not be characterised by the presence of infra-red radiation, flames or the projection of large amounts of molten material	III	3.3.4.
8.4	Equipment and/or accessories (whether or not detachable) designed and manufactured for use in low-temperature environments the effects of which are comparable to those of an air temperature of –50°C or less	III	3.3.5.
8.5	Equipment and/or accessories (whether or not detachable) designed and manufactured to provide only limited protection against chemical attack or ionising radiation. *Note :* the manufacturer shall indicate the products against which protection is provided, and the time for which such protection lasts.	III	3.3.3.
8.6	Sports equipment (in particular sport shoes) and/or accessories (whether or not detachable) designed and manufactured to protect against minor impacts and vibrations which do not affect vital areas of the body and whose effects cannot cause irreversible lesions. <u>Note:</u> sport shin-guards (e.g. for football, hockey) and protective equipment are generally category 2 unless designed only for protection against minor impacts.	I	3.1.5.
8.7	Equipment and/or accessories (whether or not detachable) designed and manufactured to provide protection against weather conditions which are neither exceptional nor extreme, for professional use	I	3.1.4.

8.8	Equipment and/or accessories (whether or not detachable) designed and manufactured to provide protection against atmospheric conditions, for private use	0	2.3.
8.9	Equipment and/or accessories (whether or not detachable) designed and manufactured specifically for use by the armed forces or in the maintenance of law and order, including equipment protecting against biological contamination or ionising radiation	0	2.1.
8.10	Some shoes, in particular sports shoes, contain components intended to absorb shock when walking, running, etc. or to ensure a good grip or stability. These components are to be regarded as being intended to increase comfort *Note:* this category includes in particular football and rugby boots and spiked running shoes.	0	Definition PPE

Type of PPE		Certification category	Reason
9	**Equipment for hand and arm protection**		
9.1	All equipment and/or accessories (whether or not detachable) designed and manufactured specifically to protect the arm and/or the hand *Note :* this includes all garments protecting the hand or part of the hand, including gloves, fingerless gloves, mittens, garments protecting the fingers only or the palm only, etc.	II	3.2.
Except:			
9.2	Equipment and/or accessories (whether or not detachable) designed and manufactured to provide protection against electrical risks for work involving dangerous voltages, or used to provide insulation against high voltages.	III	3.3.7.
9.3	Equipment and/or accessories (whether or not detachable) designed and manufactured for use in high-temperature environments the effects of which are comparable to those of an air temperature of 100°C or more and which may or may not be characterised by the presence of infra-red radiation, flames or the projection of large amounts of molten material, including fire-fighters' equipment.	III	3.3.4.
9.4	Equipment and/or accessories (whether or not detachable) designed and manufactured for use in low-temperature environments the effects of which are comparable to those of an air temperature of –50°C or less	III	3.3.5.
9.5	Equipment and/or accessories (whether or not detachable) designed and manufactured to provide only limited protection against chemical attack or ionising radiation *Note :* the manufacturer shall indicate the products against which protection is provided and the time for which such protection lasts.	III	3.3.3.
9.6	Equipment and/or accessories (whether or not detachable) designed and manufactured to protect against cleaning materials of weak action (for dishwashing, cleaning etc.), for professional use	I	3.1.2.
9.7	Equipment and/or accessories (whether or not detachable) designed and manufactured to provide protection against mechanical action the effects of which are superficial (pricks due to sewing, gardening, dirty work, sports, etc.)	I	3.1.1.
9.8	Equipment and/or accessories (whether or not detachable) designed and manufactured to protect against heat and risks encountered in the handling of hot components which do not expose the user to a temperature exceeding 50°C or to dangerous impacts and against unexceptional cold weather, for professional use	I	3.1.3. and 3.1.4.

9.9	Gloves and finger guards for medical use in the patient's environment	0	Medical use
9.10	Gloves designed and manufactured to provide protection against damp, non-extreme heat or cold, for private use	0	2.3.
9.11	Equipment and/or accessories (whether or not detachable) designed and manufactured specifically for use by the armed forces or in the maintenance of law and order, including equipment protecting against biological contamination or ionising radiation	0	2.1.

PART 2 : per type of risk

Remark: the tables in this part contain all type of PPE and are not in contradiction with the tables in part 1. These are only given for further clarification.

Type of PPE		Certification category	Reason
10.	**Equipment designed to prevent drowning or for use as buoyancy aids**		
10.1	All equipment designed and manufactured to prevent drowning or for use as buoyancy aids, including swimming aids and inflatable buoys which are not regarded as toys (for use exclusively in shallow water) *Note* : o Includes crampons, ropes and other equipment used to get out of water after falling through ice. o Also included: swimming suits with incorporated floats. o Also included: swimming armbands	II	3.2.
Except:			
10.2	Life-buoys and life-jackets for emergency use by ship and aircraft passengers *Note:* the terms “ship” and “aircraft” refer exclusively to those carrying passengers and to seagoing vessels subject to the international conventions of the IMO. Pleasure craft (motor boats and sailing boats), fishing boats, working boats, etc. are not included in this category.	0	2.4.
10.3	Buoyancy aids that are not worn but held by the user (such as foam boards, etc.)	0	PPE definition
10.4	Buoyancy aids that are not designed to be kept in place while worn or assure the upright position of the wearer (such as ‘tyre type’ buoys, floating belts, etc.)	0	PPE definition

Type of PPE		Certification category	Reason
11.	**Equipment for protection against electrical risks**		
11.1	Equipment for protection against electrical risks *Note* : Dangerous voltages means a voltage equal to or exceeding 50 V alternating current or 75 V direct current	III	3.3.7.
Except:			
11.2	Hand-held insulating tools	0	PPE definition
11.3	Protective equipment (such as shoes, garments, etc.) against static electricity *Note :* this equipment is used in environments with potential risk of explosion	II	3.2.

Type of PPE		Certification category	Reason
12.	**Equipment designed and manufactured to protect against vibration**		
12.1	All PPE designed and manufactured to protect the wearer against vibrations	II	3.2.
Except:			
12.2	Equipment protecting against minor impacts and vibrations which do not affect vital areas of the body and whose effects cannot cause irreversible lesions (such as light anti-scalping helmets, gloves, light footwear, etc.)	I	3.1.5.

Type of PPE		Certification category	Reason
13.	**Rescue equipment**		
13.1	Resuscitation masks : if the mask has, apart from allowing adequate artificial breathing, also a protective function for the rescuer (protection against contagion by contact with the mouth of the victim for instance) then they are PPE	Depending on the type of protection	
13.2	If the rescue equipment is worn before the accident which prompts the rescue, then it is PPE *Example :* a wet suit worn continuously to prevent hypothermia in the event of falling into water is PPE	Depending on the type of protection	
Except:			
13.3	If the rescue equipment is placed on the person after the accident occurs, it is not a PPE *Example :* a sling used to rescue an unconscious person from an inaccessible point	0	PPE definition