dti

PRODUCT STANDARDS

Personal Protective Equipment

GUIDANCE NOTES ON THE UK PERSONAL PROTECTIVE EQUIPMENT REGULATIONS 2002 (S.I. 2002 NO. 1144)

OCTOBER 2002

URN 02/1284

This guide is intended to assist manufacturers of Personal Protective Equipment to understand the effect of the Regulations. It is not an authoritative interpretation of the Regulations, which is a matter for the Courts.

The guide seeks to explain the requirements of the Regulations in general terms and does not attempt to address detailed issues. You should refer to the Regulations themselves (S.I.2002 No.1144) for a full statement of the requirements.

Contents

1 Personal Protective Equipment - background to the law

The EC Directive 89/686/EEC on the approximation of the laws of Member States relating to personal protective equipment was adopted by the Council on 21 December 1989. It was implemented into UK law by the Personal Protective Equipment (EC Directive) Regulations 1992 (SI 1992/3139) (the 'Principal Regulations'). These Regulations were made on 10 December 1992 and came into effect on 1 January 1993. They have since been amended three times by the Personal Protective Equipment (EC Directive) (Amendment) Regulations 1993 (SI 1993/3074), the Personal Protective Equipment (EC Directive) (Amendment) Regulations 1994 (SI 1994/2326), and the Personal Protective Equipment (EC Directive) (Amendment) Regulations 1996 (SI 1996/3039).

The Principal Regulations apply to personal protective equipment (PPE) placed on the UK market after 1 July 1992.

In 2002, the Principal Regulations and the three amendments were consolidated into one document in the interests of providing clearer legislation and at the same time additional enforcement powers were extended to the Trading Standards Departments. The consolidated regulations called the Personal Protective Equipment Regulations 2002 (SI 2002 No. 1144) came into effect on 15 May 2002. These Regulations revoke the Principal Regulations and subsequent three amendments.

As these Regulations maintain the implementation of the Personal Protective Equipment Directive, a transposition note setting out how the Government has transposed into UK law the main elements of this Directive is available from the DTI's Standards and Technical Regulations Directorate. The Contact details are on page 17. This transposition note is also published on the DTI's website at the following address: **http://www.dti.gov.uk/strd/ppetrans.pdf**.

Failure to comply with these Regulations may mean that PPE may be prohibited from being placed on the Community /European Economic Area (EEA)* market. If previously placed on the market in non-compliance, PPE may be forfeited.

PPE complying with the PPE Directive's requirements may be supplied anywhere in the EEA.

---

* There are 15 member states of the Community: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden and the UK. The EEA adds Iceland, Liechtenstein and Norway.

2 Free movement of goods

Achieving the free movement of goods - one of the four basic freedoms - lies at the heart of the drive to create the single European market. In May 1985, European Community Ministers agreed on a 'New Approach to Technical Harmonisation and Standards' to fulfil this objective.

'New Approach' Directives (that is Community laws) set out 'essential requirements' (for safety, for example), written in general terms, which must be met before products may be supplied in the United Kingdom or anywhere else in the Community. European standards then fill in the detail. Conformity with such standards is the main way for businesses to comply with the 'essential requirements'. The Directives also say how manufacturers are to show that products meet the 'essential requirements'. Products meeting these requirements carry CE marking, which means that they can be sold anywhere in the Community.

For the wider background and to find out more about what the single European market means for your business, get your copy of *Keeping Your Product on the Market* by telephoning DTI's Publications Orderline on 0870 1502 500.

3 General Product Coverage

3.1 Definition of PPE (regulation 2(2))

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

PPE also includes:

- 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;

- 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;

- interchangeable components which are essential to its satisfactory functioning and used exclusively for such equipment.

3.2 The Regulations also apply to any system placed on the market in conjunction with PPE for its connection to another external, additional device. This shall be regarded as an integral part of that PPE even if the system is not intended to be worn or held permanently by the user for the entire period of risk exposure (Regulation 4).

3.3 PPE specifically excluded from the Regulations' scope

- PPE manufactured for use in a country outside the Community, or imported into the Community for re-export to a country outside the Community.

- Non-compliant PPE for presentation at trade fairs, exhibitions and the like, provided that an appropriate notice is displayed drawing attention to the fact that:

  a) the PPE is not in conformity with the provisions of the Directive; and

  b) it may not be acquired or used until it has been brought into conformity by the manufacturer or his authorised representative established in the Community.

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

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

- PPE designed and manufactured for private use against adverse weather; damp and water; and heat.

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

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

- Second-hand PPE, except for that which, since its last use, has been subjected to further manufacture or refurbished and resold as new PPE.

- 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 of PPE.

4 Product categorisation

The Directive provides exclusive lists of 'simple' and 'complex' design PPE. The responsibility for deciding whether a product is covered by the Directive and if so, to which category that PPE belongs, rests with the manufacturer or his authorised representative in the Community.

4.1 'Simple' design PPE

Regulation 2(2) defines 'simple PPE' (sometimes unofficially referred to as Category I PPE) as PPE models of simple design where the designer assumes that 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);
- ❑ cleaning materials of weak action and easily reversible effects (gloves affording protection against diluted detergents);
- ❑ 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);
- ❑ atmospheric agents of a neither exceptional nor extreme nature (headgear, seasonal clothing, footwear);
- ❑ minor impacts and vibrations etc which do not affect vital areas of the body and whose effects cannot cause irreversible lesions (light anti-scalping helmets, gloves, light footwear);
- ❑ sunlight (sunglasses). However, this does not include PPE used for high reflecting environment or in altitude.

4.2 'Complex' design PPE

Regulation 2(2) defines 'complex PPE' (unofficially referred to as Category III PPE) as PPE of complex design intended to protect against mortal danger, or against dangers that may seriously and irreversibly harm health, the immediate effects of which the designer assumes that 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 characterised 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 to protect against electrical risks and dangerous voltages or that used as insulation in high-tension work.

4.3 'Intermediate' design PPE

This category includes all models of PPE which are neither covered by the simple design category nor the complex design category. This category is also sometimes unofficially referred to as Category II.

5 Further Sources of Advice on coverage

Because of uncertainties about the scope of the 'simple' and 'complex' categories of the Directive and the categorisation of products covered by it not only within, but also between, the Member States, the Commission has prepared guidance which is published on their website -

http://europa.eu.int/comm/enterprise/mechan_equipment/ppe/index.htm.

One section of this guidance involves clarification of PPE categories as set out in the Directive and matters of interpretation of the Directive. This guidance has been a result of work done by the PPE Standing Committee, the role of which is described below. However, that guidance should not be taken as a definitive interpretation of the law, but only as a guide to manufacturers and Notified Bodies, to help them decide how the Directive affects the PPE in question. The guidance will be amended and updated as and when appropriate, as further information becomes available.

However, if the manufacturer still cannot decide to his satisfaction whether or not his product falls within the scope of the Directive or, if it does, to which category it belongs, advice is available from the following sources:

- **British Safety Industry Federation (BSIF):** which represents the UK PPE industry in dealings with DTI concerning the Directive (and its amending Directives) and is responsible for disseminating to interested parties information about it - including matters concerning CE marking and product classification (see contact on page 17);

- **trade associations**: which BSIF keeps fully informed of all developments relating to the Directive and its implementation. They will be familiar with the products produced by the industries they represent and should be able to help individual manufacturers consider where their products fall within the Directive;

- **independent legal advice**: which should be sought by those affected by the Regulations wherever doubt remains on matters of legal interpretation of the Directive and/or how PPE should be treated under it;

- **Approved Bodies**: which are responsible for undertaking the testing and certification procedures required by the Regulations. They will liase with the other Approved Bodies, both here and in the other Member States, and as such will have a unique insight into the treatment of PPE in all Member States. These bodies should, therefore, be able to provide advice and guidance which will help to ensure that problems will not be encountered during testing and certification;

- **standards-making bodies:** which are responsible for the development of harmonised European standards and as such have access to many experts in the technical field. Specific technical and standards related problems should be referred to them for advice (see contact on page 17);

- **local enforcement authorities:** which will be familiar with any regulatory difficulties and related problems being experienced by affected industries and will be able to offer local home authority advice to businesses.

Where doubts remain, competent authorities may raise them with the Commission who, in certain circumstances, may refer these matters to either:

- the Standing Committee on PPE, which may be appraised of any matters relating to the implementation and practical application of the PPE Directive. The Commission's representative to meetings of the Standing Committee is required to present a draft of the measures to be taken by the Commission, which will be considered by the Committee and its opinion on the draft delivered. The Commission is required to take the utmost account of the Committee's opinion when making its final proposals; or

- in the case of specific problems relating to a harmonised standard's suitability for meeting the basic health and safety requirements of the Directive, the matter may be raised with the Standing Committee set up under 98/34/EEC.

6 Review of the Directive by the European Commission

It should also be noted that the Directive is under review in Brussels at present. The objective is to examine certain areas in order to improve legibility and presentation. Other aims include clarifying the scope of the Directive and removing ambiguities. Further information on the progress of the review can be obtained from DTI's Standard and Technical Regulations Directorate, contact details on page 17.

7 General duties of manufacturers, importers and others

Under the Regulations, the onus to comply lies with the manufacturer, his authorised representative established in the Community (where the manufacturer has appointed such a representative) or, in certain circumstances, the importer responsible for first placing the PPE on the Community market.

The 2002 Regulations place the duty on any 'responsible person' who places PPE on the market to comply with certain requirements. The 'responsible person' is defined in the Regulations to include the manufacturer or his authorised representative established within the Community, or where neither manufacturer

or authorised representative is established in the Community, the person who places the PPE on the market. The Regulations also require that any person who supplies PPE must ensure that it is safe. For the purposes of the Regulations, supplying PPE includes putting PPE into service in specified circumstances.

The various duties placed on each of these parties by the Regulations are set out below.

The **manufacturer** decides, in the light of all the information available to him, whether the products he manufactures fall within the scope of the Regulations and if so, to which category they fall (i.e. 'complex' design, 'simple' design or 'intermediate'). He must ensure that PPE satisfies the essential health and safety requirements as set out in Schedule 2 of the Regulations. He should then follow the appropriate conformity assessment procedures set out in the Regulations, which are described in chapter 8.

The manufacturer's **authorised representative** (where such a representative exists) is responsible for ensuring that the above-mentioned conformity assessment procedures are carried out fully and correctly, on the manufacturer's behalf.

The **importer** should ensure that all PPE which he brings directly into the European Community, with a view to placing it on the Community market, has been manufactured in accordance with the Regulations' requirements and bears the CE marking. This may involve the importer himself arranging for the conformity assessment procedures mentioned above to be undertaken, where this has not been done previously.

All **other suppliers,** i.e. wholesalers, distributors, retailers etc., in the course of a business have a statutory duty to ensure that the equipment that they supply satisfies the safety requirements of Schedule 2 of the Regulations and bears CE marking.

8 Conformity Assessment Procedures

The appropriate conformity procedures must be determined in accordance with the PPE category. For simple, complex and intermediate categories of PPE the manufacturer or his authorised representative must apply the following conformity assessment procedures as appropriate:

1. Draw up technical documentation in accordance with Schedule 3 of the Regulations. This documentation must comprise all relevant data or means used by the manufacturer to ensure that the PPE complies with the basic requirements relating to it. This documentation essentially provides the evidence against which manufacturers of all PPE demonstrate compliance with the Regulations and its CE marking requirements. Further information on what should be included in the technical documentation is in Annex A.

2. In addition, for respective categories of PPE the following procedures must be applied:

- for PPE of 'simple' design, prepare an EC Declaration of Conformity as described in Schedule 5 of the Regulations and affix the CE mark to the product as laid down in Schedule 6 of the Regulations.

- for PPE of 'complex' design, submit the product for EC type examination procedure, as described in Schedule 7 of the Regulations and apply one of the two checking of PPE manufactured procedures laid down in Schedule 8 of the Regulations, prepare the EC Declaration of Conformity and affix the CE mark to the product as above. It should be noted that in this case the identification number of the Approved Body involved in the production control phase should be indicated alongside the CE mark.

- For PPE which is neither 'simple' nor 'complex' design (i.e. intermediate), submit the product for EC type examination to an Approved Body, prepare the EC Declaration of Conformity and affix the CE mark as described above.

Further information on the format for the EC Declaration of Conformity and the specification of CE marking are described in Annexes B and C of this booklet respectively.

9 Harmonised European Standards

The PPE Directive provides manufacturers with the option of complying with its requirements by manufacturing either directly in accordance with its basic health and safety requirements, or to harmonised European standards which have been developed specifically to allow a presumption of conformity with those requirements.

Industry and many of the Approved Bodies have been involved in the development of European standards and it seems likely that these standards will be the preferred option for demonstrating compliance.

Harmonised European standards are technical specifications adopted by the European Committee for Standardisation (CEN) on the basis of the General Orientations signed between the European Standards Organisations and the Commission on 13 November 1984, following a Mandate by the Commission pursuant to Directive 98/34/EEC.

Member States are obliged to publish the harmonised European standards for the information of their manufacturers and Notified Bodies. All published ENs are implemented in the UK as BS ENs.

In the United Kingdom, the national standards body is the British Standards Institution (BSI) and it is through BSI Technical Committees that the United Kingdom contributes to the development of standards within CEN. For details of mandated standards and for the latest standards information generally, please contact BSI at the address given on page 17. A list of standards is also available at this website - **http://europa.eu.int/comm/enterprise/mechan_equipment/ppe/stand.htm**

10 Approved Bodies (referred to as 'notified bodies' in other New Approach directives)

For the purposes of the Regulations, an approved body is a body which either has been appointed by the Secretary of State for Trade and Industry as a United Kingdom body under Regulation 13, or appointed by a Member State in the Community other than the United Kingdom, to carry out one or more of the conformity assessment procedures referred to above. The name of any such body and the scope of its approval will be notified to the Commission and to other Member States. Each body is assigned a unique identification number and details published in the Official Journal of European Communities. Manufacturers or their authorized representatives are free to make use of the services of Approved Bodies based in any of the 15 Member States. A list of UK Approved Bodies is available from DTI website at the following address: **http://www.dti.gov.uk/strd/ppeablst.pdf**

In case of United Kingdom Approved Bodies, appointments will be made following assessment by the United Kingdom Accreditation Service (UKAS) in accordance with DTI guidelines for appointment (ref URN 98/981). Copies of the guidelines are available by telephoning DTI's Publications Orderline on 0870 1502 500 or can be downloaded from the DTI's website at the following address:
http://www.dti.gov.uk/strd/ppeabgde.pdf

11 Free circulation

Member States are required to ensure that PPE is 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 people, domestic animals or property, when properly maintained and used for its intended purpose.

However, Member States may not prohibit, restrict or hinder the marketing of PPE or PPE components which satisfy the provisions of the Directive and which bear CE marking. Member States are to presume that PPE satisfies the basic health and safety requirements if it bears CE marking.

12 Safeguard Procedures

Member States are required to take all appropriate measures to withdraw from the Community/EEA market, or to prohibit and restrict the supply of products bearing CE marking which may endanger the safety and health of persons, domestic animals or property. They must then inform immediately the European Commission of its action and give reasons. The Commission must consult the parties concerned as soon as possible and, where it finds the action justified, immediately inform all Member States. The Regulations provide for the supply of non-compliant PPE to be prohibited by means of prohibition and suspension notices under the Consumer Protection Act 1987, as applied by Schedule 10 of the Regulations.

13 Enforcement, offences and penalties

13.1 Enforcement

Regulation 16 provides for the enforcement of the Regulations as applied by Schedule 10, in the United Kingdom, to be the sole responsibility of local weights and measures authorities (i.e. local authority Trading Standards Departments) in Great Britain and of district councils in Northern Ireland.

To ensure that only compliant PPE is being placed on the market, these enforcement authorities will carry out their own surveillance (for both consumer and industrial PPE) and will investigate complaints from industry and the public to establish whether there are justifiable grounds for taking enforcement action in such cases. In response to complaints, Trading Standards Departments will seek evidence (with the assistance of technical experts where necessary) that the Regulations have been breached and consider what action should be taken.

LACORS (the Local Authorities Co-ordinators for Regulatory Services) is a body whose objective is to co-ordinate enforcement and provide uniformity of interpretation. Businesses should be aware of the importance attached by LACORS and the local authorities to the provision of 'home authority' advice (i.e. where each enforcement authority in whose area a business is based assumes a proactive responsibility for the provision of guidance and advice to that business). Local authorities are seeking to work with manufacturers to help them to comply with the Regulations properly as well as taking enforcement action against manufacturers of non-compliant PPE. For further advice on this subject contact your local trading standards authority.

13.2 Offences

Enforcement of the Regulations is achieved through the application of certain provisions of the Consumer Protection Act 1987, i.e. those comprised in section 13, 'prohibition notices' and 'notices to warn' and sections 14, 16 and 17, 'suspension notices' and 'forfeiture'. Action may be directed against any person supplying goods, including retailers, distributors (whose general duties under the Regulations are given on page 7).

In seeking to ensure proper compliance, Trading Standards Departments may issue 'suspension notices', under section 14 of the 1987 Act and apply the 'forfeiture' provisions of sections 16 and 17 on the grounds that there has been a contravention in relation to the PPE of a safety provision. In relation to 'suspension notices', contravention of any provisions of the Regulations (which incorporate the provisions of the Directive) will be a contravention of a safety provision for the purposes of section 14 of the 1987 Act and such notices may be served on any supplier.

In appropriate circumstances, the Secretary of State may issue 'prohibition notices' and/or 'notices to warn' under section 13 of the 1987 Act in relation to PPE considered to be unsafe. Such notices may be served on any supplier. Should any person on whom notices are served choose to ignore them, criminal penalties (including fines and/or imprisonment) are provided for by the 1987 Act and proceedings may be taken.

However, it should be noted that the Regulations provide a simplified and more flexible approach to enforcement They permit the postponement of enforcement action for administrative breaches, such as incorrect documentation, in certain circumstances, until the manufacturer or importer in the European Economic Area (EEA) has been given the opportunity to correct the breach.

13.3 Penalties

A person upon whom a 'prohibition notice', 'notice to warn' or 'suspension notice' is served who fails to comply with that notice will be committing an offence under the Consumer Protection Act 1987. As such and subject to the nature of the offence and any mitigating circumstances, a person found to have contravened the Regulations by illegally supplying non-CE marked PPE or CE marked PPE which, when properly maintained and used for its intended purpose, could compromise the safety of individuals, domestic animals or property, and continuing to contravene the principal Regulations, may be fined up to level 5 (£5,000) on the standard scale in Great Britain, £2,000 in Northern Ireland and/or imprisoned for up to three months.

14 Interaction with other legislation

14.1 The Personal Protective Equipment at Work Regulations 1992 (S.I.1992/2966)

In addition to the PPE Directive there is also a Directive dealing with the 'use of PPE in the workplace' (89/656/EEC). The latter Directive requires the use of PPE ***at work wherever there are risks to health and safety that are not adequately controlled by other means***. That Directive was implemented on 1 January 1993 by the Personal Protective Equipment at Work Regulations 1992, (SI 1992/2966), in conjunction with several other pieces of pre-existing legislation[1] (similar legislation applies in Northern Ireland). These Regulations are enforced by the HSE and Local Authority Environmental Health Offices in Great Britain and the Department of Agriculture and Economic Development and district councils in Northern Ireland. The regulations apply to both employers and the self-employed. Guidance on those Regulations can be found in the HSE booklet, Personal Protective Equipment at Work (ISBN 0 11 8863347), which is available from HSE Books, PO Box 1999, Sudbury, Suffolk, CO10 2WA, Tel 01787 881165, Fax 01787 313995, **http://www.hsebooks.co.uk.**

PPE covered by the Personal Protective Equipment at Work Regulations 1992 is defined as all equipment designed to be worn or held to protect against one or more risks to health and safety. This includes hard hats, safety footwear, lifejackets,

---

[1] Construction (Head Protection) Regulations 1989; Control of Asbestos at Work Regulations 1987; Control of Lead at Work Regulations 1980; Control of Substances Hazardous to Health Regulations 1988 (now replaced with Control of Substances Hazardous to Health Regulations 2002); Ionising Radiations Regulations 1985; and Noise at Work Regulations 1989.

eye and hearing protection, high visibility clothing and clothing to protect against adverse weather (sufficient to cause a risk to health and safety), but not ordinary working clothes and uniforms, PPE provided for road transport (e.g. crash helmets), or portable devices for detecting or signalling risks and nuisances.

Employers are required to provide PPE free of charge where there are risks to health and safety that cannot be adequately controlled by other means. Employers need to consider what PPE is available in order to select PPE most suitable for controlling the risks. PPE must also be suitable for the user and the conditions in which it is to be used (e.g. fits correctly and is compatible with other items of PPE).

The Personal Protective Equipment at Work Regulations 1992 also require:

- ❑ employers to ensure that PPE is properly maintained and that there are proper facilities for its storage;

- ❑ employees to be adequately instructed and trained in the safe and proper use of any PPE required for their work;

- ❑ to report any defect in any PPE to their employer; and

- ❑ to return PPE to it's storage place after use.

14.2 General Product Safety Directive (GPSD) (2001/95/EC [formerly 92/59/EEC])

The underlying purpose of the GPSD is to fill in gaps in existing Community product safety legislation. The Directive therefore excludes from its scope any aspect of the safety of consumer products which is covered by other Community legislation. It follows from this that there can be no overlap between this Directive and the Personal Protective Equipment Directive (89/686/EEC). However, a consumer product may be subject to the provisions of both Directives, in so far as the PPE Directive may not regulate every aspect of the safety of that product.

14.3 Medical Devices Directive (93/42/EEC)

The Commission (DG Enterprise) is considering the interaction between this Directive and the Personal Protective Equipment Directive (89/686/EEC), with a view to clarify the scope of each Directive and the demarcation between the two. It has issued guidelines which could be helpful in particular to those manufacturers whose products serve a dual purpose , for example, as a medical device for the purposes of the MDD whilst simultaneously providing protection under the PPE Directive. In these cases it is difficult to decide under which Directive the product should fall. These guidelines can be found at the following website address:
http://europa.eu.int/comm/enterprise/medical_devices/guidelinesmed/baseguidelines.htm

15 Details of relevant documents and publications

Statutory Instruments & Acts

- The Personal Protective Equipment Regulations 2002. (S.I. 2002/1144): ISBN 0-11-039830-0
- The Personal Protective Equipment at Work Regulations 1992. (S.I. 1992/2966): ISBN 0-11-025832-0
- Personal Protective Equipment at Work Regulations (Northern Ireland). 1993 (S.R. 1993 no 20): ISBN 0-337-90520-7
- The Consumer Protection Act 1987 (chapter 43): ISBN 0-10-544387-5
- Health and Safety at Work Act (Northern Ireland) Order 1978. (S.I. 1978/1039 (N.I.9)): ISBN 0-11-084039-9

All the above are available from The Stationery Office bookshop and their agents or from the HMSO Publications Centre. Tel: 0870 600 5522.

With effect from the first printed Statutory Instrument of 1987, the full text of all published Statutory Instruments is also available on the Internet via Web Pages. They are numbered in the same Statutory Instrument series, at this website address **http://www.legislation.hmso.gov.uk/stat.htm**.

DTI Publications about PPE:

The following DTI Publications are also available on DTI website as downloadable documents:

- The Personal Protective Equipment - Approved Bodies. website address: **http://www.dti.gov.uk/strd/ppeablst.pdf**
- Guidelines for organisations seeking Approved Bodies status to undertake testing and certification of personal protective equipment. website address: **http://www.dti.gov.uk/strd/ppeabgde.pdf**
- The Personal Protective Equipment Directive - Transposition Note. website address: **http://www.dti.gov.uk/strd/ppetrans.pdf**

HSE Publications about PPE:

- Personal Protective Equipment at Work: Guidance on Regulations - ISBN 0-11-886334-7 (Priced £5).

Available from HSE's Information Centres, HMSO and other selected bookshops.

European Commission documents:

- Council Directive of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment (89/686/EEC) - OJ No L399, 30.12.1989, p.18;

- Council Directive 93/68/EEC of 22 July 1993 amending various directives including Directive 89/686/EEC (Personal Protective Equipment) - OJ No L220, 30.8.1993, p.1;

- Council Directive 93/95/EEC of 29 October 1993 amending Directive 89/686/EEC on the approximation of the laws of the Member States relating to personal protective equipment - OJ No L276, 9.11.1993, p.11.

The following publications are available electronically on the European Commission's website:

- Text of the Directive consolidated with the three amendments on the website address:
  http://europa.eu.int/comm/enterprise/mechan_equipment/ppe/dir89-686.htm

- Useful Facts in relation to Personal Protective Equipment:
  http://europa.eu.int/comm/enterprise/mechan_equipment/ppe/usefulfacts.pdf

- Frequently asked questions on the Personal Protective Equipment Directive:
  http://europa.eu.int/comm/enterprise/mechan_equipment/ppe/faq.htm

- Interpretation of the PPE Directive:
  http://europa.eu.int/comm/enterprise/mechan_equipment/ppe/interpr.htm

- PPE Notified bodies of all member States:
  http://europa.eu.int/comm/enterprise/mechan_equipment/ppe/nb.htm

- PPE Standardisation:
  http://europa.eu.int/comm/enterprise/mechan_equipment/ppe/stand.htm

- PPE Directive Working Structure:
  http://europa.eu.int/comm/enterprise/mechan_equipment/ppe/struct.htm

Other useful documents

- Council Directive of 30 November 1989 on the minimum health and safety requirements for the use by workers of personal protective equipment at the workplace (89/656/EEC) OJ No L393, 30.12.1989, p.18;

- Council Directive of 14 June 1989 on the approximation of the laws of the Member States relating to machinery (89/392/EEC) - OJ No L183, 29.6.1989, p.9;

- Council Directive of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations (83/189/EEC) - OJ No L109, 26.4.1983, p.8;

- Council Directive of 29 June 1992 concerning general product safety (92/59/EEC) - OJ No L228, 11.8.1992, p.24;

- Council Directive of 14 June 1993 concerning medical devices (93/42/EEC) - OJ Number L169, 12.7.1993, p.1;

- Council Decision of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of CE marking, which are intended to be used in the technical harmonisation Directives (93/465/EEC) - OJ No L220, 30.8.1993, p.23.

The complete texts of these Commission documents have been published in the Official Journal of the European Communities and are available from your local European Information Centre or European Documentation Centre.

16 Useful contacts and addresses

The PPE (89/686/EEC) Directive and UK Regulations.

General and Trade Matters

British Safety Industry Federation
St Asaph Business Park
Glascoed Road
St Asaph
Clywd LL17 0LJ
Tel: 01745 585600
Fax: 01745 585800
Website: **http://www.bsif.co.uk**

Enforcement Matters

LACORS (Local Authorities Co-ordinators of Regulatory Services)
10 Albert Embankment
London, SE1 7SP
Tel: 020 7840 7200
Fax: 020 7735 9977
Website: **http://www.lacots.com**

Information on Standards

British Standards Institution
Consumer Group
389 Chiswick High Road
Chiswick
London W4 4AL
Tel: 020 8996 7022
Fax: 020 8996 7048
Website: **http://www.bsi-global.com**

DTI Policy Matters

Department of Trade & Industry
Standards & Technical Regulations Directorate
321 Red Zone
151 Buckingham Palace Road
London SW1W 9SS
Tel: 020 7215 1573
Fax: 020 7215 1529
Website: **http://www.dti.gov.uk/strd/ppe.htm**

Implementation of the PPE Directive in the European Community

Commission of the European Communities
DG Enterprise
Rue de la Loi 200
B-1049 Brussels
Tel: 00 322 296 0964
Fax: 00 322 296 6273
Website:
http://europa.eu.int/comm/enterprise/policy_en.htm

The PPE (89/656/EEC) 'use' Directive and Regulations

Health & Safety Executive
Rose Court
2 Southwark Bridge
London SE1 9HF
Tel: 020 7717 6992
Fax: 020 7717 6680
Website: **http://www.hse.gov.uk**

Other relevant contacts:

CEN
The Secretariat
rue de Stassart, 36
B-1050 BRUSSELS
Tel: 00 322 519 6811
Fax: 00 322 519 6819
Website: **http://www.cenorm.be/**

European Free Trade Association
74 rue de Treves
B-1040 BRUSSELS
Fax: 00 322 296 6273

United Kingdom Accreditation Service (UKAS)
21 - 47 High Street
Feltham
Middlesex
TW13 4UN
Tel: 020 8917 8400
Fax: 020 8917 8500
Website: **http://www.ukas.com/**

Medical Devices Directive

Medical Devices Agency
Department of Health
Hannibal House
Elephant and Castle
London SE1 6TQ
Tel: 020 7972 8203 / 8300
Fax: 020 7972 8112
Website:
http://www.medical-devices.gov.uk/

Motorcyclists' Crash Helmets and Visors

Department for Transport
Vehicle Standards and Engineering Division
Zone 2/06
Great Minster House
76 Marsham Street
London SW1P 4DR
Tel: 020 7944 2084
Fax: 020 7944 2069
Website:
http://www.roads.dft.gov.uk/vehicle/standards/helmets/index.htm

General Product Safety Directive

Department of Trade & Industry
Consumer Affairs Directorate
Bay 426
1 Victoria Street
London SW1H 0ET
Tel: 020 7215 0033
Fax: 020 7215 0357
Website:
http://www.dti.gov.uk/CACP/ca/work6.htm

TECHNICAL DOCUMENTATION

A technical file must be compiled by the manufacturer or his authorised representative established in the Community for all PPE prior to its being placed on the market. The format and content of the file will vary according to the type of PPE; level of risk being protected against; method of manufacture of the PPE to which it relates (i.e. against specified harmonised standards or against other technical specifications), etc. Schedule 3 of the Regulations lists the technical documentation which must be supplied by the manufacturer before placing an item of PPE on the market. The technical file is a major element of this documentation.

Information to be supplied in Technical Documentation for all PPE

The documentation referred to in regulation 11 of the Regulations must comprise all relevant data on the means used by the manufacturer to ensure that the PPE complies with the basic health & safety requirements relating to it. It may therefore contain the following:

- description of and/or sample of the PPE to which the file relates;
- list of the basic health and safety requirements relating to the PPE in question and the means used to satisfy these requirements, including:
  - details of any harmonised European standards employed, in full or in part, in the PPE's manufacture;
  - details of any other national or other standards, or recognised specifications, employed in full or in part in the PPE's manufacture;
  - any other technical specifications taken into account;
- performance characteristics and details of intended use.

In case of PPE of other than of 'simple' design, this documentation must also contain :

1. the manufacturer's technical file comprising of

   (a) overall and detailed plans of the PPE in question, together with, where appropriate particulars of the calculations employed in the design of the PPE; and the results of the tests of any prototype of the PPE in question, which are necessary to verify its compliance with the relevant basic health and safety requirements;

   (b) a complete list of the basic health and safety requirements, national standards (if any) and other technical specifications taken into account in its design;

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

3. a copy of the information notice referred to in paragraph 1.4 of Annex II of the Directive as applied by Schedule 2 of the Regulations.

EC DECLARATION OF CONFORMITY

The manufacturer's EC declaration of conformity is a declaration in the form set out in Schedule 5 of the Regulations (which corresponds to Annex VI of the Directive) or in a form substantially to the like effect. It is prepared by the manufacturer, or his authorised representative established in the Community, certifying that the PPE covered by it is in conformity with the Directive's requirements. This form is reproduced below for ease of reference.

MODEL EC DECLARATION OF CONFORMITY

The manufacturer or his authorised representative established in the Community[1]:.....

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

is in conformity with the provisions of Council Directive 89/686/EEC 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/EEC under the supervision of the approved body[3].....
.....

Done

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

.....Signature[5]

---

(1) Business name and full address; authorised 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 on behalf of the manufacturer or his authorised representative.

CE MARKING

Before any item of PPE may be placed on the European Community market, it must meet fully the requirements of the Directive, including the CE marking requirement under Articles 12 and 13. The marking currently consists of the letters ‘CE’, taking the form shown below and should be affixed to the product and to its packaging in a visible, legible and indelible form.

The marking is as illustrated below. It may not be smaller than 5mm in its vertical height, and the proportions in diagram 2 must be maintained whatever its size. The grid does not form part of the marking and is for information only.

CE

Diagram 1

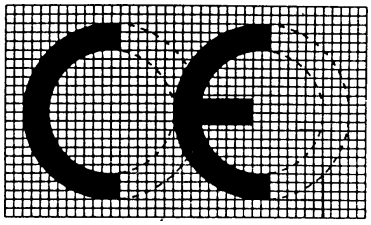

Diagram 2

Where an approved body is involved in the production control phase as indicated in Schedule 8 (corresponding Article 11 of the Directive), that body’s identification number must be added to the marking (e.g. CE 0123).

Manufacturers should note that where PPE is subject additionally to other directives which require CE marking, the affixation of CE marking shall indicate that the PPE also fulfils the provisions of the other directives.

EC TYPE-EXAMINATION PROCEDURES

Regulation 11 requires EC type-examination for all PPE covered by Article 8.2 of the Directive (i.e. all PPE except that of 'simple' design affording protection against minimal risks, as defined in Article 8.3).

Schedule 7 of the Regulations, which sets out EC Type Examination procedures of Article 10 of the Directive, requires applications to be made by the manufacturer, or the manufacturer's authorised representative, to a single approved body in respect of pre-production PPE. The application should be accompanied by an appropriate number of specimens of the PPE to which the application relates and include the following details:

a) the name and address of the manufacturer or where the application is made by an authorised representative, his name and address;

b) details of the manufacturing site which will produce the PPE to which the application relates; and

c) the manufacturer's technical file.

Unless the approved body agrees beforehand, all documentation should be in the official language(s) of the Member State in which that approved body is established.

The approved body will examine the manufacturer's technical file, in accordance with Schedule 7.4 of the Regulations, to establish that the relevant harmonised European standards and/or technical specifications applied to the PPE are suitable for demonstrating its compliance with the relevant basic health & safety requirements. It will then instigate appropriate examinations and tests of the specimens provided, to establish their conformity with the technical file.

If the approved body is satisfied that the PPE specimens provided meet fully the appropriate requirements of the Regulations, it will prepare an EC type-examination certificate (Schedule 7.5) which it will issue to the applicant. That certificate will reproduce the findings of the examinations and tests, specify any conditions attaching to its issue and incorporate descriptions and drawings necessary for the identification of the approved PPE.

Additionally, the EC type-examination certificate will be sent on request (and on a reasoned request, a copy of the manufacturer's technical file and reports on the examinations and tests carried out by that body will also be sent) to the Secretary of State, the Commission, the appropriate authorities in any other Member State and any other approved body in any Member State.

QUALITY CONTROL PROCEDURES

The Regulations require that PPE of 'complex' design should not only undergo EC type-examination, but should also be subject to one of two quality control systems as set out in its Schedule 8 (corresponding to Article 11 of the Directive). This is to ensure that PPE affording protection against mortal danger, or against dangers that may seriously and irreversibly harm the health, continue to be manufactured in such a way as to ensure conformance with the pre-production PPE which successfully passed the EC type-examination. These two systems are:

1 The 'EC' quality control system for the final product (Article 11.A of the Directive)

Under this system the manufacturer appoints an approved body (not necessarily the same body that carried out the EC type-examination) which will, at least once a year, make all checks necessary to assure itself that the PPE being manufactured:

- ❑ is homogenous;
- ❑ conforms with the pre-production PPE for which an EC type examination certificate has been issued; and
- ❑ meets the relevant basic health and safety requirements of the Directive.

To achieve this, the approved body will select at random, adequate samples of the manufactured PPE and instigate any appropriate tests as may be necessary. It is anticipated that these tests are likely to mirror those conducted under the original EC type-examination.

Where the approved body is not that which issued the relevant EC type-examination certificate, it should be able to identify and consult the issuing body.

In accordance with Article 11.A.5, the manufacturer will be provided with a report of the approved body's investigations and conclusions. If the approved body concludes in this report that it has not been able to satisfy itself that the PPE tested by it fully meets the requirements of the relevant EC type-examination certificate, it will write to the Secretary of State informing him of those findings and consider whether it should revoke that certificate. If it is not the body which issued that certificate, it is required to notify the issuing body of its findings. Upon receipt of such notification the body which issued the original certificate will itself consider revoking the certificate. If requested to do so, the manufacturer should provide the Secretary of State with a copy of the report of the approved body and permit inspection of the original thereof.

2 System for ensuring EC quality of production by means of monitoring (Article 11.B of the Directive)

This system requires the manufacturer to check each item of PPE having had his quality control system approved and periodically audited by a suitably qualified approved body. Whilst it is not a requirement of the Directive, the Commission is generally of the opinion that a quality control system that has been certified as

conforming to EN/ISO 9003 may be presumed to meet the requirements for such a system. However, companies should note that ISO 9003:1994 is now obsolete. It has been replaced by ISO 9001:2000 and they have until December 15, 2003 to upgrade to the new standard. ISO 9001:2000 will provide a presumption of conformity to the requirements of Modules D, E and H in the New Approach Directives and some explanation of how this relates to the transition period has been included in this link: **http://www.dti.gov.uk/strd/presume.htm**.

2.1 *Approval of the quality control system*

This will be undertaken by an approved body of the manufacturer's choice. The manufacturer will provide that body with all relevant information relating to the PPE concerned, including the EC type-examination certificate (together with any documents annexed to it) and the technical file. All relevant information relating to the quality control system shall also be provided, including:

- the quality objectives, organisation chart, responsibilities of executives and their powers in respect of product quality;
- the checks and tests which the manufacturer requires to be carried out after manufacture; and
- the means employed to check the efficient operation of the system. An undertaking should also be made by the manufacturer to the approved body, to maintain that system and its adequacy and efficiency in the manufacture of the PPE concerned.

The approved body will carry out an objective evaluation of the system to ascertain whether it corresponds with the information supplied by the manufacturer pertaining to it and to determine whether the system is such as to ensure that the PPE to be manufactured under it will conform with the PPE approved under the original EC type-examination. The approved body will then provide the manufacturer with a report of its findings and conclusions in accordance with Article 11.B.1C of the Directive. If it is satisfied that the system ensures that these requirements are fully met and therefore, that the relevant basic health and safety requirements of the Directive are satisfied, it will approve the system. If it is not so satisfied, it will refuse approval of the system and state its reasons for that decision.

The manufacturer should not make any change to an approved quality control system which would require the information provided to the approved body, about the system in its original application to be amended. If the manufacturer intends to make such changes, the approved body which approved the original system, must first be informed. On being so informed, that body will make all necessary investigations to satisfy itself that, if the intended changes were implemented, the modified system would still ensure conformity of the PPE with the EC type-examination certificate and the relevant basic health and safety requirements. A report of its investigations and conclusions will be made to the manufacturer in accordance with Article 11.B.2(d) of the Directive. If the body is satisfied with the modified system it will approve the changes; if it is not so satisfied, it will refuse approval giving the reasons for its decision.

2.2 Monitoring of an approved quality control system

To ensure that a manufacturer fulfils his obligations under an approved quality control system (including a system which has been modified) the approved body should be able to:

- ❑ have access to all premises relevant to any investigations necessary for this purpose;
- ❑ inspect all such premises and things therein; and
- ❑ inspect all documents which are relevant to the investigation including, in particular, those relating to the approved quality control system technical documentation and quality control manuals.

If requested, the manufacturer should also provide all such other information and assistance as the approved body may require in accordance with Article 11.B.2(b) of the Directive.

The approved body will, from time to time, carry out audits (Article 11.B.2(c) of the Directive) to ensure that the manufacturer is maintaining and applying the approved quality control system and provide the manufacturer with an audit report (Article 11.B.2(d) of the Directive). Unannounced visits to the manufacturer may also be made and a report of any such visit and audit report, if appropriate, shall also be provided to the manufacturer.

Flow chart for the conformity assessment procedures provided for in Directive 89/686/EEC on personal protective equipment