



Department of Trade and Industry

**PERSONAL PROTECTIVE
EQUIPMENT (EC DIRECTIVE)
REGULATIONS 1992**

**Guidelines for organisations seeking
Approved Body status to undertake
testing and certification of personal
protective equipment**

October 1998

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1. INTRODUCTION

This booklet is intended as a guide to potential applicants for Approved Body¹ status under The Personal Protective Equipment (EC Directive) Regulations 1992 (SI 1992/3139) ('the Regulations') which implement the Personal Protective Equipment Directive (89/686/EEC)² ('the PPE Directive') and has been prepared in the light of comments received from those already appointed and those seeking such appointment. It aims to provide guidance on the DTI's appointment criteria and bring together into one booklet the information necessary for those interested in undertaking this work.

A degree of familiarity with the Regulations, the PPE Directive and Council Decision 93/465/EEC³, 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 (see page 10), is assumed. However, copies of both are available from the DTI contact point shown on page 11.

The PPE Directive was adopted on 21 December 1989. For PPE other than that of 'simple' design protecting against minimal risks⁴, the Directive requires third party conformity assessment procedures which must be undertaken before products which fall within its scope are CE marked and placed on the Community market. These procedures are set out in Articles 10 and 11 of the Directive and are reproduced in this booklet at Appendix A.

The Regulations, which gave force to the PPE Directive's requirements in United Kingdom law, were made on 10 December 1992 and entered into force on 1 January 1993. They have since been amended by the Personal Protective Equipment (EC Directive)(Amendment) Regulations 1993 (SI 1993/3074), Personal Protective Equipment (EC Directive)(Amendment) Regulations 1994 (SI 1994/2326) and most recently by the Personal Protective Equipment (EC Directive)(Amendment) Regulations 1996 (SI 1996/3039).

The first amendment Regulations implemented Directive 93/95/EEC⁵ (adopted on 29 October 1993) and provided a transitional period until 30 June 1995 for compliance with the PPE Directive's requirements. During that time, member States had to allow PPE to be placed on the market and brought into service in conformity with national regulations in force in their territory on 30 June 1992.

Directive 93/95/EEC and the amendment Regulations also excluded motor cycle helmets and visors from the scope of the principal Directive and Regulations.

The second amending Regulations implement the CE Marking Directive 93/68/EEC⁶ in so far as it affects personal protective equipment. Its main effect is to bring

¹ A body approved by the Secretary of State for the purposes of carrying out the testing, certification & monitoring procedures laid down in the PPE Directive.

² *Official Journal of the European Communities* No. L 399, 30.12.1989, p.18-38.

³ *Official Journal of the European Communities* No. L 220, 30.8.1993, p.23-39.

⁴ see Article 8.3 of Directive 89/686/EEC.

⁵ *Official Journal of the European Communities* No. L 276, 9.11.1993, p.11-12.

⁶ *Official Journal of the European Communities* No. L 220, 30.8.1993, p.1-22.

greater consistency to the CE marking arrangements for a number of such products. The main provisions entered into force on 1 January 1995, with a two year transition period while manufacturers adapted to the changed CE marking requirements. A simplified and more flexible approach to enforcement, thereby reducing burdens on UK businesses, is also provided by these amendment Regulations.

The final amending Regulations provide that the last two digits of the year in which the CE marking was affixed is no longer a requirement.

Under regulation 4 of the Regulations, the Secretary of State for Trade and Industry may approve bodies for the purposes of undertaking the testing and certification requirements of the PPE Directive which are set out in the schedule to the Regulations as amended. Applicants for appointment will be considered against the United Kingdom's criteria which are set out in detail on pages 4 & 5. These criteria are based on the EN45000 series of standards and also take into account the minimum conditions to be fulfilled by such bodies as given in Annex V to the Directive (reproduced at Appendix B).

Any such approval by the Secretary of State may be given for specified purposes. The name of an Approved Body and the scope of its approval will be notified to the Commission and to the other member States. Notification implies, not only that Approved Bodies meet the competence criteria and that they can carry out conformity assessment activities under the Regulations, but also their willingness to take part in any co-ordination activities organised by the Commission.

Also under regulation 4, the Secretary of State may withdraw an approval if the Approved Body ceases to satisfy the minimum conditions of Annex V to the Directive. Where a body has been accredited by United Kingdom Accreditation Service (UKAS), and that accreditation has been taken into account in the assessment of that body against the criteria in these Guidelines, suspension or withdrawal of that accreditation may be taken to mean that the body no longer meets the minimum requirements.

Subject to the terms of the Secretary of State's approval, an Approved Body may:

- conduct examinations and tests and issue EC type-examination certificates in respect of pre-production PPE, other than those of 'simple' design (Article 10);
- monitor a manufacturer's production of PPE of 'complex' design (Article 11.A); and
- approve and monitor a manufacturer's quality control system for the manufacture of PPE of 'complex' design (Article 11.B).

If for any reason an Approved Body ceases to be an Approved Body, the Secretary of State may designate another to take over its functions in respect of such cases as he may specify.

The precise terms and conditions of appointment will be set out in the letter of appointment, but it will be a condition that the applicant agrees:

- to play a full part in Approved Body co-ordination activities at both UK and European level;
- to surveillance by UKAS, on behalf of the Department, annually or at whatever intervals are thought appropriate by the Department (new applicants will undergo an initial surveillance after 6 months); and
- to a full reassessment by UKAS, on behalf of the Department, every four years or at whatever intervals are thought appropriate by the Department.

2. APPLYING FOR APPROVED BODY STATUS

Organisations wishing to become Approved Bodies under the Regulations should apply to UKAS (see contact on page 11) for an assessment of the applicant against the criteria as listed below, using the application documents obtainable from UKAS. UKAS will make a recommendation to the DTI as to the applicant's ability to carry out the prescribed duties. A copy of the application to UKAS should be sent to the DTI contact shown on page 11 for information.

3. CRITERIA FOR APPOINTMENT

It is the Government's policy, in line with EU policy, to promote the use of accreditation of testing, certification and inspection bodies and to rely wherever possible on accreditation to the EN45000 series of standards in considering applications for appointment and notification to the Commission under EC directives. The EN45000 series comprise a number of standards which set out the criteria to be met by bodies issuing certificates, conducting tests or carrying out inspection.

The United Kingdom's criteria for appointment of Approved Bodies, for the purposes of the Regulations (Appendix C), therefore reflect UK Government and EU policy. Bodies appropriately accredited to one or more of the EN45000 series standards specified in this document will normally be regarded as eligible for notification as Approved Bodies provided that they also satisfy the criteria for appointment set out in these guidelines. Bodies which cannot meet fully the accreditation criteria will not necessarily be barred from appointment as an Approved Body. Assessment of these bodies against the relevant standard's general criteria in so far as they reflect the requirements for appointment of Approved Bodies in Annex V to the PPE Directive, and against any additional criteria necessary to ensure that the relevant requirements of the Directive are met will be made by UKAS. A report will be made then by UKAS to the Secretary of State on the findings and providing the applicant has demonstrated that it can carry out the duties required satisfactorily, the Secretary of State may appoint the Body but is not obliged to do so.

Assessment against EN45001 - This, when used in conjunction with additional criteria demonstrating an applicant's technical understanding and ability to assess goods against the requirements of the Directive, is appropriate for demonstrating suitability to undertake EC type-examination and EC quality control for the final product as described in Articles 10 and 11.A of the Directive.

Approved Bodies will be permitted to issue certificates for PPE which is to be manufactured in accordance with the product specific standards on that Body's assessment schedule and/or the basic health and safety requirements of the Directive. Normally, those standards will be harmonised European standards (EN's). A list of published PPE EN's is attached at Appendix D⁷. Bodies may also be appointed to undertake these functions against final draft prEN's or other suitable standards.

Where harmonised European standards have been applied, any EC type-examination certificate issued by an Approved Body shall state that the PPE type-examination models concerned have been made in accordance with those standards and this should be reflected in the manufacturers declaration of conformity.

Where prEN's or other relevant technical specifications have been applied, or compliance has been attested directly to the basic health and safety requirements, any type-examination certificate shall state that the PPE concerned has been manufactured in accordance with the basic health & safety requirements.

Assessment against EN45004 or EN45011 - This is appropriate for demonstrating suitability to undertake EC type-examination and EC quality control for the final product as described in Articles 10 and 11.A of the Directive.

Assessment against EN45012 - This is the only assessment suitable, in addition to any additional requirements specified in these guidelines, for Bodies who wish to undertake the approval and monitoring of manufacturers' quality control systems as described under Article 11.B of the Directive.

4. CIVIL LIABILITY INSURANCE

Civil liability insurance cover is one of the minimum conditions to be fulfilled by bodies seeking appointment as an Approved Body under the Regulations. The Secretary of State will need to be satisfied, therefore, that any organisation being considered for appointment possesses the appropriate insurance cover.

Civil liability insurance means insurance to cover all claims which might be made against an Approved Body other than in a criminal court, including liability arising from an arbitration award.

When it has received UKAS' recommendation, DTI will ask the applicant for details of its insurance cover. The insurance should include both public liability and professional indemnity insurance, and the cover should extend to the whole of the

⁷ Correct at 14 June 1997.

European Economic Area. The Secretary of State will not, in any case, cover the applicant's liability. The Approved Body at all times is acting as principal in relation to the performance of its duties and functions and not as agent of the Secretary of State and shall remain solely liable in respect of its activities as an Approved Body.

Following a successful application for appointment, the Approved Body should make available to UKAS evidence of valid liability insurance at each annual surveillance visit undertaken by UKAS.

5. TESTING & INSPECTION FACILITIES, AND SUBCONTRACTING

If the Approved Body operates its own testing facilities these, and the associated activities, shall conform to the relevant requirements of the European Standard EN45001 (General criteria for the operation of testing laboratories). Where testing is performed on its behalf by external bodies, the Approved Body shall ensure that these bodies conform to the relevant requirements of EN45001. When the Approved Body uses the services of an external body for testing, a properly documented agreement covering the arrangements, including confidentiality, shall be drawn up.

Where the Approved body operates its own inspection activity, this shall conform to the relevant requirements of the European Standard EN45004 or EN45011. Where inspection is carried out on its behalf by external bodies, the Approved Body shall ensure that these bodies conform to the same requirements. When the Approved Body uses the services of an external body for inspection, a properly documented agreement covering the arrangements, including confidentiality, shall be drawn up.

To meet the requirements of EN45001, the quality manual referred to in EN45004 and EN45011 should address the requirements of EN45001 which are not covered in EN45004 and EN45011.

Where testing is performed by an external body, the quality manual should describe the procedures adopted by the Approved Body to comply with the requirements specified in the above paragraph. A list of examination facilities used by the external body in order to undertake its activities should be included, showing as far as possible, those which are required for each element of the Approved Body's scope.

Whenever an external body is used to perform any function, the Approved Body should possess documented evidence to demonstrate that the external body is competent to do so. This would, amongst other things, include evidence that the external body has the ability fully to conform to all the requirements that are placed on the Approved Body itself in respect of the function to be performed on its behalf. Documented procedures for assessing and monitoring an external body's competence should be kept for reference. The quality manual may include them or should state where they are to be found.

The Approved Body should have properly documented agreements with all external bodies. A register of all external bodies employed by the Approved Body should be maintained; the quality manual may include it or should state where it is to be found. The register should include:

- a) the name of the external body;
- b) its legal status and details of any relationship with a parent company, group of companies or any other organisation of which the external body is a part;
- c) names and qualifications of all staff engaged in the technical work sub-contracted by the Approved Body;
- d) functions performed by the external body;
- e) results of any assessments performed to check compliance with the requirements of EN45001, EN45004, EN45011 or EN45012.

The agreements and the register should be available for scrutiny at any time on request by the Secretary of State or such other person as may be appointed by the Secretary of State.

Where the Approved Body sub-contracts activities, it shall use a qualified and experienced person who is able to form an independent assessment of the results of these activities.

The responsibility for undertaking the conformity assessment in accordance with the requirements of the Regulations, including the necessary analytical technical judgements, and liability for failure to do so always rests with the Approved Body itself, irrespective of whether it makes use of the services of consultants, external test or inspection bodies or anyone else.

6. QUALITY MANUAL

The Approved Body should have a quality manual and associated documented operational procedures, appropriate to the conformity assessment modules and category of product which it wishes to certify. The quality system set out in the documentation shall ensure that all the requirements of the relevant standard(s) in the EN45000 series are met plus any further requirements for accreditation or assessment and criteria for appointment and operation as a Approved Body. The quality documentation shall contain policies and procedures to include:

- a) a statement on the training of staff engaged in the conformity assessment process;
- b) details of the documented procedures for assessing initial and audit product testing;
- c) a general statement on the range of testing and inspection facilities appropriate to its activities;
- d) details of documented procedures for the surveillance of a manufacturer's quality system;

- e) a list of sub-contractors and details of the documented procedures for assessing and monitoring their competence;
- f) details of appeals procedures and the procedure for ensuring that complaints to the Approved Body are investigated to ensure that any shortcomings of the certification activities are revealed;
- g) a list of staff members responsible for investigating complaints and those having the authority to take remedial action;
- h) a copy of instructions to staff on confidentiality;
- i) a copy of the written undertaking by staff not to divulge any information gained about the client to a third party;
- j) a copy of the provisions in all sub-contracts to maintain confidentiality.

The Approved Body will be required to inform the assessment body (UKAS) (and the Secretary of State) immediately of any changes relating to its application or scope. This includes any change in its status as an organisation.

7. DOCUMENTS TO BE RETAINED BY THE APPROVED BODY

The Approved Body is required to produce and update as necessary lists of PPE for which it has issued type-examination or quality assurance certificates. It is also required to name the companies to which such certificates have been issued. The list should be available on request by the Secretary of State or such other person as may be specified by the Secretary of State. A description of the certification system shall also be available in published form whilst maintaining commercial confidentiality and professional secrecy.

8. INTERNAL AUDIT AND PERIODIC REVIEW

The Approved Body shall undertake internal audits and management reviews as required by the particular EN45000 standard to which it is working. Audits and reviews shall include checking compliance with the criteria for appointment as a Approved Body and checking that the certification process is correctly and effectively implemented.

9. MISUSE OF CERTIFICATES AND CONFORMITY NUMBERS

The quality manual should state the Approved Body's policy and procedure for controlling the use of its certificates and conformity numbers. Incorrect references to the certification system or misleading use of information found in advertisements, catalogues etc. must be dealt with by suitable means including corrective action, publication of the transgression and, if necessary, legal action.

The Approved Body should have documented procedures covering the control and use of its conformity number and any associated mark(s) with guidelines on action to be taken in cases of misuse. These should be described briefly in the quality manual and the reference numbers of the documentation listed. The Approved Body should not allow its mark(s) to be used without its express permission on any form of documentation issued by the PPE manufacturer or their authorised representative unless, in addition to satisfying other regulations governing the use of the mark(s), either:

- a) each product has been inspected or tested by the Approved Body (100% testing) and found to be in compliance with the relevant standard; or
- b) products of the same type have been tested initially and subsequent manufacture is subjected to periodic surveillance and in each case been found to be in compliance with the standard. In this case it is a further condition that each marked product or safety component should be produced under the same quality system for producing the tested or inspected items, the quality system concerned having been certificated by a body accredited for that function.

If, for example, an irregularity or oversight is discovered it might be necessary to withdraw the EC type examination certificate. The DTI must be informed immediately in such cases.

10. COUNCIL DECISION (93/465/EEC) 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 THE CE CONFORMITY MARKING, WHICH ARE INTENDED TO BE USED IN THE TECHNICAL HARMONISATION DIRECTIVES.

This Decision sets out a range of conformity assessment procedures ('modules') to be used in technical harmonisation directives, with the intention of achieving greater coherence at least in future directives.

Although the above Decision relates to future technical harmonisation directives and not to the PPE Directive specifically, it is indicative of what the Council would regard as good practice in certain areas. It would, therefore, be taken into account by the Secretary of State when considering whether or not an Approved Body had carried out its duties and functions under the Regulations to his satisfaction.

The modules corresponding to the testing & certification procedures of the PPE Directive are:

- Module B - type examination (Article 10 in the PPE Directive);
- Module C - conformity to type (Article 11A in the PPE Directive); and
- Module D - production quality assurance (Article 11B in the PPE Directive).

Applicants for Approved Body status should be familiar with this Council Decision and are encouraged to undertake their work in accordance with the modules, without imposing unnecessary burdens on businesses.

The modules also specify that the sub-contracting of work by an Approved Body is permissible, subject to the following conditions guaranteeing:

- the competence of the establishment working as sub-contractor, on the basis of conformity with the EN45000 series of standards, and the capability of the member State that has notified the sub-contracting body to ensure effective monitoring of such compliance; and
- the ability of the Approved Body to exercise effective responsibility for the work carried out under sub-contract.

11. APPROVED BODY CONTACT POINTS

Policy & appointments:

Isaac Phillip
Department of Trade & Industry
Standards and Technical
Regulations Directorate 4
321 Red Zone
151 Buckingham Palace Road
London SW1W 9SS

Tel: 020-7215 1573

Fax: 020-7215 1529

General PPE matters:

Geoff Hooke
British Safety Industry Federation
St Asaph Business Park
Glascoed Road
St Asaph
Clywd
LL17 0LJ

Tel: 01745 585600

Fax: 01745 585800

Assessment/Accreditation:

David Evans
UKAS
21-47 High St
Feltham
Middlesex
TW13 4UN

Tel: 020-8917 8436

Fax: 020-8917 8500

CONFORMITY ASSESSMENT PROCEDURES**EC TYPE-EXAMINATION****Article 10**

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

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

3. The application shall comprise:

- the name and address of the manufacturer or his authorised 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.

4. The inspection body of which notification has been given shall conduct the EC type-examination in accordance with the undermentioned 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 harmonised standards referred to in Article 5;
- Where a manufacturer has not applied, or has only partly applied, the harmonised 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.

(b) Examination of the model:

- When examining the model, the 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 harmonised standards;

- Where a manufacturer has not applied or has only partly applied the harmonised 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.

5. If the model satisfies the relevant provisions, the 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 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.

6. Any body which refuses to issue an EC type-examination certificate shall inform the other approved 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.

CHECKING OF PPE MANUFACTURED

Article 11

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.
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.
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 harmonised standards or necessary to show conformity to the basic requirements of this Directive shall be carried out to check the conformity of PPE.
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.
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.
6. The manufacturer must be able to present, on request, the report of the body of which notification has been given.

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

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.
- (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 organisation 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.
- (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 harmonised 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.

- (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.

2. Supervision

- (a) The purpose of supervision is to ensure that a manufacturer correctly fulfils the obligations arising from the approved quality-control system.
- (b) The manufacturer shall authorise 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.
- (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.
- (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.
- (e) The manufacturer must be able to present, on request, the report of the body of which notification has been given.

ANNEX V TO COUNCIL DIRECTIVE OF 21ST DECEMBER 1989 ON THE APPROXIMATION OF THE LAWS OF MEMBER STATES RELATING TO PERSONAL PROTECTIVE EQUIPMENT

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 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.

CRITERIA FOR APPOINTMENT OF UK APPROVED BODIES

FUNCTION		
EC type-examination (module B)	EC quality control for the final product (module C)	Ensuring EC quality of production by means of monitoring (module D)
EN45001 together with additional criteria or EN45004 or EN45011	EN45001 together with additional criteria or EN45004 or EN45011	EN45012

Notes:

- 1 The types of PPE for which a Body will be approved will reflect its assessed scope.
- 2 UKAS assessment forms the basis for deciding whether a Body should be approved. The tasks of the Body, once approved, will be as set out in the Regulations.
- 3 The Directive requires Approved Bodies carrying out EC type-examination to 'conduct the necessary examinations and tests': it is therefore essentially for the Approved Body to decide to what extent material provided by the manufacturer reduces the extent of the necessary tests and examinations.
- 4 These criteria are subject to modification in the light of experience.

HARMONISED STANDARDS WHICH GIVE PRESUMPTION OF CONFORMITY WITH THE PPE DIRECTIVE

REFERENCE	YEAR OF RATIFICATION	TITLE	PUBLICATION IN OJEC
EN 132	1990	Respiratory protective devices - Definitions	C 180/26 14.06.97
EN 133	1990	Respiratory protective devices - Classification	C 180/26 14.06.97
EN 134	1990	Respiratory protective devices - Nomenclature of components	C 180/26 14.06.97
EN 135	1990	Respiratory protective devices - List of equivalent terms	C 180/26 14.06.97
EN 136	1989	Respiratory protective devices - Full face masks - Requirements, testing, marking	C 180/26 14.06.97
EN 136- 10	1992	Respiratory protective devices - Full face masks for special use - Requirements, testing, marking	C 180/26 14.06.97
EN 137	1993	Respiratory protective devices - Self-contained open-circuit compressed air breathing apparatus - Requirements, testing, marking	C180/26 14.06.97
EN 138	1994	Respiratory protective devices - Fresh air hose breathing apparatus for use with full face mask, half mask or mouthpiece assembly Requirements, testing, marking -	C 180/26 14.06.97
EN 139	1994	Respiratory protective devices - Compressed air line breathing apparatus for use with a full face mask, half mask or a mouthpiece assembly - Requirements, testing, marking	C 180/26 14.06.97
EN 140	1989	Respiratory protective devices - Half masks and quarter masks - Requirements, testing, marking	C 180/26 14.06.97
EN 141	1990	Respiratory protective devices - Gas filters and combined filters - Requirements, testing, marking	C 180/26 14.06.97
EN 142	1989	Respiratory protective devices – Mouthpiece assemblies - Requirements, testing, marking	C 180/26 14.06.97
EN 143	1990	Respiratory protective devices - Particle filters - Requirements, testing, marking	C 180/26 14.06.97
EN 144-1	1991	Respiratory protective devices - Gas cylinder valves - Thread connection for insert connector	C 180/26 14.06.97
EN 145	1988	Respiratory protective devices - Self-contained closed-circuit breathing apparatus, compressed oxygen type - Requirements, testing, marking	C 180/26 14.06.97
EN 145-2	1992	Respiratory protective devices - Self-contained closed-circuit compressed oxygen breathing apparatus for special use - Requirements, testing, marking	C 180/26 14.06.97
EN 146	1991	Respiratory protective devices – Powered particle filtering devices incorporating helmets or hoods - Requirements, testing, marking	C 180/26 14.06.97

EN 147	1991	Respiratory protective devices - Power assisted particle filtering devices incorporating full face masks, half masks or quarter masks - Requirements, testing, marking	C 180/26 14.06.97
EN 148-1	1987	Respiratory protective devices - Threads for facepieces - Standard thread connection	C 180/26 14.06.97
EN 148-2	1987	Respiratory protective devices - Threads for facepieces - Centre thread connection	C 180/26 14.06.97
EN 148-3	1992	Respiratory protective devices - Threads for facepieces - Part 3: Thread connection M 45 x 3	C 180/26 14.06.97
EN 149	1991	Respiratory protective devices - Filtering half masks to protect against particles -Requirements, testing, marking	C 180/26 14.06.97
EN 165	1995	Personal eye-protection - Vocabulary	C 180/26 14.06.97
EN 166	1995	Personal eye-protection - Specifications	C 180/26 14.06.97
EN 167	1995	Personal eye-protection - Optical test methods	C 180/26 14.06.97
EN 168	1995	Personal eye-protection - Non-optical test methods	C 180/26 14.06.97
EN 169	1992	Personal eye-protection - Filters for welding and related techniques - Transmittance requirements and recommended utilisation	C 180/26 14.06.97
EN 170	1992	Personal eye-protection - Ultraviolet filters -Transmittance requirements and recommended use	C 180/26 14.06.97
EN 171	1992	Personal eye-protection - Infrared filters - Transmittance requirements and recommended use	C 180/26 14.06.97
EN 172	1994	Personal eye protection - Sunglare filters for industrial use	C 180/26 14.06.97
EN 174	1996	Personal eye protection - Ski goggles for downhill skiing	C 180/26 14.06.97
EN 207	1993	Personal eye-protection - Filters and eye- protection against laser radiation	C 180/26 14.06.97
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EN 250	1993	Respiratory equipment - Open-circuit self-contained compressed air diving apparatus - Requirements, testing, marking	C 180/26 14.06.97
EN 269	1994	Respiratory protective devices - Powered fresh air hose breathing apparatus incorporating a hood - Requirements, testing, marking	C 180/26 14.06.97
EN 270	1994	Respiratory protective devices - Compressed air line breathing apparatus incorporating a hood -Requirement, testing, marking	C 180/26 14.06.97
EN 271	1995	Respiratory protective devices - Compressed air line or powered fresh air hose breathing apparatus incorporating a hood for use in abrasive blasting operations - Requirements, testing, marking	C 180/26 14.06.97
EN 340	1993	Protective clothing - General requirements	C 180/26 14.06.97

EN 341	1992	Personal protective equipment against falls from a height - Descender devices	C 180/26 14.06.97
EN 344	1992	Requirements and test methods for safety, protective and occupational footwear for professional use	C 180/26 14.06.97
EN 344-2	1996	Safety, protective and occupational footwear for professional use - Part 2: Additional requirements and test methods	C 180/26 14.06.97
EN 345	1992	Specification for safety footwear for professional use	C 180/26 14.06.97
EN 345-2	1996	Safety footwear for professional use - Part 2: Additional specifications	C 180/26 14.06.97
EN 346	1992	Specification for protective footwear for professional use	C 180/26 14.06.97
EN 346-2	1996	Protective footwear for professional use - Part 2: Additional specifications	C 180/26 14.06.97
EN 347	1992	Specification for occupational footwear for professional use	C 180/26 14.06.97
EN 347-2	1996	Occupational footwear for professional use - Part 2: Additional specifications	C 180/26 14.06.97
EN 348	1992	Protective clothing - Test method: Determination of behaviour of materials on impact of small splashes of molten metal	C 180/26 14.06.97
EN 352-1	1993	Hearing protectors - Safety requirements and testing - Part 1: Ear muffs	C 180/26 14.06.97
EN 352-2	1993	Hearing protectors - Safety requirements and testing - Part 2: Earplugs	C 180/26 14.06.97
EN 352-3	1996	Hearing protectors - Safety requirements and testing - Part 3: Ear-muffs attached to an industrial safety helmet	C 180/26 14.06.97
EN 353-1	1992	Personal protective equipment against falls from a height - Part 1: Guided type fall arresters on a rigid anchorage line	C 180/26 14.06.97
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EN 364	1992	Personal protective equipment against falls from a height - Test methods	C 180/26 14.06.97
EN 365	1992	Personal protective equipment against falls from a height - General requirements for instructions for use and for marking	C 180/26 14.06.97
EN 366	1993	Protective clothing - Protection against heat and fire - Method of test: Evaluation of materials and material assemblies when exposed to a source of radiant heat	C 180/26 14.06.97
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EN 368	1992	Protective clothing - Protection against liquid chemicals - Test method: Resistance of materials to penetration by liquids	C 180/26 14.06.97
N 369	1993	Protective clothing - Protection against liquid chemicals - Test method: Resistance of materials to permeation by liquids	C 180/26 14.06.97
N 371	1992	Respiratory protective devices - AX gas filters and combined filters against low boiling organic compounds - Requirements, testing, marking	C 180/26 14.06.97
N 372	1992	Respiratory protective devices - SX gas filters and combined filters against specific named compounds - Requirements, testing, marking	C 180/26 14.06.97
N 373	1993	Protective clothing - Assessment of resistance of materials to molten metal splash	C 180/26 14.06.97
EN 374-1	1994	Protective gloves against chemicals and micro-organisms - Part 1: Terminology and performance requirements	C 180/26 14.06.97
EN 374-2	1994	Protective gloves against chemicals and micro-organisms - Part 2: Determination of resistance to penetration	C 180/26 14.06.97
EN374-3	1994	Protective gloves against chemicals and micro- organisms - Part 3: Determination of resistance to permeation by chemicals	C 180/26 14.06.97
EN379	1994	Specification for welding filters with switchable -luminous transmittance and welding filters with dual luminous transmittance	C 180/26 14.06.97
EN381-1	1993	Protective clothing for users of hand-held - chainsaws - Part 1: Test rig for testing resistance to cutting by a chainsaw	C 180/26 14.06.97
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EN381-3	1996	Protective clothing for users of hand-held chain- saws - Part 3: Test methods for footwear	C 180/26 14.06.97
EN381-5	199S	Protective clothing for users of hand-held chain saws - Part 5: Requirements for leg protectors	C 180/26 14.06.97
EN381-8	1997	Protective clothing for users of hand-held chain saws - Part 8: Test method for chain saw protective gaiters	C 317/2- 18.10.97
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EN393	1993	Lif jackets and personal buoyancy aids -Buoyancy aids - 50 N	C 180/26-14.06.97
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EN400	1993	Respiratory protective devices for self-rescue -Self-contained closed-circuit breathing apparatus - Compressed oxygen escape apparatus - Requirements, testing, marking	C 180/26-14.06.97
EN401	1993	Respiratory protective devices for self-rescue - Self-contained closed-circuit breathing apparatus - Chemical oxygen (KO ₂) escape apparatus - Requirements, testing, marking	C 180/26-14.06.97
EN402	1993	Respiratory protective devices for escape - Self- contained open-circuit compressed air breathing apparatus with full face mask or mouthpiece assembly - Requirements, testing, marking	C 180/26-14.06.97
EN 403	1993	Respiratory protective devices for self-rescue - Filtering devices with hood for self-rescue from fire - Requirements, testing, marking	C 180/26-14.06.97
EN 404	1993	Respiratory protective devices for self-rescue - Filter self-rescuer - Requirements, testing, marking	C 180/26-14.06.97
EN 405	1992	Respiratory protective devices - Valved filtering half masks to protect against gases or gases and particles - Requirements, testing, marking	C 180/26-14.06.97
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EN 412	1993	Protective aprons for use with hand knives	C 180/26-14.06.97
N 420	1994	General requirements for gloves	C 180/26-14.06.97
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EN 458	1993	Hearing protectors - Recommendations for selection, use, care and maintenance – Guidance document	C 180/26-14.06.97
EN 463	1994	Protective clothing - Protection against liquid chemicals - Test method: Determination of resistance to penetration by a jet of liquid (Jet Test)	C 180/26-14.06.97
EN 464	1994	Protective clothing - Protection against liquid and gaseous chemicals, including aerosols and solid particles - Test method: Determination of leak-tightness of gas-tight suits (Internal pressure test)	C 180/26-14.06.97

EN 465	1995	Protective clothing - Protection against liquid chemicals - Performance requirements for chemical protective clothing with spray-tight connections between different parts of the clothing (Type 4 Equipment)	C 180/26 14.06.97
EN 466	1995	Protective clothing - Protection against liquid chemicals - Performance requirements for chemical protective clothing with liquid-tight connections between different parts of the clothing (Type 3 Equipment)	C 180/26 14.06.97
EN 467	1995	Protective clothing - Protection against liquid chemicals - Performance requirements for garments providing protection to parts of the body	C 180/26 14.06.97
EN 468	1994	Protective clothing - Protection against liquid chemicals - Test method: Determination of resistance to penetration by spray (Spray Test)	C 180/26 14.06.97
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EN 532	1994	Protective clothing - Protection against heat and flame - Test method for limited flame spread	C 180/26 14.06.97
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EN 568	1997	Mountaineering equipment - Ice anchors - Safety requirements and test methods	C 180/26 14.06.97
EN 659	1996	Protective gloves for fire-fighters	C 180/26 14.06.97
EN 702	1994	Protective clothing - Protection against heat and flame - Test method: Determination of the contact heat transmission through protective clothing or its materials	C 180/26 14.06.97
EN 813	1997	Personal protective equipment for prevention of falls from a height - Sit harnesses	C 180/26 14.06.97
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EN 1061	1996	Respiratory protective devices for escape - Self-contained closed-circuit breathing apparatus - Chemical oxygen (NaC103) escape apparatus - Requirements, testing, marking	C 180/26 14.06.97
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EN 1082-1	1996	Protective clothing - Gloves and arm guards protecting against cuts and stabs by hand knives - Part 1: Chain mail gloves and arm guards	C 180/26 14.06.97
EN 1146-1	1997	Respiratory protective devices for self-rescue - Self-contained open-circuit compressed air breathing apparatus incorporating a hood (compressed air escape apparatus with hood) - Requirements, testing, marking	C 180/26 14.06.97
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EN 1731	1997	Mesh type eye and face protectors for industrial and non-industrial use against mechanical hazards and/or heat	C 180/26 14.06.97
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EN 1868	1997	Personal protective equipment against falls from a height - List of equivalent terms	C 317/2 18.10.97
EN ISO 4869-2	1995	Acoustics - Hearing protectors - Part 2: Estimation of effective A-weighted sound pressure levels when hearing protectors are worn (ISO 4869-2: 1994)	C 180/26 14.06.97
EN ISO 10819	1996	Mechanical vibration and shock - Hand-arm vibration - Method for the measurement and evaluation of the vibration transmissibility of gloves at the palm of the hand (ISO/DIS 10819:1993)	C 180/26 14.06.97
EN 24869-1	1993	Acoustics - Hearing protectors – Subjective method for the measurement of sound attenuation (ISO 4869-1: 1990)	C 180/26 14.06.97
EN 24869-3	1993	Acoustics - Hearing protectors - Part 3: Simplified method for the measurement of insertion loss of ear-muff type protectors for quality inspection purposes (ISO/TR 4869-3:1989).	C 180/26 14.06.97