BIS | Department for Business Innovation & Skills

THE PERSONAL PROTECTIVE EQUIPMENT REGULATIONS 2002

Guidelines on the appointment of UK Approved Bodies

SEPTEMBER 2012

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PERSONAL PROTECTIVE EQUIPMENT REGULATIONS (PPE) 2002

GUIDELINES ON THE APPOINTMENT OF UK APPROVED BODIES

ISSUED BY THE DEPARTMENT FOR BUSINESS, INNOVATION AND SKILLS (BIS) ON BEHALF OF THE SECRETARY OF STATE FOR BIS

1. Introduction

1.1 These guidelines describe the requirements applying in the United Kingdom for the assessment and appointment of Approved Bodies under the PPE Regulations 2002 (S.I. 2002/1144), which implement the provisions of the EC PPE Directive (89/686/EEC) in UK law. These regulations replace in their entirety the PPE Regulations 1992 (as amended)] Approved Bodies are appointed under and operate according to the law which transposes the provisions of the Directive The text of the Directive was adopted by the European Parliament and the Council on 21 December 1989 and published in the Official Journal No. L399 of 30 December 1989, p.18. The Directive applies in the European Economic Area (EEA).

1.2 These guidelines replace those issued in 1998. They apply to all approved bodies applying for notification under the Personal Protective Equipment Regulations 2002 from the date of publication. Approved Bodies appointed under the PPE Regulations before that date will need to comply with these guidelines by the end of July 2013 at the latest. They should apply to UKAS in accordance with paragraph 2.2 and will be assessed as part of their usual surveillance cycle.

1.3 The PPE Regulations 2002 apply to any device or appliance designed to be worn or held by an individual for protection against one or more health and safety hazards which falls within the definition in Regulation 2 (2) (a).

1.4 The conformity assessment procedures under the Regulations consist of manufacturer's self-declaration (Article 12 of the PPE Directive, corresponding to Module A[1]); type-examination (Article 10 in the PPE Directive, corresponding to Module B); conformity to type (Article 11A in the PPE Directive, corresponding to Module C);production quality assurance (Article 11B in the PPE Directive, corresponding to Module D).

1.5 Some of the conformity assessment procedures outlined above (ie Article 10, 11A and 11B) require the involvement of third party conformity assessment bodies. Subject to paragraph 7 (below), these third party bodies are appointed by member/EEA States. In the United Kingdom, they are appointed under regulations 13 and 14 of the PPE Regulations 2002. These third party bodies, once assessed for their competence and appointed by the Secretary of State, are then notified to the European Commission and become "Approved Bodies". The scope of products within the Regulations which an Approved Body is authorised to assess will be published and will also be specified in the letter of appointment. The Secretary of State for Business, Innovation and Skills at

[1] The Conformity Assessment Modules as set out in Annex II of Decision 768/2008/EC of 9 July 2008.

present has the responsibility for appointing Approved Bodies in the United Kingdom to carry out the functions referred to above and for notifying the appointments to the European Commission and other member/EEA States.

2. Criteria, Application and Appointment

2.1 An organisation wishing to be appointed as an Approved body in the United Kingdom will need to meet the requirements set out in Annex V of the Directive. It should, however, be noted that meeting the requirements for appointment will not automatically lead to such an appointment as this remains at the discretion of the Secretary of State. Reference should also be made to paragraph 3.12 regarding insurance arrangements.

2.2 Applicants will be required in the first instance, to make an application for accreditation to the United Kingdom Accreditation Service (UKAS) which will undertake an assessment of the applicant against the relevant harmonised standard(s) (see para 3.4 below) to ensure that the applicant complies with the requirements. Applications should be submitted using the relevant UKAS form (AC1 to AC4 - available to download from the UKAS website at www.ukas.com) dependent upon the standard against which accreditation is required. The scope of accreditation will be defined by reference to the specific products set out in the Regulations and applicants should indicate the particular product(s) (if not all) in respect of which they wish to be appointed. UKAS will quote and charge applicants against its standard scales of charges for its accreditation activities under the provisions of these guidelines. UKAS has established procedures to handle complaints or appeals associated with its assessment activities.

2.3 At the same time as it submits its application for accreditation to UKAS, the applicant will be required to send a copy to the Department. This will provide the Secretary of State with advance notice of the intention to apply for appointment.

2.4 Once UKAS has completed its accreditation, it will issue an accreditation certificate and schedule to the applicant. The applicant should then submit an application for appointment to the Department. The application should describe the conformity assessment activities and the products for which the applicant wishes to be appointed and should be accompanied by the accreditation certificate and schedule and the final assessment report issued by UKAS and evidence of the applicant's insurance cover (see para 3.12). The Secretary of State may request further information from UKAS about the applicant's accreditation, as required. The Secretary of State will then make a decision on appointment on the basis of all of the evidence. If satisfied that the applicant is fit for appointment under the Regulations, the Secretary of State will issue a letter of appointment.

2.5 The precise terms of appointment will be set out in the individual letters of appointment, but they will include conditions that the applicant agrees:

- to take part in co-ordination activities at both UK and European level;
- to surveillance annually or at whatever intervals are thought appropriate by the Department (newly appointed Approved Bodies may be required to undergo an initial surveillance after 6 months);

- to a full reassessment every four years or at whatever intervals are thought appropriate by the Department.

Once acceptance of the conditions of the letter of appointment has been received, the Department will notify the European Commission and the other member/EEA States of the appointment. The appointment will become effective two weeks after the notification provided that no objections are raised by the European Commission or member/EEA states and will be confirmed at that point.

2.6 Reassessment and surveillance will be carried out on behalf of the Secretary of State, by UKAS in line with usual accreditation practice and para 2.5 above. Reassessment and surveillance may also be carried out by the Secretary of State. UKAS will advise the Department of the outcome of annual surveillance, four yearly re-assessment and any other necessary monitoring in intervening periods in order for the Department to take any necessary decisions about the continuation of the appointment. The Secretary of State may request further information about the assessment and surveillance activities, as required.

2.7 To be eligible for appointment as a United Kingdom Approved Body for the purposes of the Regulations, an applicant must be a legal entity in the United Kingdom. An applicant must exercise management control of the process, have technical capability and carry out its final assessment functions within the jurisdiction of the United Kingdom. It may conduct technical activities, or have technical activities conducted on its behalf, outside the jurisdiction of the United Kingdom.

2.8 Approved Bodies should ensure that they do not unreasonably restrict the access of manufacturers of products within the scope of the Regulations to their services. They must not place undue financial or other conditions upon such manufacturers. The procedures under which an Approved Body operates must be administered in a non-discriminatory manner.

3. Meeting the criteria

Accreditation

3.1 Applicants are required to demonstrate conformity with the requirements set out in the Regulations by being accredited, to the appropriate scope, of one, or more, of the relevant EN 45000 and ISO 17000 series of standards, which contain requirements for bodies issuing certificates, performing inspections or conducting tests.

3.2 All applicants, as part of the accreditation process, will need to meet any additional requirements set out in these guidelines which may change from time to time.

3.3 As indicated in paragraph 2.2 and 2.4 (above), applicants will need to state for which products specified in the Regulations they wish to be appointed. The scope of accreditation and subsequent appointment will be determined by reference to the categories of product specified.

3.4 Accreditation will be carried out against the most relevant EN 45000 or ISO 17000 series standard for the organisation concerned, taking into account the requirements of other relevant standards depending on the modules for which the applicant wishes to be

appointed. The relevant standards, mapped against the modules, are as set out in Appendix 1

In all cases, the standards will be applied in accordance with EA 2/17 – Guidance on the horizontal requirements for the accreditation of conformity assessment bodies for notification purposes[2].

Note that consideration is being given at both national and European level to the use of the various EN 45000 and ISO/IEC 17000 standards for the accreditation of conformity assessment bodies for notification purposes. The standards against which accreditation may be carried out for the purposes of appointment in accordance with these guidelines may change depending on the outcome of this work.

3.5 All applicants will need to be able to demonstrate their professional ability and a necessary level of understanding of the Directive and of the implementing Regulations to be able to determine whether products offered for assessment satisfy the Basic Health and Safety Requirements (BHSRs) and the other relevant provisions.

3.6 Applicants should also be able to demonstrate that the company has sufficient resources to deliver the necessary level of professional knowledge and experience. Compliance with the nominated deputy provisions of EN ISO 17020 would be a satisfactory method of achieving this requirement and ensure the company can provide effective and continuous service.

Harmonised Standards

3.7 The Directive also defines the role of harmonised standards, which are produced in response to a mandate from the European Commission to the European standards organisations, the Comité Européan de Normalisation (CEN) and the European Committee for Electrotechnical Standardization (CENELEC) and listed in the Official Journal of the European Union. Products within the scope of the Directive produced in accordance with such standards will enjoy a presumption of conformity with the relevant BHSRs (set out in Schedule 2 to the Regulations). Under the appropriate conformity assessment procedures, applicants will need to be able to examine or inspect against the BHSRs and other relevant provisions directly. They will also need to be able to inspect against the harmonised standards.

Quality System

3.8 All applicants will need to have a Quality System, usually specified in a Quality Manual and associated documented operational procedures, appropriate to the conformity assessment modules and types of product which it wishes to certify. The Quality System will need to ensure that all of the relevant requirements of the appropriate standards in the EN 17000 and 45000 series are met plus any further requirements for appointment and operation as an Approved Body.

[2] Available from the EA website at www.european-accreditation.org/n1/doc/EA-2_17.pdf

Sub-contracting

3.9 Where an applicant wishes to sub-contract any part of the assessment process, the Quality Manual of the applicant will need to describe the procedures to be followed by the applicant to ensure compliance by the sub-contractors with the relevant requirements and to demonstrate that the sub-contractor is competent to carry out the task for which it has been engaged. Such competence will include, but is not limited to, the ability fully to conform to the requirements that are placed on the applicant itself in respect of the task contained within the subcontract. The applicant will need to maintain documented procedures for the assessment and monitoring of sub-contractors, and a list of sub-contractors and the facilities used by them to carry out work packages on behalf of the applicant. The list will need to form part of the Register specified in the next paragraph.

3.10 An applicant will need to have fully documented agreements with its sub-contractors. A Register of all sub-contractors which may be used by the applicant will need to be maintained; the Quality Manual will either contain the Register or will state where the Register is to be found. The agreements and the Register will need to be available for scrutiny at any reasonable time on request by the Secretary of State or such other person as may be appointed on behalf of the Secretary of State for that purpose.

3.11 An Approved Body will at all times be responsible for ensuring that the conformity assessment is carried out in accordance with the requirements of the implementing Regulations.

Insurance

3.12 All applicants will be required to demonstrate that they have adequate public liability and professional indemnity insurance for the activities they wish to carry out. Evidence of this should be submitted to UKAS and to the Department at the point at which a body makes an application to be appointed as an Approved Body. Thereafter, the Approved Body should make available to UKAS evidence of insurance at each annual surveillance undertaken by UKAS. Such cover should extend to the whole of the Community, the European Economic Area (EEA), or, if the applicant intends to carry out work under the Directive outside these areas; world-wide. The Secretary of State will not in relation to any case or circumstance cover an Approved Body's liability.

4. Duties of Approved Bodies

4.1 It will be the duty of an Approved Body to assess the conformity of the products or quality systems, which fall within the scope of its appointment, against the requirements of the Regulations. When an Approved Body assesses products as being in conformity with those Regulations, it will be required to issue the appropriate conformity assessment documentation as specified in the Regulations. This would include a type examination or quality assurance certificate stating that the product or quality system concerned complies with the terms of the Directive which apply to it and has been assessed as such.

4.2 An applicant will be required to have documented procedures covering all aspects of its work relating to the conformity assessment activities for which it seeks approval. As part of the accreditation process, an assessment will be made of the adequacy of the internal organisation and the procedures adopted to give confidence in the quality of the applicant's services. Where judgements or interpretation of a standard or requirement are implicit or explicit in a decision to grant or withhold certification, the applicant will be

required to have procedures for achieving consistency. Guidance for achieving wider national and European agreement on interpretation and application of the Directive and the implementing Regulations can be sought from the Department, or through the national and European fora already in place for the exchange of views and discussion of interpretative issues in which prospective applicants are expected to fully participate.

4.3 An Approved Body will be required to maintain an up to date record of any certification which it has issued, and to whom it has been issued. The records will need to be made available on request to the Secretary of State or such other person as may be authorised by the Secretary of State.

4.4 An Approved Body will be required to inform the Secretary of State and UKAS immediately of any changes within itself which, in any way, affect its ability to carry out the duties within the authorised scope to the declared procedures. This includes any change in its status, ownership, location, key personnel, technical competence, facilities etc.

5. Misuse of Certificates and Conformity Numbers

5.1 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. will be dealt with by suitable means including corrective action, publication of the transgression and, if necessary, legal action.

5.2 An Approved Body will need to have documented procedures for the control and use of its identification number complete with guidelines on action to be taken in cases of misuse. The procedures will need to be contained or referenced within the Quality Manual.

6. Use of UKAS Symbols

6.1 Approved Bodies may make reference to UKAS Accreditation or include the relevant National Accreditation Symbol on certificates issued where the conformity assessment work reported is included within the scope of accreditation of the Approved Body.

6.2 Certificates bearing an accreditation symbol must comply with the requirements of the relevant conformity assessment body standard against which accreditation is held (e.g. EN 45011, ISO/IEC 17020 etc), with the requirements for notification and with the requirements in BIS publication 09/1090 'Conditions' document and any other requirements specified by UKAS.

7. Mutual Recognition Agreements

7.1 Applicants should note that the European Community aims to reach Mutual Recognition Agreements (MRAs) with key trading partners. Under these agreements, EC Approved Bodies may be eligible to perform conformity assessments as required by the third country's laws and, similarly, those trading partners' equivalents to Approved Bodies may be eligible for appointment to perform conformity assessments under EC Directives. If an applicant organisation wishes to be considered for appointment under MRAs, it should inform the Department.

8. Contact Points

8.1 Contact addresses are:

Department for Business, Innovation and Skills
1 Victoria Street
London SW1H 0ET

Tel: 0207 - 215 5000
Email: prodregs@bis.gsi.gov.uk

Kevin Belson (or your usual accreditation manager)
United Kingdom Accreditation Service
21 - 47 High Street
Feltham
Middlesex, TW13 4UN

Tel: 0208 - 917 8400
Fax: 0208 - 917 8500
Email: kevin.belson@ukas.com

9. Sources of relevant documents

9.1 Copies of the PPE Directive are available from the Europa website at www.europa.eu

9.2 Copies of the PPE Regulations 2002 may be obtained from:

TSO Orders/Post Cash Department,
PO Box 29
Norwich, NR3 IGN

Tel: 0870 600 5522
Fax: 0870 600 5533
Email: customer.services@tso.co.uk
Textphone 0870 240 3701
www.tsoshop.co.uk

Or from The National Archives Office website at www.legislation.gov.uk

9.3 Information on the EN 17000 and EN 45000 series of standards and the harmonised standards is available from:

BSI British Standards
389 Chiswick High Road
London, W4 4AL

Tel: 0208-996 9001
Fax: 0208-996 7001
Web: http://www.bsigroup.com

Appendix I: Table of Modules and applicable standards[3]

Module	EN Standard(s) applicable
AI, A2	EN ISO/IEC 17025 (+ability to decide on conformity), or EN ISO/IEC 17020 (EN ISOIIEC 17025 to be taken into account for testing required), or EN 45011 (EN ISO/IEC 17025 to be taken into account for testing required)
B	EN ISO/IEC 17020 (EN ISO/IBC 17025 to be taken into account for testing required), or EN 45011 (EN 17025 to be taken into account for testing required)
CI, C2	EN ISO/IEC 17025 (+ability to decide on conformity), or EN ISO/IEC 17020 (EN ISO/IEC 17025 to be taken into account for testing required), or EN 45011 (EN ISO/IEC 17025 to be taken into account for testing required)
D, DI	EN ISO/IEC 17021 (+product related knowledge)
E, EI	EN ISOEEC 17021(+product related knowledge)
F, F1	EN ISO/IEC 17025 (+ability to decide on conformity), or EN ISO/IEC 17020 (EN 17025 to be taken into account for testing required), or EN ISO/IEC 45011 (EN 17025 to be taken into account for testing required)
G	EN ISO/IEC 17020 (EN 17025 to be taken into account for testing required), or EN 45011 (EN 17025 to be taken into account for testing required)
H	EN 1SO/IEC 17021 (+product related knowledge)
H1	EN ISOEEC 17021 (+product related knowledge) + EN ISO/IEC 17020 (EN ISO/IEC 17025 to be taken into account for testing required), or EN ISO/IEC 17021 (+product related knowledge) + EN ISO/IEC 45011 (EN ISO/IEC 17025 to be taken into account for testing required)

[3] Reproduced from the European Commission working paper Certif 2009/8: “Using standards to assess the competence of conformity assessment bodies in the context of the New Legislative Framework.”.

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