



Department of Trade and Industry

THE PRESSURE EQUIPMENT REGULATIONS 1999

GUIDELINES FOR THE APPOINTMENT OF CONFORMITY ASSESSMENT BODIES

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Appendix 1: Annex IV of the PED - Minimum criteria to be met when designating the notified bodies referred to in Article 12 and the recognised third party organisations referred to in Article 13.

Appendix 2: Annex V of the PED - criteria to be met when authorising user inspectorates referred to in Article 14.

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GUIDELINES ON THE APPOINTMENT OF CONFORMITY ASSESSMENT BODIES

ISSUED BY THE DEPARTMENT OF TRADE AND INDUSTRY ON BEHALF OF THE SECRETARY OF STATE FOR TRADE AND INDUSTRY

1. INTRODUCTION

- 1.1. The European Community Directive on the approximation of the laws of the member States concerning pressure equipment ('the PED') was adopted by the European Parliament and the Council on 29 May 1997 as Directive 97/23/EC and published in the Official Journal No. L 181 of 9 July 1997. The PED has been implemented in the United Kingdom by the Pressure Equipment Regulations 1999 (S.I.1999/2001) ('the Regulations'). The Regulations will come into force on 29 November 1999, apart from regulations 1, 2, 20 and 22, which come into force on 31 August 1999 and provide for the appointment of conformity assessment bodies. The Regulations will be mandatory from 29 May 2002.
- 1.2. The Regulations apply to the design, manufacture and conformity assessment of pressure equipment and assemblies with a maximum allowable pressure greater than 0.5 bar. The conformity assessment procedures are based on EC Decision 93/465/EEC (the Modules Decision) and provide manufacturers with a choice of conformity assessment 'modules', or combination of modules, ranging from internal production control to unit verification by an independent party. Provision is also made for conformity assessment based on quality assurance systems. The greater the hazard associated with the pressure equipment or assembly, as classified in accordance with the Regulations, the more demanding the conformity assessment requirements. The conformity assessment procedures are referred to in regulations 13 and 14 and set out in Schedule 4 of the Regulations.
- 1.3. The more demanding modules require the involvement of conformity assessment bodies (CABs), appointed by member States, either in the approval and monitoring of the manufacturers' quality assurance system or in direct product inspection. The Regulations specify three types of CABs:

'Notified bodies' may be appointed to carry out the procedures laid down in any of the modules set out in Schedule 4 (regulations 13 and 14), to carry out the approval of permanent joining procedures and personnel as required by section 3.1.2 of Schedule 2 (essential safety requirements (ESRs)) and to issue 'European approval for materials' (regulations 2.2 and 17) for those materials for the manufacture of pressure equipment which are not covered by a harmonised European standard;

'Recognised third-party organisations' may be appointed to carry out the approval of permanent joining procedures and personnel and non-destructive testing personnel as required by sections 3.1.2 and 3.1.3 of Schedule 2 of the Regulations;

‘User inspectorates’ may be appointed to carry out the tasks of notified bodies in respect of pressure equipment and assemblies for use within their own group under modules A1, C1, F and G (regulation 22).

- 1.4 The Regulations give the Secretary of State for Trade and Industry the responsibility for appointing, in the United Kingdom, CABs to carry out the functions referred to above and for notifying the appointments to the European Commission and other member States.

2. CRITERIA

- 2.1. Organisations wishing to be appointed as a notified body or recognised third-party organisation in the United Kingdom will need to meet the minimum criteria set out in Annex IV of the PED (reproduced as Appendix 1 to these Guidelines). Organisations wishing to be appointed as a user inspectorate in the United Kingdom will need to meet the criteria set out in Annex V of the PED (reproduced as Appendix 2 to these Guidelines). The United Kingdom Accreditation Service (UKAS) will undertake an assessment of the applicant against the criteria and report to the Secretary of State on that assessment. However, it should be noted that meeting the minimum criteria for appointment will not automatically lead to appointment as appointment remains at the discretion of the Secretary of State.

3. MEETING THE CRITERIA

- 3.1. Accreditation to an appropriate scope to one, or more, of the EN 45000 series standards, which contain specifications for bodies issuing certificates, performing inspections or conducting tests, may be used as the basis for demonstrating conformity with the criteria set out in Appendices 1 & 2 to these Guidelines. Although accreditation to one of the EN 45000 series standards is encouraged, it is not mandatory and the relevant criteria may be satisfied in other ways. Applicants which are not accredited will normally be assessed by UKAS to the relevant requirements of the appropriate EN 45000 standard and will need to demonstrate equivalent levels of ability in terms of competence, resources, organisational arrangements, policies and all other relevant matters.
- 3.2. All applicants, whether accredited to one of the EN 45000 series of standards or not, will need to meet the additional requirements set out in these guidelines which may change from time to time. In particular, they will need to demonstrate:
 - a thorough technical understanding of the range of pressure equipment, assemblies and materials for which appointment is sought;
 - the ability to undertake the conformity assessment activities laid down in the Regulations in respect of which they seek appointment; and
 - a thorough knowledge of the PED and the Regulations.

- 3.3. Applicants will therefore need to state for which pressure equipment and/or assemblies and for which conformity assessment activities they wish to be appointed. The scope of assessment and subsequent appointment will be determined by reference to the modules and activities described in the Regulations and the type of equipment. Applicants will be required to demonstrate the capability fully to undertake the functions defined by a particular module or activity for the relevant types of equipment.
- 3.4. EN 45004 is to be the basic standard for assessing the suitability of applicants wishing to operate under the inspection modules of the Regulations (i.e. Modules A1, B, B1, C1, F and G). Applicants wishing to be appointed as a notified body or recognised third-party organisation on the basis of EN 45004 will need to satisfy the requirements of that standard for Type A bodies. Applicants wishing to be appointed as a user inspectorate on the basis of EN 45004 will need to satisfy the requirements of that standard for Type B bodies within user organisations. Applicants assessed on the basis of EN 45004 wishing to operate under the quality assurance modules (i.e. Modules D, D1, E, E1, H and H1) will need to demonstrate that they meet the relevant additional requirements of EN 45012, e.g. knowledge and expertise in the assessment and monitoring of quality assurance systems.
- 3.5. EN 45012 is to be the basic standard for assessing the suitability of applicants wishing to operate under the quality assurance modules of the Regulations. However, as CABs operating under the quality assurance modules will need to be able to carry out, or have carried out on their behalf, tests for surveillance purposes, applicants will need to demonstrate that they meet the relevant additional requirements of EN 45004. This will apply particularly to applicants wishing to operate under module H1 which will be required to demonstrate that they are able to carry out design examinations. Equally, applicants assessed on the basis of EN 45012 wishing to operate under the inspection modules will need to demonstrate that they meet the relevant additional requirements of EN 45004, e.g. knowledge and expertise in design examination and inspection activities.
- 3.6. EN 45004 is to be the basic standard for assessing the suitability of applicants wishing to issue European approvals of materials.
- 3.7. EN 45004 is to be the basic standard for assessing the suitability of applicants wishing to be appointed as recognised third-party organisations for the approval of permanent joining procedures. EN 45013 is to be the basic standard for assessing the suitability of applicants wishing to be appointed as recognised third-party organisations for the approval of non-destructive testing personnel while those wishing to be appointed for the approval of permanent joining personnel may demonstrate operation in accordance with EN 45004 (as a Type A body) or EN 45013.
- 3.8. Applicants accredited to EN 45011 will be eligible for appointment once their competence has been demonstrated against the relevant additional requirements of EN 45012 (e.g. knowledge and expertise in the assessment and monitoring of quality assurance systems) and EN 45004 (e.g. knowledge and expertise in design assessment and inspection activities), where this is not covered by their accreditation scope.

- 3.9. Assessment of an applicant will be related to its ability to understand the ESRs and other relevant provisions of the Regulations relevant to its proposed scope of approval. No applicant may be appointed for part of a conformity assessment module. Applicants will need to be able to demonstrate their professional ability and understanding of the Regulations necessary to determine whether pressure equipment and assemblies offered for assessment satisfy the ESRs and the other relevant provisions.
- 3.10. The Regulations also define the role of harmonised standards. These are to be produced in response to a mandate from the European Commission to the European standards organisation, the Comité Européen de Normalisation (CEN). Pressure equipment and assemblies produced in accordance with such standards will enjoy a presumption of conformity with the relevant ESRs (regulation 7(3)(a)). Under the appropriate conformity assessment procedures, applicants will need to be able to examine or inspect against the ESRs and other relevant provisions direct. They will also need to be able to inspect against the CEN standards.
- 3.11. Where an applicant operates its own testing facilities or utilises those of a manufacturer, these, and the associated activities, will need to conform to the relevant requirements of EN 45001 (General criteria for the operation of testing laboratories) though accreditation is not mandatory. Where testing is performed on its behalf by a manufacturer or by a subcontractor, the applicant will need to ensure that that organisation is capable of carrying out the tasks effectively and meets the relevant requirements of EN 45001 although accreditation is not mandatory.
- 3.12. Where an applicant operates its own inspection facilities or utilises those of a manufacturer, these, and the associated activities, will need to conform to the relevant requirements of EN 45004 (General criteria for the operation of various types of bodies performing inspection) though accreditation is not mandatory. Although a CAB should normally carry out inspections which it contracts to undertake, where elements of the inspection will be performed on its behalf by a manufacturer or by a subcontractor, the applicant will need to ensure that that organisation is capable of carrying out the tasks effectively and meets the relevant requirements of EN 45004 although accreditation is not mandatory.
- 3.13. Where an applicant wishes to subcontract testing, the Quality Manual of the applicant will need to describe the procedures to be followed by the applicant to ensure compliance by the subcontractors with the relevant requirements and to demonstrate that the subcontractor 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 to the task contained within the subcontract. The applicant will need to maintain documented procedures for the assessment and monitoring of subcontractors, and a list of subcontractors 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.
- 3.14. An applicant will need to have fully documented agreements with its subcontractors. A Register of all subcontractors 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.

- 3.15. A CAB will at all times be responsible for ensuring that the conformity assessment is carried out in accordance with the requirements of the Regulations.
- 3.16. An applicant will be expected 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 the relevant requirements of the appropriate standards in the EN 45000 series are met plus any further requirements for appointment and operation as a CAB.
- 3.17. 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. Such cover should extend to the whole of the European Economic Area (EEA), or, if the applicant intends to carry out work under the PED outside the EEA, world-wide. The Secretary of State will not in relation to any case or circumstance cover a CAB's liability.
- 3.18. Applicants wishing to be appointed as a user inspectorate will need to demonstrate that the group to which it belongs applies a common safety policy regarding the technical specification for the design, manufacture, inspection, maintenance and use of the types of equipment for which it wishes to be appointed, in accordance with regulation 22 .
- 3.19. A CAB 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.

4.0 MAKING AN APPLICATION

- 4.1 Applicants will be required in the first instance, to make an application to UKAS at the address on page 10. Applications should be submitted using UKAS form DF 101. The scope of the appointment should be defined by reference to the type of conformity assessment body (i.e. notified body, recognised third party organisation, or user inspectorate), to the modules if these are applicable and in terms of the definitions of pressure equipment (i.e. vessels, piping, pressure accessories and safety accessories) and assemblies given in regulation 2 if these are applicable. CABs are expected to be able to deal with the full range of equipment within a technical scope description. UKAS will quote and charge applicants against its standard scales of charges for its assessment activities under the scope of these guidelines. UKAS has established procedures to handle complaints or appeals associated with its assessment activities.
- 4.2. At the same time as it submits its application for assessment to UKAS, the applicant will be required to send a copy to the DTI contact at the address on page 10. This will represent formal application to the Secretary of State for appointment.

4.3 An applicant CAB will be required to have documented procedures covering all aspects of its work relating to the conformity assessment activities for which it seeks approval or to the issue of European approvals for materials. On behalf of the Secretary of State, 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 PED and implementing Regulations will be provided by the Department, or through the systems in place for the exchange of views on the PED.

5.0 APPOINTMENT

5.1 Once UKAS has submitted its report, the Secretary of State will then make a decision on appointment on the basis of all the evidence. If satisfied that the applicant is fit for appointment under the Regulations, the Secretary of State will issue a letter of appointment.

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

- to take part in co-ordination activities at both UK and European level;
- to undergo an initial surveillance no later than 6 months from the date of appointment, and then annually, or at whatever intervals are thought appropriate by the Department;
- to a full reassessment every four years or at whatever intervals are thought appropriate by the Department.

5.3 Reassessment and surveillance will be carried out on behalf of the Secretary of State, normally by UKAS. A report on the reassessment and surveillance will be sent to the Secretary of State. Reassessment and surveillance may also be carried out by the Secretary of State.

5.4 Once acceptance of the conditions of the letter of appointment has been received, the appointment will be confirmed and the DTI will notify the European Commission and the other member States of the appointment.

5.5 To be eligible for appointment as a United Kingdom CAB for the purposes of the Regulations, an applicant must be a legal entity in the United Kingdom and carry out its assessment functions within the jurisdiction of the United Kingdom. It may, where necessary, conduct tests, or have tests conducted, outside the jurisdiction of the United Kingdom.

5.6 CABs should ensure that they do not unreasonably restrict access of manufacturers of pressure equipment and assemblies to their services. CABs must not place undue financial or other conditions upon such manufacturers. The procedures under which a CAB operates must be administered in a non-discriminatory manner.

6.0 DUTIES OF CONFORMITY ASSESSMENT BODIES

The precise duties to be fulfilled by a CAB will be set out in individual letters of appointment but the following obligations are likely to appear.

- 6.1 It will be a duty of a CAB appointed to operate under the inspection modules accurately to assess the conformity of the products for which it is approved against the requirements of the Regulations in accordance with the modules for which it has been appointed. When a CAB assesses pressure equipment as conforming with the requirements, it will be required to issue the appropriate conformity assessment documentation as specified in the Regulations.
- 6.2. It will be a duty of a CAB appointed to operate under the quality assurance modules accurately to assess and approve a manufacturer's quality system for the manufacture of the pressure equipment for which it is approved against the requirements of the implementing Regulations, in accordance with the modules for which it has been appointed. In assessing quality systems against the requirements of a quality assurance module, CABs must presume compliance with these requirements in respect of those elements of the quality system which conform to the relevant harmonised standard (the relevant standard from the BS EN ISO 9000 series). When a CAB assesses a manufacturer's quality system as conforming with the requirements, it will be required to issue the appropriate conformity assessment documentation as specified in the Regulations.
- 6.3. It will be a duty of a notified body appointed to approve permanent joining procedures and personnel accurately to carry out the approvals as set out in section 3.1.2 of Schedule 2 to the Regulations.
- 6.4. It will be a duty of a notified body appointed to issue European approvals of materials accurately to assess the conformity of the materials with the requirements of the Regulations. When a notified body assesses materials as conforming with the requirements, it will be required to follow the procedures set out in the Regulations before issuing the appropriate documentation.
- 6.5 It will be a duty of recognised third party organisations accurately to assess and approve the permanent joining procedures and personnel and non-destructive testing personnel as set out in sections 3.1.2 and 3.1.3 of Schedule 2 to the Regulations.
- 6.6 A CAB will be required to maintain an up to date record of any certification which it has issued, to whom it has been issued and for what pressure equipment. 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.

7. MISUSE OF CERTIFICATES AND CONFORMITY NUMBERS

- 7.1. The Quality Manual should state the CAB'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.
- 7.2. A CAB 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.

8. MUTUAL RECOGNITION AGREEMENTS

- 8.1. Applicants should note that the European Community aims to reach Mutual Recognition Agreements (MRAs) with key trading partners. Under these agreements, EC CABs may be eligible to perform conformity assessments as required by the third country's laws and, similarly, those trading partners' equivalents to CABs 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 DTI at the address on page 10.

9. CONTACT POINTS

Applications should be sent to:

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

Tel : 020 8917 8500
Fax : 020 8917 8499

and copied to:

Peter Rutter
Department of Trade and Industry
Standards & Technical Regulations Directorate
151 Buckingham Palace Road
London SW1W 9SS

Tel : 020 7215 1437
Fax : 020 7215 1970
E-mail:
peter.rutter@tidv.dti.gov.uk

10. SOURCES OF DOCUMENTS

The **Pressure Equipment Directive** (97/23/EC) has been published in the Official Journal of the European Communities (L181 of 9.7.97). Copies can be obtained from European Information Centres and the Stationery Office.

The **Pressure Equipment Regulations** 1999 (S.I.1999 2001) may be obtained from The Stationery Office Ltd (mail, telephone and fax orders only):

The Stationery Office Ltd
The Publications Centre
PO Box 276
London SW8 5DT

General enquiries : 020 7873 0011
Telephone orders : 020 7873 9090
Fax orders : 020 7873 8200

Information on the **EN 45000 series of standards** and the **harmonised standards** being developed in support of the PED is available from:

BSI
389 Chiswick High Road
London W4 4AL

Tel : 020 8996 9001
Fax : 020 8996 7001
Web: <http://www.bsi.org.uk>

Appendix 1: Extract from the EC Pressure Equipment Directive (97/23/EC)

ANNEX IV

MINIMUM CRITERIA TO BE MET WHEN DESIGNATING THE NOTIFIED BODIES REFERRED TO IN ARTICLE 12 AND THE RECOGNISED THIRD-PARTY ORGANISATIONS REFERRED TO IN ARTICLE 13

1 The body, its director and the personnel responsible for carrying out the assessment and verification operations may not be the designer, manufacturer, supplier, installer or user of the pressure equipment or assemblies which that body inspects, nor the authorised representative of any of those parties. They may not become directly involved in the design, construction, marketing or maintenance of the pressure equipment or assemblies, nor represent the parties engaged in these activities. This does not preclude the possibility of exchanges of technical information between the manufacturer of pressure equipment or assemblies and the notified body.

2 The body and its personnel must carry out the assessments and verifications with the highest degree of professional integrity and technical competence and must be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of the inspection, especially from persons or groups of persons with an interest in the result of verifications.

3 The body must have at its disposal the necessary personnel and possess the necessary facilities to enable it to perform properly the technical and administrative tasks connected with the inspection and surveillance operations, it must also have access to the equipment required to perform special verifications.

4 The personnel responsible for inspection must have:

- sound technical and vocational training,
- satisfactory knowledge of the requirements of the inspections they carry out and adequate experience of such operations,
- the ability required to draw up the certificates, records and reports to demonstrate that the inspections have been carried out.

5 The impartiality of the inspection personnel must be guaranteed. Their remuneration must not depend on the number of inspections carried out, nor on the results of such inspections.

6 The body must take out liability insurance unless its liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the inspections.

7 The personnel of the body must observe professional secrecy with regard to all information gained in carrying out their tasks (except vis-à-vis the competent administrative authorities of the State in which their activities are carried out) under the Directive or any provision of national law giving effect to it.

Appendix 2: Extract from the EC Pressure Equipment Directive (97/23/EC)

ANNEX V

CRITERIA TO BE MET WHEN AUTHORISING USER INSPECTORATES REFERRED TO IN ARTICLE 14

1 The user inspectorate must be organisationally identifiable and have reporting methods within the group of which it is part which ensure and demonstrate its impartiality. It must not be responsible for the design, supply, installation, operation or maintenance of the pressure equipment or assemblies, and must not engage in any activities that might conflict with its independence of judgement and integrity in relation to its inspection activities.

2 The user inspectorate and its personnel must carry out the assessments and verifications with the highest degree of professional integrity and technical competence and must be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of the inspection, especially from persons or groups of persons with an interest in the results of verifications.

3 The user inspectorate must have at its disposal the necessary personnel and possess the necessary facilities to enable it to perform properly the technical and administrative tasks connected with the inspection and surveillance operations, it must also have access to the equipment required to perform special verifications.

4 The personnel responsible for inspection must have:

- sound technical and vocational training,
- satisfactory knowledge of the requirements of the inspections they carry out and adequate experience of such operations,
- the ability required to draw up the certificates, records and reports to demonstrate that the inspections have been carried out.

5 The impartiality of the inspection personnel must be guaranteed. Their remuneration must not depend on the number of inspections carried out, nor on the results of such inspections.

6 The user inspectorate must have adequate liability insurance unless liability is assumed by the group of which it is part.

7 The personnel of the user inspectorate must observe professional secrecy with regard to all information gained in carrying out their tasks (except vis-à-vis the competent administrative authorities of the State in which their activities are carried out) under the Directive or any provision of national law giving effect to it.