Department for Business, Energy & Industrial Strategy

EU PRODUCT REGULATION

Guidelines on the appointment of UK Notified Bodies

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Contents

GUIDELINES ON THE APPOINTMENT OF UK NOTIFIED BODIES

1. Introduction

1.1 These guidelines describe the general requirements applying in the United Kingdom for the assessment and appointment of Notified Bodies under the Regulations listed below, which implement the provisions of the corresponding EU Directives in UK law.

- Pressure Equipment (Safety) Regulations 2016;
- Simple Pressure Vessels (Safety) Regulations 2016;
- Equipment and Protective Systems Intended for use in Potentially Explosive Atmospheres Regulations 2016;
- Lifts (Safety) Regulations 2016;
- Measuring Instruments Regulations 2016;
- Non-automatic Weighing Instruments Regulations 2016;
- Electromagnetic Compatibility Regulations 2016;
- Radio Equipment Regulations 2016;
- Recreational Craft Regulations 2016;
- Pyrotechnic Articles (Safety) Regulations 2016
- Explosives Regulations 2014 (Amendment) Regulations 2016

Note: certain Directives have additional requirements for Notified Bodies, so you should also check the information on gov.uk for the appropriate Directive.

1.2 Notified Bodies are appointed under and operate according to the law which transposes the provisions of the corresponding Directives. The Directives apply in the European Economic Area (EEA).

1.3 These guidelines replace the guidelines issued under any previous legislation that these Regulations have replaced. They apply to all conformity assessment bodies applying for notification under the Directives and implementing Regulations from the date of publication.

1.4 The Regulations apply to those products that fall within the definitions of each set of Regulations.

1.5 The conformity assessment procedures are set out in each set of Regulations.

1.6 Some of the conformity assessment procedures will require the involvement of third party conformity assessment bodies. Subject to paragraph 7, these third party bodies are appointed by member/EEA States.

1.7 In the United Kingdom, the conformity assessment bodies are appointed by the Secretary of State in accordance with the Regulations. 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 “Notified Bodies” for the purposes of carrying out conformity assessment of products under the Directive.

1.8 The letter of appointment will specify the scope of products within the Regulations which a Notified Body is authorised to assess. The Secretary of State for Business, Innovation and Skills is responsible for notifying the appointments to the European Commission and other member/EEA States and publishing the appointments of Notified Bodies and the scope of their approved activities.

2. Criteria, Application and Appointment

2.1 An organisation wishing to be appointed as a Notified Body in the United Kingdom will need to meet the requirements set out in the relevant Directive (an example can be found in Appendix II to this document). They must be accredited by the United Kingdom Accreditation Service (UKAS) or provide evidence to demonstrate that they meet the requirements. It should 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 3.13 regarding insurance arrangements.

2.2 Applicants may apply for appointment through accreditation or by a non-accredited route (see paragraph 3.5).

2.3 UKAS, the UK's national accreditation body, has been appointed by the Secretary of State to carry out assessment of eligibility of applicants. All applicants will be required in the first instance, to make an application for accreditation to UKAS which will undertake an assessment of the applicant against the minimum requirements of the relevant Directive and (where applicable) the relevant harmonised standard(s) (see paragraph 3.4) to ensure that the applicant complies with the requirements.

2.4 Applications should be submitted using the relevant UKAS form (AC1 to AC4 - available to download from the UKAS website) dependent upon the standard against which accreditation is required.

2.5 To be eligible for appointment as a United Kingdom Notified Body for the purposes of the relevant Regulations, an applicant must be a legal entity in the United Kingdom.

2.6 An applicant will be required to have documented procedures covering all aspects of its work relating to the conformity assessment procedures 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.

2.7 The scope of appointments will be defined by reference to the specific products covered by the relevant Regulations and applicants should indicate the conformity assessment procedure, activities and particular product(s) (if not all) in respect of which they wish to be appointed.

2.8 Harmonised standards are produced in response to a mandate from the European Commission to the European standards organisations, the Comité Européen de Normalisation (CEN) and the European Committee for Electrotechnical Standardisation (CENELEC). When adopted, they are listed in the Official Journal of the European Union. Products within the scope of the relevant Directive produced in accordance with harmonised standards will enjoy a presumption of conformity with the relevant essential requirements (ERs) or essential requirements. Under the appropriate conformity assessment procedures, applicants must be able to examine or inspect against the ERs and other relevant provisions directly. They will also need to be able to inspect against the CEN and CENELEC standards and relate these to the ERs.

2.9 UKAS will quote and charge applicants against its standard scales of charges for its accreditation activities. UKAS has established procedures to handle complaints or appeals associated with its assessment activities.

2.10 At the same time as it submits its application 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.

2.11 Once UKAS has completed its assessment, it will issue an accreditation certificate and schedule to the applicant.

2.12 The applicant should then submit an application for appointment to the Department. The application should describe the conformity assessment procedures, activities and the products for which the applicant wishes to be appointed and should be accompanied by the accreditation certificate, schedule, final assessment report issued by UKAS and evidence of the applicant's insurance cover (see paragraph 3.13).

2.13 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.

2.14 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 undergo surveillance annually or at whatever intervals are thought appropriate by the Secretary of State (newly appointed Notified Bodies may be required to undergo an initial surveillance after six months);
- To undergo a full reassessment every four years or at whatever intervals are thought appropriate by the Secretary of State.

2.15 Once the body provides its acceptance of the conditions of the letter of appointment, the Secretary of State 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 following the issue of an identification number, the appointment will be confirmed.

2.16 Reassessment and surveillance will be carried out on behalf of the Secretary of State, by UKAS in line with usual accreditation practice and paragraph 2.14, second indent, above. 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. UKAS will advise the Secretary of State of the outcome of annual surveillance, four-yearly re-assessment and any other necessary monitoring in intervening periods in order for the Secretary of State to take any necessary decisions about the continuation of the appointment. The Secretary of State may request further information about the reassessment and surveillance activities, as required.

3. Meeting the criteria

Applications for Accreditation

3.1 Applicants for accreditation 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 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 paragraphs 2.7 and 2.12, applicants will need to state the products specified in the Regulations in respect of which 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 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 EA-2/17 INF: 2014: EA Document on Accreditation for Notification Purposes.

Applications from non-accredited organisations

3.5 Accreditation is the preferred route for assessment and appointment of Notified Bodies, since it allows assessments to be compared like for like and judged on similar criteria. However, the legislation allows for applications via a non-accreditation route. Applicants will need to submit evidence to the Secretary of State demonstrating that their organisation, its processes and systems meet the requirements for appointment.

3.6 Applicants should be aware of the following when considering making an application for appointment without accreditation:

- Taking the non-accredited route to appointment may mean that assessments will take longer and involve the use of third party assessors appointed by the Secretary of State whose costs will have to be met by the applicant;
- Full justification and supporting evidence for their appointment must be disclosed to the European Commission and other Member States;
- Successful applicants through this route will have a standstill period of at least two months before their appointment is confirmed by the European Commission (as compared with two weeks' standstill for accredited appointments). This is to allow

Member States time to examine the supporting evidence for their appointment and raise questions or ask for clarification.

- Member States are entitled to ask for translation of the supporting evidence, this will be provided by the European Commission, but will add considerably to the standstill period.

All applicants

3.7. 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 essential requirements (ERs) or essential requirements and the other relevant provisions.

Harmonised Standards

3.8 An applicant that can demonstrate compliance with the criteria set out in a relevant harmonised standard or part of a harmonised standard that is published in the Official Journal is presumed to comply with the requirements of a conformity assessment body set out in the Directive and Regulations.

Quality System

3.9 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 ISO 17000 series are met plus any further requirements for appointment and operation as a Notified Body.

Sub-contracting

3.10 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.

3.11 An applicant will need to have fully documented agreements with its sub-contractors. Applicants will need to maintain a Register of all sub-contractors which may be used by the applicant 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.

3.12 A Notified Body will at all times be responsible for ensuring that the conformity assessment is carried out in accordance with the requirements of the relevant Directive or implementing Regulations.

Insurance

3.13 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 at the point at which a body makes an application to be appointed as a Notified Body. Thereafter, the Notified Body should make available to UKAS evidence of insurance at each annual surveillance visit undertaken by UKAS.

3.14 Such cover should extend to the whole of the European Union, 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 a Notified Body's liability.

4. Duties of Notified Bodies

4.1 It will be the duty of a Notified Body to assess the conformity of the products or quality systems which fall within the scope of its appointment, against the requirements of the relevant Directive or implementing Regulations. When a Notified Body assesses products as being in conformity, it will be required to issue the appropriate conformity assessment documentation as specified in the relevant Directive or 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 Guidance for achieving wider national and European agreement on interpretation and application of the Directive and the implementing Regulations can be sought from the Secretary of State, 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 participate fully.

4.3 A Notified 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 A Notified 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.

4.5 A Notified Body 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.

4.6 A Notified Body should ensure that it does not unreasonably restrict the access to its services by manufacturers of products within the scope of the Regulations. It must not place undue financial or other conditions upon such manufacturers. The procedures under which a Notified Body operates must be administered in an independent, impartial and non-discriminatory manner.

4.7 An example of the operation obligations of Notified Bodies as set out in the legislation is provided at Appendix III.

5. Misuse of Certificates and Notified Body Identification Numbers

5.1 The Notified Body should set out its policy and procedure for controlling the use of its certificates and Notified Body identification numbers in the Quality Manual.

5.2 The Secretary of State will deal with incorrect references to the certification system or misleading use of information found in advertisements, catalogues etc. by suitable means including corrective action, publication of the transgression and, if necessary, legal action.

5.3 A Notified 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 Notified Bodies may make reference to UKAS Accreditation or include the relevant National Accreditation Symbol on certificates issued by the accredited Notified 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. ISO 17020 etc), with the requirements for notification and with the requirements in BIS publication URN 16/25 "The National Accreditation Logo & Symbols: Conditions for use by UKAS and UKAS accredited organisations" and any other requirements specified by UKAS.

7. Mutual Recognition Agreements

7.1 Applicants should note that the European Union aims to reach Mutual Recognition Agreements (MRAs) with key trading partners. Under these agreements, EU Notified Bodies may be eligible to perform conformity assessments as required by the third country's laws and, similarly, those trading partners' equivalents to Notified Bodies may be eligible for appointment to perform conformity assessments under EU 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, Energy and Industrial Strategy, 1 Victoria Street, London,

SW1H 0ET

Tel: 020-7215 5000 Email: prodregs@bis.gsi.gov.uk

Kevin Belson (or your usual accreditation manager), United Kingdom Accreditation Service, 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR

Tel: +44 (0) 1784 429000 Email: kevin.belson@ukas.com

9. Sources of relevant documents

9.1 Copies of the Directive texts are available from the Europa website.

9.2 Copies of the implementing Regulations may be obtained from:

The Stationery Office Limited, PO Box 29, Norwich, NR3 1GN

Phone: +44 (0)333 202 5070Fax: +44 (0)333 202 5080

Email: book.orders@tso.co.uk Web: www.tso.co.uk/bookshop

Or from the UK Legislation website.

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

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

Tel: 0845 086 9001 Fax: 0208-996 7001

Email: cservices@bsigroup.com Web: http://www.bsigroup.com

Appendix I:

Table 1: Modules and applicable standards

Module	EN Standard(s) applicable
Al, 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
B	EN ISO/IEC 17020 (EN ISO/IBC 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
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

Module	EN Standard(s) applicable
	taken into account for testing required),
G	EN ISO/IEC 17020 (EN 17025 to be taken into account for testing required), or
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

Appendix II: Requirements relating to notified bodies

Note: this is an example, some legislation may have different requirements, so you should check the relevant provision in the specific Regulations.

1. For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11.

2. A conformity assessment body shall be established under the national law of a Member State and have legal personality.

3. A conformity assessment body shall be a third-party body independent of the organisation or the product it assesses.

A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of products which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.

4. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the products which they assess, nor the representative of any of those parties. This shall not preclude the use of assessed products that are necessary for the operations of the conformity assessment body or the use of such products for personal purposes.

A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of those products, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

5. Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

6. A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Annexes III to VII and Annex IX and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

At all times and for each conformity assessment procedure and each kind or category of products in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary:

(a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;

(b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;

(c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.

A conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.

7. The personnel responsible for carrying out conformity assessment tasks shall have the following:

(a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;

(b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;

(c) appropriate knowledge and understanding of the essential health and safety requirements set out in Annex II, of the applicable harmonised standards, of the relevant provisions of Union harmonisation legislation and of national legislation;

(d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

8. The impartiality of the conformity assessment bodies, their top level management, and of the personnel responsible for carrying out the conformity assessment tasks shall be guaranteed.

The remuneration of the top level management and personnel responsible for carrying out the conformity assessment tasks of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

9. Conformity assessment bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.

10. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under Annexes III to VII

and Annex IX or any provision of national law giving effect to it, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.

11. Conformity assessment bodies shall participate in, or ensure that their personnel responsible for carrying out the conformity assessment tasks are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under the relevant Union harmonisation legislation and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

Appendix III: Operational obligations of Notified Bodies

1. Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Annexes […]to […].

2. Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.

In so doing they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the product with the requirements of this Directive.

3. Where a notified body finds that the essential health and safety requirements set out in Annex […] or corresponding harmonised standards or other technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a certificate of conformity.

4. Where, in the course of the monitoring of conformity following the issue of a certificate, a notified body finds that a product no longer complies, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate if necessary.

5. Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates, as appropriate.

This publication available from www.gov.uk/bis

Contacts us if you have any enquiries about this publication, including requests for alternative formats, at:

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