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Accreditation for the Purposes of Appointment as Approved and Notified Bodies

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Changes since last edition

The document has been updated to reflect current status of related documents, the recent changes to EA-2/17 (including the change of status to Mandatory and the introduction of preferred standards) and changes to contact details.

1. Introduction

UKAS has been involved in the assessment of bodies seeking notified or approved body status under the UK regulations implementing certain EC Directives or under other UK regulations for many years. These assessments, leading to a recommendation rather than accreditation, are carried out on behalf of the Secretary of State for The Department for Business, Energy and Industrial Strategy (BEIS) and other UK competent authorities that have the responsibility for appointing and notifying bodies to the European Union to carry out the duties prescribed under EU Regulations and Directives, or appointing bodies for other purposes. These arrangements subsequently came under the legal framework introduced through EU Decision No 768/2008/EC and EU Regulation No 765/2008/EC on a common framework for the marketing of products, and the related requirements for accreditation and market surveillance. This was further enhanced from 2011 onwards when the UK competent authorities stated that the preferred methodology for appointment of notified bodies was to be one based upon accreditation.

The term Notified Body is used generically in this document and should be read to include other categories of appointment such as Appointed Bodies, Designated Bodies and Technical Assessment Bodies.

The EU Regulations and Directives and other UK regulations covered under these arrangements are listed in the Appendix to this information sheet.

2. Criteria

The criteria to be met by bodies seeking appointment are set out in the relevant UK regulations and in associated *Guidelines for Appointment* or equivalent documents issued by the competent authority. These documents make reference to, and require compliance with, relevant conformity assessment standards in the ISO/IEC 17000 series that have been harmonised by citation in the Official Journal of the European Union (OJEU). In addition, to harmonise implementation of the requirements across Europe, the guidance produced by the European cooperation for Accreditation ([EA-2/17 M](#)) shall also be complied with.

It is the Government's policy, in line with EC policy, to use accreditation of bodies seeking to undertake conformity assessment tasks under EU Regulations and Directives and to regard accreditation to the relevant standards in the ISO/IEC 17000 series to an appropriate scope as supporting evidence that the applicant body satisfies the requirements of the minimum criteria.

NB: Not all UK competent authorities use UKAS accreditation to determine the technical competence and appropriate compliance of notified bodies: Some, such as MHRA for Medical Devices, have adopted other accepted processes.

3. Application

On receipt of an application for accreditation for the purposes of appointment UKAS will initiate the assessment and accreditation of the applicant body against the relevant criteria and the requirements of the applicable standard(s) for the specified scope. Upon grant of accreditation the applicant body shall then formally apply to the relevant competent authority for appointment as a notified body, providing its certificate of accreditation, associated schedule, and assessment report as evidence of competence. The Secretary of State, or other competent authority, if satisfied that the applicant holds appropriate accreditation and can satisfactorily carry out the duties required, will make a decision on whether to appoint the body on the basis of the evidence provided/made available.

Copies of the Guidelines for Appointment, equivalent documents or other relevant publications should be obtained from the competent authorities listed in the Appendix to this document.

Applicants for assessment should apply to UKAS using the Application Form and relevant AC supplement(s) (i.e. AC1, AC2 or AC4) that are available from UKAS at <http://www.ukas.com>. The application must be accompanied by a signed *Notified Body Confidentiality Waiver* form, allowing UKAS to share related information with the relevant competent authority where necessary. This form can be found on the UKAS website along with the application forms. The AC supplement form should also be used by bodies already accredited by UKAS for the purposes of appointment who are seeking an extension to their scope of existing accreditation or when seeking an appointment under another Directive or other regulations.

In parallel, applicants should advise the appropriate UK competent authority of their application and satisfy any specific, additional application requirements. In some cases, specific competent authorities may require the applicant to apply for Notified Body status at the same time as applying for accreditation and may request further information, for example, with regard to appropriate insurance cover.

4. Assessment

UKAS will appoint a member of its staff to manage and coordinate the assessment process and will carry out an assessment of the applicant body in accordance with its normal procedures, using the requirements of the applicable standards in the ISO/IEC 17000 series, the horizontal criteria contained within the European cooperation for Accreditation guidance EA-2/17 '*EA Document on Accreditation For Notification Purposes*', any specific requirements within the Regulation or Directive and the relevant UK Guidelines for Appointment in so far as they reflect the criteria for appointment specified by the competent authority.

EA-2/17 includes a listing of preferred standards per module, wherever possible the preferred standard identified for the modules concerned will be used as the basis for accreditation, of for any reason this is not possible alternatives may be discussed with the applicant.

In carrying out the assessment UKAS will make due allowance for pre-existing accreditations and appointments of relevant scope held by the applicant body. Where an applicant holds relevant accreditation from a National Accreditation Body (as defined in Regulation 765/2008/EC), UKAS will base its assessment on the additional requirements for appointment. Wherever possible, UKAS will aim to coordinate assessment, surveillance and, reassessment activities relating to regulatory appointments with the applicant's other accredited activities.

Upon confirmation that all criteria have been fully met, and that competence has been demonstrated, UKAS will grant accreditation for the applicant scope. The newly accredited body should then formally apply to the competent authority that holds responsibility for appointments to the Regulation or Directive of concern (please note: in some cases, specific Competent Authorities may require the application for NB status to be made at the same time as the application for accreditation). The application for appointment should be supported by the body's certificate of accreditation, associated schedule, and assessment report as evidence of competence. The competent authority shall consider the available evidence, and may seek further information/clarification direct from UKAS, before making an appointment to undertake specified conformity assessment duties. The competent authority will advise the applicant of its decision on appointment.

Following confirmation of the appointment the body will be subject to surveillance and reassessment of its continuing competence and capability to carry out the duties for which it has been appointed. Such surveillance and reassessment will be in accordance with standard UKAS procedures and practice. Where required UKAS will report the results of the surveillance and reassessments of appointed bodies to the competent authority and in particular advise where UKAS determines that the appointed body no longer meets the requirements for accreditation.

For terms and conditions with respect to the fees charged by UKAS please refer to the UKAS website <http://www.ukas.com>.

5. Appendix

Activities Covered By These Arrangements

For the Department for Business, Energy and Industrial Strategy (BEIS)

- Electromagnetic compatibility ⁽¹⁾
- Equipment for use in explosive atmospheres ⁽¹⁾
- Gas Appliances ⁽¹⁾
- Lifts ⁽⁴⁾
- Machinery ⁽⁴⁾
- Noise emission in the environment by equipment for use outdoors ⁽¹⁾
- Personal protective equipment ⁽⁵⁾
- Pressure equipment ⁽¹⁾
- Radio equipment ⁽¹⁾
- Recreational craft ⁽⁴⁾
- Simple pressure vessels ⁽¹⁾
- Toys ⁽⁶⁾
- Certain EU/third country Mutual Recognition Agreements ⁽¹⁾
- Pyrotechnical Articles ⁽⁷⁾

Contact address

Department for Business, Energy & Industrial Strategy
1 Victoria Street
London
SW1H 0ET

Contact persons

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|--------------------------------|---|
| ⁽¹⁾ Richard Harris | Email: richard.harris@bis.gsi.gov.uk |
| ⁽⁴⁾ Kevin Lane | Email: kevin.lane@beis.gov.uk |
| ⁽⁵⁾ Harsha Patel | Email: harsha.patel@bis.gsi.gov.uk |
| ⁽⁶⁾ Tony Eden-Brown | Email: tony.edenbrown@bis.gsi.gov.uk |
| ⁽⁷⁾ Christine Knox | Email: christine.knox@beis.gov.uk |

Further information is available on the BEIS website at <https://www.gov.uk/european-commission-product-directives>. Guidelines, product standard booklets and other relevant documents are also directly downloadable from the BEIS website. Guidelines and booklets also contain references to the relevant UK implementing regulations.

For the Department for Transport (DfT)

- The inspection of tanks for the carriage of dangerous goods by road and rail and the inspection of transportable pressure receptacles for the carriage of dangerous goods by road and rail

Contact person

Ian Bryer
Vehicle Certification Agency, Dangerous Goods Office (VCA DGO)

Email: tanks@vca.gov.uk

Further information on the transport of dangerous goods by road and rail can be found at <https://www.gov.uk/government/policies/providing-effective-regulation-of-freight-transport/supporting-pages/safe-carriage-of-dangerous-goods>

Further information on transportable pressure receptacles can be found at <http://www.legislation.gov.uk/ukxi/2009/1348/contents/made>; and <http://www.legislation.gov.uk/ukxi/2011/1885/note/made>

- The Railways (Interoperability) Regulations 2011 No 3066

Contact person

Ian Jones
Rail International and Safety Policy
Department for Transport
3/19 Great Minster House
33 Horseferry Road
London
SW1P 4DR
Email: Ian.Jones@dft.gsi.gov.uk

Further information on the Interoperability Regulations can be found at <http://www.legislation.gov.uk/ukxi/2011/3066/made>

For the Department for Communities and Local Government (DCLG)

- Construction Products Regulation

Contact person

Ahad Sayed
Department for Communities and Local Government
Building Regulations and Standards Division
2 Marsham Street
London
SW1P 4DF
Email: Ahad.Sayed@communities.gsi.gov.uk

Further information on the Construction Products Regulation can be found at <http://www.planningportal.gov.uk/buildingregulations/buildingpolicyandlegislation/>

For Regulatory Delivery (Part of BEIS)

- Non-Automatic Weighing Instruments (NAWI) and Measuring Instruments Directive (MID)

Contact person

Robert Harper
Regulatory Delivery
Stanton Avenue
Teddington
Middlesex
TW11 0JZ
Tel: 020 8943 7272
Email: Robert.Harper@beis.gov.uk

Further information on NAWI and MID can be found at <https://www.gov.uk/government/collections/weights-and-measures-regulations-guidance>
<https://www.gov.uk/guidance/notified-bodies-appointment-and-co-ordination>

For The Maritime and Coastguard Agency (MCA)

- The Marine Equipment Directive

Contact person

Andy Wibroe
Marine Technology Unit
Spring Place
105 Commercial Road
Southampton,
SO15 1EG
Email: Andy.Wibroe@mca.gov.uk

Further information regarding the Marine Equipment Directive can be found at
<http://www.dft.gov.uk/mca/mcga07-home/shipsandcargoes.htm>

UKAS contacts

General enquiries related to the above Directives and applications:

Mr Kevin Belson
Technical Manager
Email: kevin.belson@ukas.com

General Enquires
Email: info@ukas.com

Application forms and publications may be downloaded from <http://www.ukas.com>.