



Department of Trade and Industry

**THE EUROPEAN COMMUNITY  
LOW VOLTAGE DIRECTIVE**

**GUIDELINES FOR THE APPOINTMENT  
OF NOTIFIED BODIES**

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

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# THE EUROPEAN COMMUNITY LOW VOLTAGE DIRECTIVE

## GUIDELINES FOR THE APPOINTMENT OF NOTIFIED BODIES

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

#### 1 INTRODUCTION

- 1.1 Council Directive 73/23/EEC<sup>1</sup> ("the Directive") on the approximation of the laws of the member States relating to electrical equipment designed for use within certain voltage limits (as amended by Council Directive 93/68/EEC<sup>2</sup> ("the CE Marking Directive")) is implemented in UK law by the Electrical Equipment (Safety) Regulations 1994<sup>3</sup> ("the Regulations"), which are made under the Consumer Protection Act 1987<sup>4</sup> and the European Communities Act 1972<sup>5</sup>.
- 1.2 The Directive provides, among other things, for the appointment of Notified Bodies competent to draw up reports on conformity and opinions in respect of electrical equipment, as described in Articles 8 and 9 of the Directive. Should the compliance of any goods, listed in Article 1 of the Directive (regulation 4 of the Regulations) and placed on the Community Market, be challenged, the supplier (manufacturer, their authorized representative, the importer, etc.) may submit a report on conformity from a Notified Body (see regulation 8 of the Regulations), or in the event of two member States being in dispute, the European Commission may ask a Notified Body of a member State not involved to carry out an assessment and provide an opinion.
- 1.3 In the UK, the Secretary of State for Trade and Industry has responsibility for appointing Notified Bodies to carry out the functions described in paragraph 1.2 above and for informing the Commission and other member States of such appointments. For purposes of information only, a complete list of Notified Bodies in each member State will, from time to time, be published in the Official Journal.
- 1.4 An organization wishing to be appointed as a Notified Body under the Directive must satisfy certain criteria. The Directive is silent as to specific criteria to be met, but the tasks which it assigns to Notified Bodies and the position in relation to other Directives which provide for the appointment of Notified Bodies suggest what is appropriate in relation to the Directive. Section 3 of these guidelines sets out the minimum criteria specified by the Department of Trade and Industry ("the Department") for appointment as a Notified Body.

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<sup>1</sup> O.J. No. L77, 26.3.1973

<sup>2</sup> O.J. No. L220, 30.8.1993

<sup>3</sup> S.I. No. 1994/3260

<sup>4</sup> 1987 c.43

<sup>5</sup> 1972 c.68

## **2 APPLICATION AND APPOINTMENT AS A NOTIFIED BODY**

- 2.1 To be eligible for appointment as a United Kingdom Notified Body for the purposes of the Directive, an applicant must be a legal entity in the United Kingdom and carry out its assessment activities within the jurisdiction of the United Kingdom. It may, where necessary, conduct tests, or have tests conducted outside the jurisdiction of the United Kingdom
- 2.2 Application should be made, in the first instance, to the United Kingdom Accreditation Service (UKAS) using the application documents obtainable from UKAS; for the UKAS contact address see paragraph 2.15.
- 2.3 At the same time as it submits its application for assessment to UKAS, the applicant will be required to send a copy to the Department. This will represent formal application to the Secretary of State for appointment; for the Department's contact address see paragraph 2.15.
- 2.4 UKAS will undertake an assessment of the applicant against the criteria set out in these guidelines, which may be updated from time to time, and report to the Secretary of State for Trade and Industry on that assessment
- 2.5 UKAS will use suitably qualified assessors or assessment teams to undertake the assessment of applicants for notification. UKAS will make clear to applicants when sub-contracted assessors are to be used and give applicants the right to object to specific assessors if there are concerns about potential conflicts of interest.
- 2.6 UKAS will quote and charge applicants against its standard scale 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.
- 2.7 The Department will require details of the applicant's insurance cover. The cover must include both public liability and professional indemnity insurance, and should extend to the whole of the European Economic Area (EEA), and, if the applicant intends to carry out work under the Low Voltage Directive outside the EEA (see paragraph 2.1), should extend to include the applicable markets. The Notified Body will be required to maintain that cover during its period of appointment. The Secretary of State will not under any circumstances cover any liability of a Notified Body. Evidence of the insurance cover should be submitted to UKAS and to the Department 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 undertaken by UKAS.

- 2.8 Once UKAS has submitted its report, the Secretary of State will then make a decision on appointment on the basis of all the evidence. In the light of information provided by UKAS, there may be other information required by the Department. If satisfied that the applicant is suitable for appointment and should be appointed, the Secretary of State will issue a letter of appointment. A copy of the letter of appointment will be provided to UKAS.
- 2.9 The precise terms and conditions of appointment will be set out in the individual letters of appointment, but it will be a standard condition that the applicant agrees:
- a. to surveillance annually or at whatever intervals are thought appropriate by the Department (new applicants will undergo an initial surveillance after 6 months); and
  - b. to a full reassessment every four years or at whatever intervals are thought appropriate by the Department.
- 2.10 Reassessment and surveillance will be carried out on behalf of the Secretary of State, normally by UKAS. A report on the reassessment or surveillance will be sent to the Secretary of State. Such information will relate only to the Notified Body's activities as a notified body and will not include any other accredited activity which is not relevant to the Notified Body's appointment. Reassessment and surveillance may also be carried out by the Secretary of State.
- 2.11 Once acceptance of the conditions of the letter of appointment has been received, the appointment will be confirmed and the Department will notify the European Commission and the other member States of the appointment.
- 2.12 UKAS will advise the Department if it believes that a Notified Body fails to continue to comply with the terms of its letter of appointment, including compliance with the minimum criteria laid down in these guidelines.
- 2.13 In the case of a Notified Body which has been accredited for a scope included within the scope of the Directive, UKAS will advise the Department if that accreditation is suspended, withdrawn or reduced in scope and, following any appropriate appeals procedure, UKAS will recommend to the Department whether it considers that constitutes a failure to continue to comply with the minimum criteria laid down in these guidelines. UKAS will notify the Department when an accreditation which supports notification is re-instated following suspension, withdrawal or reduction in scope.
- 2.14 The Department will advise UKAS if, for whatever reason, a Notified Body has its notification suspended or withdrawn.

2.15 Contact addresses are:

Gas & Electrical Policy Advisor  
Standards and Technical Regulations Directorate 6  
Room 329  
Department of Trade and Industry  
151 Buckingham Palace Road  
London  
SW1W 9SS

Tel: 020 7215-1349  
Fax: 020 7215-1340

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

Tel: 020 8917-8400  
Fax: 020 8917-8500

### **3 CRITERIA FOR APPOINTMENT AS A NOTIFIED BODY**

- 3.1 The minimum criteria to be met by an organization seeking appointment as a Notified Body are set out in these guidelines. Meeting the criteria does not lead to automatic appointment; appointment is at the discretion of the Secretary of State. The criteria can be met in part by accreditation to a relevant scope to one, or more, of the EN 45000 series of standards which set out the requirements to be met by bodies carrying out product certification, performing inspections or conducting tests.
- 3.2 These criteria should be read with reference to Articles 9 and 11 of the Directive.
- 3.3 For applicants already accredited, or planning to be accredited to EN 45001, EN 45004 or EN 45011, meeting the following requirements would demonstrate compliance with the minimum criteria for appointment as a Notified Body:
- a. Accreditation to EN 45001 (General criteria for the operation of testing laboratories), plus additional criteria as defined in section 1.2 of Annex A to demonstrate professional competence and the ability to draw up reports on conformity and opinions as required under paragraph 1.2 of these guidelines, plus the demonstration of an applicant's technical understanding and ability to assess goods against the requirements of the Directive as specified in paragraph 3.6 of these guidelines;

- b. Accreditation to EN 45004 (General criteria for the operation of various types of bodies performing inspection), plus the demonstration of an applicant's technical understanding and ability to assess goods against the requirements of the Regulations as referred to in paragraph 3.6 of these guidelines;

Note: See section 2 of Annex A for the requirements relating to the subcontracting of testing to Testing Laboratories.

or

- c. Accreditation to EN 45011 (General requirements for bodies operating product certification systems), plus the demonstration of an applicant's technical understanding and ability to assess goods against the requirements of the Directive as referred to in paragraph 3.6 of these guidelines.

Note: See section 3 of Annex A for the requirements relating to the subcontracting of testing to Testing Laboratories.

- 3.4 Accreditation is not mandatory, though it is encouraged, and the relevant criteria may be satisfied in other ways. An applicant which is not accredited will normally be assessed by UKAS to the relevant requirements taken from the appropriate EN 45000 standard (see Annex A of these guidelines) where the applicant will need to demonstrate equivalent levels of ability in terms of competence, resources, organizational arrangements, policies and all other relevant matters. A report will then be made to the Secretary of State and this will form part of his assessment of the application.

The applicant will also need to demonstrate its technical understanding and ability to assess goods against the requirements of the Regulations as referred to in paragraph 3.6 of these guidelines.

It should be noted that, in these circumstances, successful assessment for notification will not imply that the applicant is accredited to any of the EN 45000 standards, and such applicants shall not attempt to make any claims to the contrary.

- 3.5 If an applicant wishes to offer evidence of accreditation already held or applied for from a relevant EA/IAF signatory recognised body then due account will be taken during the assessment process.

- 3.6 A Notified Body must also be able to demonstrate:

- a. a thorough technical understanding of the range of goods for which appointment is being sought;
- b. the clear ability to determine whether goods, in respect of which they seek appointment, offered for assessment satisfy the Principal Elements of the Safety Objectives and the other relevant provisions of the Regulations; and
- c. a thorough knowledge of the Regulations.

- 3.7 Applicants will need to state which of Articles 8 (regulation 8 of the Regulations) or 9 or both of the Directive and for what range of goods they wish to be appointed. The range of goods specified by the applicant shall form the basis of the scope of goods for which the applicant, when appointed as a Notified Body, may draw up a report in accordance with the provisions of Article 8 of the Directive or give an opinion in accordance with Article 9 of the Directive. That scope will be included in the letter of appointment. Where an applicant is not accredited, an agreed scope of assessment for appointment will be drawn up.
- 3.8 Where an applicant operates its own testing facilities these, and their associated activities, will need to conform to the relevant requirements of EN 45001 (General criteria for the operation of testing laboratories) and continue to do so during the period of appointment as a Notified Body, though accreditation is not mandatory. Where testing is to be performed on its behalf by a subcontractor, the Notified Body shall be responsible for ensuring that the subcontractor is capable of carrying out the tasks effectively and meets those requirements of EN 45001 which are necessary in carrying out its tasks under the Directive. The use of a subcontractor accredited to any of the EN 45000 standards is not mandatory; see also paragraph 3.9.
- 3.9 Where a Notified Body wishes to subcontract testing, its Quality Manual shall describe, or make reference to, the procedures to be followed by it to ensure compliance by the subcontractors with the 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 to fully conform to the requirements that are placed on the Notified Body itself in respect to the task contained within the subcontract. The Notified Body shall 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 Notified Body. The list shall form part of the Register specified in paragraph 3.10.
- 3.10 It will be a requirement of appointment that:
- (a) a Notified Body shall have fully documented agreements with its subcontractors;
  - (b) a Register of all subcontractors, which may be used by the Notified Body, shall be maintained;
  - (c) the Quality Manual will either contain the Register or shall state where the Register is to be found; and
  - (d) the agreements and the Register shall be available for scrutiny at any reasonable time on request by the Secretary of State or such other person as may be appointed by the Secretary of State for that purpose.

- 3.11 A Notified Body shall at all times be and remain responsible for ensuring that the conformity assessment is carried out in accordance with the requirements of the Directive, notwithstanding any subcontracting of testing undertaken.
- 3.12 A Notified Body shall have a Quality System, usually specified in a Quality Manual, and associated documented operational procedures. The Quality System shall contain all the relevant requirements of the appropriate standards and any further requirements for appointment as a Notified Body.
- 3.13 A Notified Body will be required to inform the Secretary of State immediately of any changes which, in any way, affect its ability to carry out the duties within the authorized scope to the declared procedures. This includes any change in its status.
- 3.14 All manufacturers and importers of the goods described in Article 1 of the Directive (regulation 4 of the Regulations) must have access to the services of a Notified Body. Notified Bodies shall not place undue financial or other conditions upon them. The procedures under which a Notified Body operates shall be administered in a non-discriminatory manner.

#### **4 DUTIES OF A NOTIFIED BODY**

**The precise duties to be fulfilled by a Notified Body will be set out in individual letters of appointment but the following obligations are likely to appear:**

- 4.1 It shall be the duty of a Notified Body to accurately assess the conformity of the goods with the Principal Elements of the Safety Objectives of the Directive for the scope of goods for which the Notified Body has been appointed. The assessment will be carried out in accordance with the procedures contained or referenced in the Quality Manual and which have been assessed as part of its appointment as a Notified Body.

When a Notified Body assesses goods' conformity with the requirements of the Directive (as specified in Articles 8 and 9 of the Directive), that Notified Body will issue the appropriate report or opinion.

- 4.2 A prospective Notified Body is required to have documented procedures covering all aspects of its work relating to activities it would undertake as a Notified Body. The adequacy of the internal organization and the procedures adopted to give confidence in the quality of the applicant's services will be assessed by or on behalf of the Secretary of State. Where judgments or interpretation of a standard or requirement are implicit or explicit in a decision as to whether an item complies with the Principal Elements of the Safety Objectives, a Notified Body is required to have procedures for achieving consistency. Guidance for achieving wider national and European agreement on interpretation and application of the Directive will be provided by the Department, or through any systems in place for the exchange of views on the Directive.

- 4.3 A Notified Body must be able to ascertain whether the goods specified in the scope of the Directive (regulation 4 of the Regulations) for which they are appointed are compliant with the Principal Elements of the Safety Objectives. A Notified Body may reference either harmonized, or national standards where no harmonized standard exists, to achieve this. (Note: The procedure laid down in Article 6(2) and (3) of the Directive has never been applied). Where goods are compliant with the Principal Elements of the Safety Objectives, a Notified Body will issue a report or opinion, as appropriate, stating compliance.
- 4.4 A Notified Body should provide full details of any defective harmonized standard and, if relevant, any inappropriate application of harmonized standards to the Department. Defective standards are those which do not allow the Principal Elements of the Safety Objectives of the Directive to be met in full.
- 4.5 A Notified Body is required to maintain a record of any report or opinion which has been issued, to whom it has been issued and for what goods. The records shall be made available on request to the Secretary of State or such other person as may be authorized by the Secretary of State.
- 4.6 A Notified Body is required to play a full part in Notified Body co-ordination activities at both the national and European level.

## **5 MISUSE OF REPORTS AND OPINIONS**

- 5.1 The Quality Manual shall state a Notified Body's policy and procedure for controlling the use of its reports and opinions.

## **6 MUTUAL RECOGNITION AGREEMENTS**

- 6.1 Applicants should note that the European Community aims to reach Mutual Recognition Agreements (MRAs) with key trading partners. Under these agreements, European Community (EC) Notified Bodies may be eligible to perform conformity assessments as required by these key trading partners' laws and, similarly, those trading partners' equivalents to EC Notified Bodies may be eligible to perform conformity assessments under EC Directives.

A Notified Body should inform the Department if they wish to be considered for appointment under the MRAs.

## **7 SOURCES OF RELEVANT DOCUMENTS**

### **7.1 Copies of the Directive may be obtained from:**

European Information Centres.

European Commission's website: <http://europa.eu.int/>

### **7.2 Copies of the Regulation may be obtained from**

The Stationery Office Ltd  
Nine Elms Lane  
London  
SW8 5DR

Tel: 020 7873-9090

Fax: 020 7873-8463

### **7.3 The standards may be obtained from:**

BSI Standards  
389 Chiswick High Road  
London  
W4 4AL

Tel: 020 8996-7021

Fax: 020 8996-7048

Web: <http://www.bsi.org.uk>

### **7.4 Further information on the Directive, and a copy of these Guidelines, may be found on the Department's website:**

<http://www.dti.gov.uk/strd>

## ANNEX A

### THIS ANNEX DETAILS THE ASSESSMENT OPTIONS THAT AN APPLICANT WHICH IS NOT ACCREDITED MAY FOLLOW TO DEMONSTRATE COMPETENCE TO BE APPOINTED AS A NOTIFIED BODY UNDER THE DIRECTIVE

An applicant may demonstrate compliance as follows:

#### EITHER:

#### 1. BY USING EN 45001:1989 GENERAL CRITERIA FOR THE OPERATION OF TESTING LABORATORIES.

- 1.1 The Department will require applicant Notified Bodies seeking appointment under the Directive to demonstrate compliance with this standard in so far as it relates specifically to the duties and activities to be carried out by a Notified Body. Subcontracting to non-accredited bodies is allowed provided such subcontracting is in accordance with the agreed procedures. Where a Notified Body is not accredited to EN 45001, but has demonstrated compliance with the requirements of EN 45001 to the satisfaction of the Secretary of State no accreditation or approval by the Secretary of State is to be either inferred or implied.
- 1.2 The Department will also require compliance with additional criteria from either EN 45004 or EN 45011, as follows:

#### either:

- (i) Additional criteria from EN 45004:1995:

**Clause 3      Administrative Requirements**

**Clause 4      Independence, impartiality and integrity**

For a Notified Body a clause 4.2.1 Type A is required; clauses 4.2.2 and 4.2.3 are not appropriate. An undertaking must not be involved in design, manufacture, supply or installation.

**Clause 8      Personnel      Sub-clause 8.2 only**

**Clause 13     Inspection reports and inspection certificates**

**Clause 15     Complaints and appeals**

#### OR

- ii) Additional criteria from EN 45011:1998:

**Clause 4.1.    General provisions    Sub-clauses 4.1.1 and 4.1.2 only**

The Department will require compliance with this clause of the standard in so far as it relates only to a Notified Body's activities with regard to reports and opinion, but does not extend to any certification activity.

**Clause 4.2 Organization**

The Department will require compliance with this clause of the standard in so far as it relates only to a Notified Body's activities with regard to reports and opinion, but does not extend to any certification activity.

**Clause 7 Appeals, complaints and disputes**

**Clause 10 Evaluation**

However the evaluation shall be carried out against the criteria of Directive 73/23/EEC as modified

**Clause 11 Evaluation Report**

It is emphasized that compliance with the above clauses relates only to a Notified Body's activities with regard to reports and opinions, but does not extend to any certification activity.

**OR:**

**2. BY USING EN 45004:1995 GENERAL CRITERIA FOR THE OPERATION OF VARIOUS TYPES OF BODIES PERFORMING INSPECTION**

- 2.1. The Department will require compliance with this standard in so far as it relates only to a Notified Body's activities with regard to reports and opinions, but does not extend to any certification activity.
- 2.2. It should be noted that with regard to clause 4.2 of EN 45004 the inspection body shall be of type A.
- 2.3 Subcontracting to non-accredited bodies is allowed provided such subcontracting is in accordance with the agreed procedures.

**OR:**

**3. BY USING EN 45011:1998 GENERAL REQUIREMENTS FOR BODIES OPERATING PRODUCT CERTIFICATION SYSTEMS.**

- 3.1. The Department will require full compliance with this standard in so far as it relates only to a Notified Body's activities with regard to reports and opinions but does not extend to any certification activity; the following relaxations are also permitted:

### **Clause 4.3. Operations**

Paragraph 1 is not applicable

Paragraph 2 -This clause refers to ISO/IEC Guide 25 (EN 45001); see above for permitted relaxations to this standard.

### **Clause 10 Evaluation**

However the evaluation shall be carried out against the criteria of Directive 73/23/EEC as modified

### **Clauses 6, 8, 12, 13, 14, 15**

The requirements of these clauses do not need to be satisfied.

- 3.2 All other clauses of EN 45011:1998 are only relevant in so far as they relate to the work to be carried out to give opinions and provide reports.
- 3.3 Subcontracting to non-accredited bodies is allowed provided such subcontracting is in accordance with the agreed procedures.

**NOTE: In all cases, the applicant will additionally need to demonstrate its technical understanding, and ability to assess the goods against the requirements of the Regulations as referred to in paragraph 3.6 of these guidelines.**