



Department of Trade and Industry

**The Noise Emission in the
Environment by Equipment for use
Outdoors Regulations 2001**

**Guidelines for Organisations seeking
Notified Body status to Undertake
Noise Emission Testing, Inspection
and Certification**

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1. INTRODUCTION

1.1 The European Community Directive on the approximation of the laws of the member States relating to noise emission in the environment by equipment for use outdoors - (“the Directive”) 2000/14/EC (Official Journal No. L162 Volume 43 of 3 July 2000) - entered into force on 3 July 2000.

1.2 The Directive makes provision, among other things, for the appointment of Notified Bodies to carry out assessments of technical documentation and compile reports or issue certificates and inspection and verification testing of equipment as described under its Annex VI, or by unit verification as described under its Annex VII, before they can be placed on the market or put into service. Provision is also made for the conformity assessment of equipment based on a manufacturer’s quality assurance system. (See Annex VIII of the Directive).

1.3 Member States were required to transpose the Directive into national law by 3 July 2001. Transposition in the United Kingdom was effected by the Noise Emission in the Environment by Equipment for use Outdoors Regulations 2001 (“the Regulations”) SI 2001/1701 made under the European Communities Act 1972. The Regulations give the Secretary of State for Trade and Industry the responsibility for appointing, in the UK, Notified Bodies to carry out the functions referred to above and for notifying the appointments to the European Commission and other member States.

2. CRITERIA AND APPLICATION

2.1 Organisations wishing to become Notified Bodies must meet in full the minimum criteria set out in Annex IX of the Directive (attached as Appendix 1). Meeting the minimum criteria for appointment does not automatically lead to appointment as appointment remains at the discretion of the Secretary of State.

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

2.2 Application for assessment for the purposes of appointment should be made in the first instance to the United Kingdom Accreditation Service (UKAS) and copied to the Department of Trade and Industry at the addresses indicated on page 11. The copy application to the Department will form the application for appointment as a Notified Body. Application to UKAS should be made using the forms obtainable from the UKAS contact (see page 11). UKAS will then carry out an assessment of the undertaking on behalf of the Secretary of State for Trade and Industry against the criteria set out in these guidelines which will be updated from time to time.

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.

An applicant for Notified Body status need not apply to be appointed for every conformity assessment module which involves the services of a Notified Body. A body cannot however be appointed for part of an assessment module.

2.3 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.

The Department will require details of the applicant's insurance cover which should be forwarded to UKAS with the application and copied to the Department. The insurance should include both public liability and professional indemnity insurance, and extend to the whole of the Community, or, if the applicant intends to carry out work under the Regulations outside the Community, should extend to include the applicable markets. It is for the applicant to effect appropriate insurance arrangements, in terms of scope and level, depending on the nature of its business, but the Department will consider whether the applicant's insurance meets the mandatory insurance requirements. In this respect see paragraph 6 of Annex IX of the Directive. The Secretary of State will not, in any case, cover the applicant's liability. The Notified Body is acting at all times as principal in relation to the performance of its duties and functions and not as an agent of the Secretary of State and shall remain solely liable in respect of its activities as a Notified Body.

2.4 Following appointment by the Secretary of State, the Notified Body will be required under its conditions of appointment to make available to UKAS evidence of liability insurance at each annual surveillance visit undertaken by UKAS.

2.5 All manufacturers of equipment shall have access to the services of a Notified Body. There shall not be undue financial or other conditions imposed on the manufacturer. The procedures under which the Notified Body operates shall be administered in a non-discriminatory manner.

2.6 For the purposes of understanding the conformity assessment modules referred to above, applicants for Notified Body status should refer to Schedules 9 to 11 of the Regulations (Annexes VI to VIII of the Directive).

3. MEETING THE CRITERIA

3.1 It is the Government's policy, in line with EU policy, to promote the use of accreditation of testing, certification and inspection bodies and to rely wherever possible on accreditation to the EN45000 series of standards in considering applications for appointment and notification to the Commission under EC Directives. The EN45000 series comprise a number of standards which set out the criteria to be met by bodies issuing certificates, performing inspections or

conducting tests and in some cases add requirements as to the way in which they operate.

3.2 Accreditation is not mandatory, although it is strongly encouraged, and the relevant criteria for appointment may be satisfied in other ways. An applicant which is not accredited will be assessed by UKAS to the specified requirements taken from the appropriate EN45000 standard where the applicant will need to demonstrate equivalent levels of ability in terms of competence, resources, organisational arrangements, policies and all other relevant matters.

3.3 All applicants, whether accredited or assessed to the appropriate EN45000 standard(s), 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 equipment for which appointment is sought;
- the ability to undertake the conformity assessment requirements laid down in the Regulations in respect of which they seek appointment; and
- a thorough knowledge of the Regulations.

3.4 Applicants will therefore need to state for which equipment, and for which conformity assessment activities (as listed in paragraph 5.4) they wish to be appointed. The scope of assessment by UKAS and any subsequent appointment by the Secretary of State will be determined by reference to the modules and the categories of equipment subject to noise limits described in the Regulations. Applicants will be required to demonstrate the capability fully to undertake the functions defined by a particular module and category of equipment (this requirement does not preclude the possibility of sub-contracting).

3.5 The body should employ or demonstrate that it has access to technical and other persons to enable it to effectively undertake the duties of a Notified Body for the relevant scope. Such persons are expected to have appropriate combinations of professional and academic qualifications or training, practical and current experience to enable the relevant conformity assessment in the Regulations to be undertaken effectively.

3.6 The Regulations also defines the methods of measurement of airborne noise. Under the appropriate conformity assessment procedures, applicants will need to examine or inspect against the relevant provisions.

3.7 Either EN45004 (plus EN45001¹ to be observed for testing required) or EN45011 (plus EN45001 to be observed for testing required) or EN45001 (plus EN45004 to be observed for assessment) will be the basic standard for assessing those applicants wishing to operate under the internal control of production with assessment of technical documentation and periodical checking (module Aa).

3.8 Either EN45004 (plus EN45001 to be observed for testing required) or EN45001 (plus EN45004 to be observed for assessment) or EN45011 (plus EN45001 to be observed for testing required) will be the basic standard for assessing those applicants wishing to operate under the unit verification module of the Regulations (module G).

3.9 EN45012 will be the basic standard for assessing applicants wishing to operate under the full quality assurance module of the Regulations (module H).

3.10 Bodies that are accredited to or assessed against EN45012 will be required to meet further criteria, based on EN45001 and EN45004, if they wish their scope of approval to cover other modules where third party testing and inspection are involved. Bodies accredited or assessed against EN45001, EN45004 or EN45011 and wishing to have their scope of approval extended to cover the full quality assurance module of the Regulations would need to satisfy additional criteria based on EN45012.

4. APPOINTMENT

4.1 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 fulfils the criteria for appointment and is fit for appointment under Regulation 14, the Secretary of State may issue a letter of appointment.

4.2 The precise terms and conditions of appointment will be set out in the letter of appointment, but it will be a condition that the applicant agrees:

- a. to take part in Notified Body co-ordination activities at both UK and European level;
- b. to surveillance by UKAS, on behalf of the Secretary of State, annually or whatever intervals are thought appropriate by the Secretary of State. (new applicants will undergo an initial surveillance after 6 months); and

¹ References to EN45001 throughout this document:

It is expected that the new standard ISO/IEC 17025: 1999 – General requirements for the competence of testing and calibration laboratories will replace EN45001 as the basis of assessment of testing and calibration laboratories. It is likely that organisations applying for or holding a Notified Body appointment based, or partially based, on EN45001 compliance will be asked to demonstrate equivalent compliance with ISO/IEC 17025 by the end of March 2002.

- c. to a full reassessment by UKAS, on behalf of the Secretary of State, every four years or whatever intervals are thought appropriate by the Secretary of State.

4.3 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 or someone else on his behalf.

4.4 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.

4.5 UKAS will advise DTI if it believes that a Notified Body fails to continue to comply with the terms of its letter of appointment, including the minimum criteria of the Directive. In the case of a Notified Body which has been accredited for a scope that is within the relevant Regulations, UKAS will advise DTI if that accreditation is suspended, withdrawn or reduced in scope and, following any appropriate appeals procedure, will recommend to DTI whether it considers that the result of that action constitutes a failure by the Notified Body to continue to comply with the minimum criteria of the Directive. UKAS will notify DTI when an accreditation which supports the appointment of a Notified Body is re-instated following suspension, withdrawal or reduction in scope.

4.6 The Notified Body will be required to inform the Secretary of State immediately of any internal changes which, in any way, affect its ability to carry out the duties within the authorised scope to the declared procedures. This includes any changes in its status.

5. CONFORMITY ASSESSMENT

5.1 Under the appropriate conformity assessment procedures it will be the duty of the Notified Body to assess accurately the conformity of equipment with the provisions of the Regulations. Having concluded that the product and/or quality assurance system (as the case may be) is in conformity, they should issue the appropriate conformity assessment documentation as specified in the Schedule to the Regulations, which lays down the relevant procedure.

5.2 Applicants for Notified Body status should thoroughly familiarise themselves with the Regulations and the Directive and the conformity assessment procedures in respect of which they seek appointment.

5.3 As provided for in Regulation 7(5) (Article 21 of the Directive), the Notified Body shall take account of type-examination certificates issued and measurements carried out **for the assessment of the conformity of equipment placed on the market before 3 January 2002**, in respect of the test codes which are applicable under:

Directives 79/113/EEC, 84/532/EEC, 84/533/EEC, 84/534/EEC, 84/535/EEC, 84/536/EEC, 84/537/EEC, 84/538/EEC and 86/ 662/EEC (as adapted to technical progress and amended)

as the case may be depending on the type of equipment being assessed.

5.4 The conformity assessment system under the Regulations is based on the modular approach (as set out in Council Decision 93/465/EEC of 22 July 1993, Official Journal No. L220, 30.8.1993, p.23 - concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonization directives). This gives the manufacturer a number of options from which to make a selection. For the purposes of understanding the conformity assessment modules and procedures referred to above, applicants for Notified Body status should refer to Schedules 8 to 11 of the Regulations (Annexes V to VIII of the Directive) (together with all the relevant provisions of the Directive but with particular reference to Article 14). In summary the procedures are:

For equipment subject to noise limits referred to in Schedule 1 (Article 12 of the Directive) the options are either:

- a) the internal control of production with assessment of technical documentation and periodical checking procedure referred to in Schedule 9 (Annex VI of the Directive),
- b) or the unit verification procedure referred to in Schedule 10 (Annex VII of the Directive),
- c) or the full quality assurance procedure referred to in Schedule 11 (Annex VIII of the Directive).

Equipment subject to labelling only referred to in Schedule 2 (Article 13 of the Directive) shall be subject to the internal control of production procedure referred to in Schedule 8 (Annex V). There is no Notified Body involvement in this module.

5.5 In the case of internal control of production with assessment of technical documentation and periodic checking procedures (Schedule 9), the manufacturer is required to inform the Notified Body of any modifications made, or planned to be made, to equipment. The Notified Body will then be required to examine those modifications to ascertain whether further approval is required and, if appropriate, issue an addition to the original report pursuant to paragraph 5 of Schedule 9.

5.6 In assessing quality systems against the requirements of module H (Schedule 11), Notified Bodies must presume compliance with these requirements in respect of a quality system that implements EN ISO 9001.

5.7 The presumption of conformity of a quality assurance system implementing EN ISO 9001 does not negate the responsibility of the Notified Body for assessing it and conducting periodic surveillance of it. It is not required to presume conformity

without taking into account that it does, indeed, implement EN ISO 9001 covering the scope of the equipment manufactured.

5.8 A Notified Body may carry out its duties and functions, in respect of which it has been appointed, under contract with a client (for conformity assessment procedures) based outside the Community.

6. TESTING/INSPECTION FACILITIES AND SUB-CONTRACTING

6.1 Where a Notified Body 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 Notified Body 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.

6.2 Where a Notified Body 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 Notified Body 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 Notified Body 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.

6.3 Where a Notified Body wishes to subcontract testing, the Quality Manual of the Notified Body will need to describe the procedures to be followed by the Notified Body 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 Notified Body itself in respect to the task contained within the subcontract. The Notified Body 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.

6.4 A Notified Body will need to have fully documented agreements with its subcontractors. A Register of all subcontractors which may be used by the Notified Body 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.

6.5 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 implementing Regulations.

7. QUALITY MANUAL

7.1 An applicant 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 the relevant requirements of the appropriate standards in the EN 45000 series are met plus any further requirements for appointment and operation as a Notified Body.

8. CONFIDENTIALITY

8.1 Subject to any arrangements in respect of the release of information to other Notified Bodies in accordance with the relevant conformity assessment procedures, the Notified Body shall have adequate arrangements for ensuring confidentiality of information obtained in the course of its conformity assessment activities between itself and its clients. This should include:

- a) a copy of the instructions to staff on confidentiality;
- b) a copy of the written undertaking that staff are required to give, not to divulge any information gained about the client to third parties;
- c) a copy of the provisions in all sub-contracts to maintain confidentiality.

9. DOCUMENTS TO BE RETAINED BY THE NOTIFIED BODY

9.1 The Notified Body is required to maintain an up to date record of any report, quality assurance or unit verification certificate which has been issued, to whom it has been issued and for what equipment. The records shall be made available, on request, to the Secretary of State or such other person as may be authorised by the Secretary of State.

10. MISUSE OF REPORTS, CERTIFICATES AND IDENTIFICATION NUMBERS

10.1 The quality manual should state the Notified Body's policy and procedure for controlling the use of its reports, certificates and identification 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 for example corrective action, publication of the transgression or, if necessary, legal action.

10.2 The Notified Body should have documented procedures covering the control and use of its identification number with guidelines on action to be taken in case of misuse. These should be described briefly in the quality manual and the reference numbers of the documentation listed.

10.3 If, for example, an irregularity or oversight is discovered it might be necessary to withdraw a quality assurance certificate. The Department of Trade and Industry must be informed in such cases.

11. MUTUAL RECOGNITION AGREEMENTS

11.1 Applicants should note that the European Community aims to reach Mutual Recognition Agreements (MRAs) with key trading partners. Under these agreements, 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 it wishes to be considered for appointment under the MRAs.

12. CONTACT POINTS

Fran Buckle
Department of Trade & Industry
Standards & Technical Regulations Directorate 4
322 Red Zone
151 Buckingham Palace Road
London SW1W 9SS

Tel: 020 7215 1977
Fax: 020 7215 1529
E-mail: fran.buckle@dti.gov.uk
Website: www.dti.gov.uk/strd/

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

Tel: 020 8917 8436
Fax: 020 8917 8499
E-mail: de@ukas.com
Website: www.ukas.com

13. SOURCES OF RELEVANT DOCUMENTS

The complete text of the Directive has been published in the *Official Journal of the European Communities* (No L162 of 3.7.00). Copies of this text and the Regulations may be obtained from:

The Stationery Office
Norwich
NR3 1GN

Tel: 0870 600 5522
Fax: 0870 600 5533
E-mail: book.orders@theso.co.uk
Website: www.clicktso.com

or from European Information Centres.

Information on the EN 45000 series of standards is available from:

BSI
389 Chiswick High Road
London
W4 4AL

Tel: 020 8996 9001
Fax: 020 8996 7048
Website: www.bsi-global.com

APPENDIX 1

Annex XI of the Directive

Minimum Criteria to be Taken into Account by Member States for the Notification of Bodies

MINIMUM CRITERIA TO BE TAKEN INTO ACCOUNT BY MEMBER STATES FOR THE NOTIFICATION OF BODIES

1. The body, its director and the staff responsible for carrying out the verification operations may be neither the designer, manufacturer, supplier or installer of equipment nor the authorised representative of any of those parties. They may become involved neither directly nor as authorised representatives in the design, construction, marketing or maintenance of such equipment nor represent the parties engaged in these activities. This does not preclude the possibility of exchanges of technical information between the manufacturer and the body.
2. The body and its staff must carry out the assessments and verifications with the highest degree of professional integrity and technical competence and shall be free from all pressures and inducements, particularly financial, which may influence their judgement or the results of their work, especially from persons or groups of persons with an interest in the results of verification.
3. The body shall have at its disposal the necessary staff and possess the necessary facilities to enable it to perform properly the administrative and technical tasks connected with inspection and surveillance operations; it must also have access to the equipment required for any special verification.
4. The staff responsible for inspection shall have:
 - sound technical and professional training;
 - satisfactory knowledge of the requirements for the assessment of technical documentation;
 - satisfactory knowledge of the requirements of the tests which they carry out and adequate experience of such tests;
 - the ability to draw up the certificates, records and reports required to authenticate the performance of the tests.
5. The impartiality of inspection staff shall be guaranteed. Their remuneration shall not depend on the number of tests carried out or on the results of such tests.
6. The body shall 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 tests.
7. The staff of the body must observe professional secrecy with regard to all information gained in carrying out its tests (except *vis-à-vis* the competent administrative authorities of the State in which its activities are carried out) under this Directive or any provision of national law giving effect to it.

APPENDIX 2

Bases of Assessment for Appointment of Notified Bodies for the Purpose of the Noise Emission in the Environment by Equipment for Use Outdoors Regulations 2001

**BASES OF ASSESSMENT FOR APPOINTMENT OF NOTIFIED BODIES
FOR THE PURPOSE OF THE REGULATIONS**

	FUNCTION		
	Internal control of production with assessment of technical documentation and periodical checking (Schedule 9)	Unit verification (Schedule 10)	Full quality assurance (Schedule 11)
Equipment subject to noise limits	EN45004 (+ observe relevant requirements in EN45001 for testing) or EN45011 (+ observe relevant requirements in EN45001 for testing) or EN45001 (+ observe relevant requirements in EN45004 for assessment)	EN45004 (+ observe relevant requirements in EN45001 for testing) or EN45001 (+ observe relevant requirements in EN45004 for assessment) or EN45011 (+ observe relevant requirements in EN45001 for testing)	EN45012 (+ product knowledge)

Please note that where more than one standard is listed in a column these are alternative bases for assessment for appointment - assessment will draw on these standards