



**The Radio Equipment and
Telecommunications Terminal
Equipment (RTTE) Regulations 2000**

**Guidelines on the appointment of
Notified Bodies**

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PREFACE

These guidelines describe the requirements which apply in the United Kingdom for the assessment and appointment of the Notified Bodies required by the Radio Equipment and Telecommunications Terminal Equipment (RTTE) Directive. UK Notified Bodies will be appointed under and will operate according to the RTTE Regulations SI No.730 2000 (the “Regulations”) which transpose the Directive into UK law.

These guidelines may be updated from time to time. In this event, those organisations that are Notified Bodies at the time of the update will be provided with a copy of the new guidelines.

1. INTRODUCTION

1.1 The European Community Directive on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity (the “Directive”) 99/5/EC (Official Journal No. L91/10 of 7 April 1999) - entered into force on 8 April 2000.

1.2 The Directive makes provision, among other things, for the appointment of Notified Bodies to identify test suites that are considered to be essential as described in Annex III of the Directive (Schedule 3 of the Regulations) and to review technical construction files and issue opinions as described in Annex IV of the Directive (Schedule 4 of the Regulations). Provision is also made in Annex V of the Directive (Schedule 5 of the Regulations) for the conformity assessment of equipment based on a manufacturer’s quality assurance system.

1.3 The involvement of Notified Bodies in conformity assessment is not necessary in most cases. The person who places equipment on the market will, in general, be regarded as taking full responsibility for its conformity to essential requirements, and for properly informing users as to its application. Only in the case of radio equipment for which harmonised standards are not available, are not used, or where they do not specify the essential radio test suites, is it mandatory to consult a notified body. However, at the choice of the manufacturer, a notified body may be consulted in other cases.

1.4 In the UK, the Secretary of State for Trade and Industry has responsibility for appointing Notified Bodies to carry out the functions described in 1.2 above and for informing the Commission of such appointments. For purposes of information only, a list of Notified Bodies in each Member State will, from time to time, be published in the Official Journal.

1.5 The previous UK and European type approval regimes for radio equipment and telecommunications terminal equipment ended on 7 April 2000. Notwithstanding this, equipment approved before that date may continue to be placed on the market until 7 April 2001. Thereafter all individual items of equipment must be placed on the market under the new regime.

- 1.6 Notified bodies have three roles under the Regulations:
- To identify the essential radio test suites – Schedule 3 (Annex III of the Directive);
 - To review and give opinions of technical construction files – Schedule 4 (Annex IV of the Directive);
 - To assess and perform periodic surveillance of manufacturers full quality assurance systems – Schedule 5 (Annex V of the Directive).

2. CRITERIA AND APPLICATION

2.1 Organisations wishing to become Notified Bodies must meet in full the minimum criteria set out in Schedule 6 of the Regulations (Annex VI of the Directive) - reproduced as Appendix 1 of this document. 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 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 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 9). 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.

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.

2.3 All applicants will be required to demonstrate that they have adequate liability 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 areas. 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 Schedule 6 of the Regulations (Annex VI 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 The services of a Notified Body shall be made equally available to all applicants to which the relevant conformity assessment procedures apply. The procedures under which the Notified Body operates and their administration shall be non-discriminatory and shall be administered in a non-discriminatory manner.

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. In particular, they will need to demonstrate:

- a thorough technical understanding of the range of equipment for which appointment is sought including knowledge of the applicable standards;
- they have used their best endeavours to obtain a thorough knowledge of spectrum management issues and regulated radio interfaces (article 4.1 of the Directive) in respect of the member states or geographical areas where the equipment is intended to be used;
- the ability to undertake the conformity assessment requirements laid down in the Regulations and the Directive in respect of which they seek appointment; and
- a thorough knowledge of the Regulations and the Directive.

3.4 Applicants will need to state for which equipment, and for which conformity assessment activities (as listed in paragraph 5.2 b to d) 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 relevant conformity assessment Schedules of the Regulations/Annexes of the Directive and by equipment type. Appendix 3 lists categories of equipment used to define scopes for Notified Bodies under the RTTE Regulations. Applicants will be required to demonstrate the capability fully to undertake the functions defined by a particular conformity assessment Annex for the relevant equipment types (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 Regulation 5(2) requires that any apparatus satisfies the essential requirements set out in regulation 4. Where a harmonised standard covers one or more essential requirements, the apparatus constructed according to the harmonised standard is presumed to comply with those essential requirements. However, the use of harmonised standards is not mandatory and an applicant must be able to make assessments directly to the essential requirements.

3.7 Either EN45004 or EN45011 will be the basic standard for assessing those applicants wishing to operate under Schedule 3 (Internal production control plus specific apparatus tests) and/or Schedule 4 (Technical construction file) of the Regulations (Annexes III and IV of the Directive, respectively).

3.8 EN45012 will be the basic standard for assessing applicants wishing to operate under Schedule 5 (Full quality assurance) of the Regulations (Annex V of the Directive).

3.9 Bodies that are accredited to or assessed against EN45012 will be required to meet further criteria, based on EN45004, if they wish their scope of appointment to cover Schedule 3 or 4 of the Regulations (Annex III or IV of the Directive). Bodies accredited or assessed against EN45004 or EN45011 and wishing to have their scope of approval extended to cover Schedule 5 of the Regulations for full quality assurance (Annex V of the Directive) would need to satisfy additional criteria based on EN45012.

3.10 These requirements are summarised in Appendix 2 with additional guidance for bodies that are not accredited.

4. APPOINTMENT

4.1 Once UKAS has submitted its report, the Secretary of State will 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 the implementing Regulations, 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 who are not already accredited or otherwise assessed by UKAS will undergo an initial surveillance after 6 months);
- 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; and
- d. upon request, send promptly to the DTI all documentation arising out of its duties and functions as a Notified Body;

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 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 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 Regulations. 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 Regulations. 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 and UKAS immediately of any internal changes which, in any way, may affect its ability to carry out the duties within the scope of its appointment. This includes any changes in its status.

4.7 The Department will advise UKAS if, for whatever reason, a Notified Body has its notification suspended or withdrawn.

5. CONFORMITY ASSESSMENT

5.1 Applicants for appointment as a Notified Body should thoroughly familiarise themselves with the Regulations, the Directive and the conformity assessment procedures for which they seek appointment.

5.2 The conformity assessment system under the Regulations provides the manufacturer with a number of conformity assessment options, which depend on the type of apparatus and whether harmonised standards have been used or not. In summary these options are:

- a) internal production control (Schedule 2), or
- b) internal production control plus specific apparatus tests (Schedule 3), or
- c) technical construction file procedure (Schedule 4), or
- d) full quality assurance procedure (Schedule 5).

5.3 In assessing quality systems against the requirements of Schedule 5 (Annex V of Directive), Notified Bodies must presume compliance with these requirements in respect of a quality system that implements EN ISO 9001*.

5.4 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. The Notified Body is not required to presume conformity without satisfying itself that the quality management system addresses the relevant requirements of the Regulations.

5.5 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. SUB-CONTRACTING & TESTING FACILITIES

6.1 Although a Notified Body should normally carry out the activities which it contracts to undertake, where elements will be performed on its behalf 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 the appropriate EN 45000 standards although accreditation is not mandatory.

6.2 Where a Notified Body wishes to subcontract elements of its activities, 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.

* ISO 9001: 2000 has superseded ISO 9001: 1994 as the relevant harmonised standard. However, a three year transition is in progress and the period of co-existence will end on 15 December 2003.

6.3 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.

6.4 Where testing under Schedule 5 paragraph 4.4 of the Regulations is performed by a Notified Body or on its behalf by a manufacturer or by a subcontractor, the Notified Body shall ensure that whoever does the testing is capable of carrying out the tasks effectively and meets the relevant requirements of EN45001 although accreditation is not mandatory.

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 SYSTEM

7.1 The applicant body will operate management systems which indicate how the organisation meets the requirements of these guidelines and the relevant requirements of the conformity assessment and technical standards. The system will be documented in relevant manuals, procedures and work instructions, which will form the basis for control of the organisation, by its management for the duties to be performed.

7.2 Details of the requirements for management systems are given in the relevant conformity assessment standards. The applicant body will operate a management system based on a relevant standard in the EN 45000 series. Where the body wishes to undertake work that falls within the scope of more than one standard within the series, the management system will identify the base standard, the additional standards, and ensure that relevant requirements not covered within the base standard are met. Further details and guidance on relevant requirements are given in Table 1 and in Appendix 2

8. CONFIDENTIALITY

8.1 Subject to any requirements 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.

9. RECORDS

9.1 The Notified Body shall operate a record retention system appropriate to the scope of its activities. The system shall include a record of any opinion or quality assurance approval 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 OPINIONS, 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 opinions, certificates and identification numbers. Incorrect references to the Notified Body 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.

11 APPEALS AND COMPLAINTS

11.1 The Notified Body shall have documented procedures for dealing with complaints received from clients or other parties about its activities

11.2 The Notified Body shall have documented procedures for the consideration and resolution of appeals against its decisions.

11.3 A record of all appeals, complaints and disputes and action taken shall be kept.

12 NOTIFIED BODY COORDINATION

12.1 Notified Body is required to play a full part in Notified Body coordination activities at the national level and to participate at the European level.

12.2 The Notified Bodies' arrangements for participation in coordination activities shall include procedures for accessing test suite decisions and for advising other NBs of the relevant information concerning quality system approvals including the products concerned, issued or withdrawn.

13. MUTUAL RECOGNITION AGREEMENTS

13.1 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.

14. CONTACT POINTS

Peter Howick
Department of Trade & Industry
STRD4
328 Red Zone
151 Buckingham Palace Road
London SW1W 9SS

Tel: 020 7215 1595
Fax: 020 7215 1529
E-mail: peter.howick@dti.gsi.gov.uk

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

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

15. SOURCES OF RELEVANT DOCUMENTS

The complete text of the Directive has been published in the *Official Journal of the European Communities* (No L91/10 of 07.04.99) and is available from HMSO or with other useful information on the EU website.

<http://europa.eu.int/comm/enterprise/rte/dir99-5.htm>

Copies of the Regulations may also be obtained HMSO or as a direct download from <http://www.legislation.hmsogov.uk/si/si2000/2000730.htm>

The DTI maintains information relevant to the Regulations and the Directive, including the text of both documents in PDF format, on the TAPC website:

<http://www.tapc.org.uk>

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 7001
Web: <http://www.bsi-global.com>

APPENDIX 1 Minimum criteria to be taken into account by Member States when designating notified bodies in accordance with Article 11(1)

Schedule 6 of the RTTE Regulations (ANNEX VI of the Directive)

1. The notified body, its director and the staff responsible for carrying out the tasks for which the notified body has been designated must not be a designer, manufacturer, supplier or installer of radio equipment or telecommunications terminal equipment, or a network operator or a service provider, nor the authorised representative of any of such parties. They must be independent and not become directly involved in the design, construction, marketing or maintenance of radio equipment or telecommunications terminal 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 notified body.
2. The notified body and its staff must carry out the tasks for which the notified body has been designated with the highest degree of professional integrity and technical competence and must be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of any inspection, especially from persons or groups of persons with an interest in such results.
3. The notified body must have at its disposal the necessary staff and facilities to enable it to perform properly the administrative and technical work associated with the tasks for which it has been designated.
4. The staff responsible for inspections must have:
 - sound technical and professional training,
 - satisfactory knowledge of the requirements of the tests or inspections that are carried out and adequate experience of such tests or inspections,
 - the ability to draw up the certificates, records and reports required to authenticate the performance of the inspections.
5. The impartiality of inspection staff must be guaranteed. Their remuneration must not depend on the number of tests or inspections carried out nor on the results of such inspections.
6. The notified body must take out liability insurance unless its liability is assumed by the Member State in accordance with national law, or the Member State itself is directly responsible.
7. The staff of the notified body is bound to observe professional secrecy with regard to all information gained in carrying out its tasks (except vis-à-vis the competent administrative authorities of the Member State in which its activities are carried out) under this Directive or any provision of national law giving effect thereto.

APPENDIX 2 Basis of Assessment for Appointment of Notified Bodies for the Purpose of the Radio Equipment and Telecommunications Terminal Equipment (RTTE) Regulations SI 2000 No. 730

GUIDANCE ON 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

Internal production control plus specific apparatus test (Schedule 3)	Technical construction file (Schedule 4)	Full quality assurance (Schedule 5)
EN45004 or EN45011	EN45004 or EN45011	EN45012 (+ product knowledge)

TABLE 1: Basis for Assessment of Notified Bodies

1. Where applicable as indicated in Table 1, above, an applicant may demonstrate compliance as follows:

EITHER:

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 Schedules 3 and 4 (the identification of test suites and the review of technical construction files and where appropriate the provision of opinions). The use of this standard does not extend to any quality systems assessment 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 CRITERIA FOR CERTIFICATION BODIES OPERATING PRODUCT CERTIFICATION.

3.1 The Department will require compliance with this standard in so far as it relates only to a Notified Body's activities with regard to Schedules 3 and 4 (the identification of test suites and the review of technical construction files and where appropriate the provision of opinions). The use of this standard

does not extend to any quality systems assessment activity. The following relaxations are also permitted:

Clauses 4.1.3, 6, 8,10, 12, 13, 14, and 15 need not be satisfied

3.2 Subcontracting to non-accredited bodies is allowed provided such subcontracting is in accordance with the agreed procedures.

AND/OR

4. BY USING EN 45012:1998 GENERAL REQUIREMENTS FOR BODIES OPERATING ASSESSMENT AND CERTIFICATION/REGISTRATION OF MANAGEMENT SYSTEMS

4.1 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 Schedule 5 (quality systems assessment). The use of this standard does not extend to any test suite identification or technical construction file review activity. The following relaxations are permitted:

4.2 The requirements of Clause 2.1.2 Organisation, (second sentence and Note 2 only), are not mandatory.

APPENDIX 3 Categories of Equipment used to define Scopes for Notified Bodies under the R&TTE Regulations

Aeronautical Equipment (not excluded by Annex I)
Base Station for Mobile Network
Broadcast (including Programme Making and Outside Broadcast)
Citizens' Band
Cordless Telephone
Distress/Position Indicating Beacon
Fixed Link
Fixed Wireless Access
Industrial, Scientific and Medical within the scope of the Directive
Maritime (for non-SOLAS vessels only)
Mobile (Cellular) Telephone Handsets
Paging (Radio Messaging)
Private/Professional Mobile Radio
Radar
Radio Frequency Identification (RFID)
Radio Local Area Network
Satellite Earth Station (Fixed/Mobile)
Short Range Device
Telemetry/Telecommand
TTE for fixed (wired) network (all types)
Ultrawideband Applications (including Ground Probing Radar)
Wireless Microphone

- Note 1 Only equipment within the scope of the R&TTE Directive itself and the licensing regimes of the Member States is included, irrespective of the generality of any of the equipment types listed above.
- Note 2 The competence of the NB must include the relevant technologies and spectrum requirements for the applicable equipment types in respect of which NB function is exercised. The above descriptions should therefore be qualified individually or collectively, as appropriate, by reference to the relevant technologies, frequency bands and modulation techniques.
- Note 3 A NB may deal with any equipment that falls within the scope of Note 1 and is within its competence as generally defined by the relevant categories above and their associated qualifications.

- Note 4 Scopes will also be defined in terms of conformity assessment procedures (ie Schedule 3, 4 and/or 5 of the Regulations).
- Note 5 Appointments will not be made in respect of TTE for fixed (wired) networks alone.