



Department of Trade and Industry

The Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 1996

**Guidelines for Organisations seeking
Notified Body status to Undertake
Testing, Inspection and Certification of
Equipment and Protective Systems
Intended for Use in Potentially Explosive
Atmospheres**

April 1999

Contents

	Page
1 Introduction	2
2 Application, Criteria and Appointment	2
3 Criteria for appointment as a Notified Body	3
4 Meeting the Criteria	4
5 Appointment	6
6 Conformity Assessment	7
7 Testing/Inspection facilities and Sub-contracting	10
8 Quality Manual	11
9 Confidentiality	12
10 Documents to be Retained by the Notified Body	12
11 Internal Audit and Periodic Review	12
12 Misuse of Certificates and Marks of Conformity	13
13 Mutual Recognition Agreements	13
14 Contact Points	14

Appendix 1: Annex XI of the ATEX Directive - Minimum criteria to be taken into account by member States for the notification of bodies

Appendix 2: Bases of assessment for appointment of Notified Bodies for the purposes of the ATEX Directive 94/9/EC

Appendix 3: Conformity assessment procedures (diagram)

1. INTRODUCTION

1.1 The European Community Directive on the approximation of the laws of the member States relating to equipment and protective systems intended for use in potentially explosive atmospheres - (“the ATEX Directive”) 94/9/EC (Official Journal No. L100 Volume 37 of 19 April 1994) - has been implemented in Great Britain by means of The Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 1996 (S.I.1996/192) (“the Regulations”) which were made under the European Communities Act and came into force on 1 March 1996. The application of the ATEX Directive was extended to the European Economic Area (EEA) from 1 December 1994 by virtue of Decision 14/94 of the EEA Joint Committee.

1.2 The Regulations require, among other things, the type-examination, inspection and verification testing of equipment, protective systems, devices and components (as defined in the Regulations) before they can be placed on the market and put into service. Provision is also made for the conformity assessment of such equipment, protective systems, devices and components based on a manufacturer’s quality assurance system. (See Article 8 and Annexes III to IX of the Directive which have been implemented in regulation 10 and Schedules 6 to 12 of the Regulations).

1.3 In Great Britain, the Secretary of State for Trade and Industry has responsibility for appointing and notifying to the European Commission and other member States the Notified Bodies to carry out these functions. Any appointment of Notified Bodies in Northern Ireland (NI) will be effected under the relevant provisions in the NI legislation.

2. APPLICATION, CRITERIA AND APPOINTMENT

2.1 Organisations wishing to become Notified Bodies under the Regulations must meet in full the minimum criteria set out in Annex XI of the ATEX 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.

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 14. 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 14). 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.

2.3 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 European Economic Area. 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 XI of the ATEX 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.

3. CRITERIA FOR APPOINTMENT AS A NOTIFIED BODY

3.1 The following criteria should be regarded as satisfying the minimum requirement specified for the assessment, appointment and notification as a Notified Body for the purposes of the Regulations. They should be read in association with Annex XI of the ATEX Directive.

3.2 Assessment of an organisation will be related to the essential health and safety requirements and conducted against a specified range of activities to be known as the scope of approval. The scope will be defined in terms of the following:

a) the conformity assessment procedures referred to in section 6 below in respect of which the applicant wishes to be appointed. 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.

b) the product in respect of which the applicant wishes to be appointed in relation to:

i) Equipment Group I Category M1 and Equipment Group II Category 1;

ii) Equipment Group I Category M2 and Equipment Group II Category 2;

iii) Equipment Group II Category 3 ¹;

iv) Protective systems;

v) Devices;

vi) Components.

¹ Equipment Group II Category 3 products are normally dealt with through Internal Control of Production with no Notified Body involvement.

3.3 For the purposes of the Regulations, the criteria against which conformity assessment is to be made are the essential health and safety requirements (EHSRs) relating to the design and construction of equipment, protective systems, devices and components intended for use in potentially explosive atmospheres listed in Schedule 3 to the Regulations together with the other relevant provisions of the Directive and the Regulations.

3.4 Article 5 of the ATEX Directive also defines the role of harmonised standards. These are to be produced in response to a mandate from the European Commission to the European standards organisations, the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (CENELEC), the federation of Europe's national standards institutions. Equipment, protective systems, devices and components produced in accordance with such standards enjoy a presumption of conformity with the relevant EHSRs of the ATEX Directive.

3.5 In the absence of harmonised standards, member States may bring to the attention of the parties concerned the existing national technical standards and specifications which they regard as important or relevant to the proper implementation of the EHSRs in Annex II of the Directive. Production in accordance with these national standards and specifications does not, however, give a presumption of conformity with the EHSRs.

3.6 Under the appropriate conformity assessment procedures, applicants must be able to examine or inspect products and assess their design, manufacture and operation directly against the EHSRs and other relevant provisions of the ATEX Directive. They must also be able to inspect against the CEN and/or CENELEC standards. In the absence of CEN and CENELEC standards, should the UK authorities decide to bring national standards and specifications to the attention of the parties concerned, the Notified Bodies must demonstrate the professional ability and understanding of the ATEX Directive and the Regulations necessary to judge the extent to which fulfilment of these can satisfy the EHSRs and the other relevant provisions of the ATEX Directive and Regulations.

3.7 All manufacturers of equipment, protective systems, devices and components 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.

4. MEETING THE CRITERIA

4.1 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.

4.2 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.

4.3 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, protective systems, devices and components 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 ATEX Directive and the Regulations

4.4 Applicants will therefore need to state for which equipment, protective systems, devices and components and for which conformity assessment activities they wish to be appointed. The scope of assessment by UKAS and subsequent appointment by the Secretary of State will be determined by reference to the modules and activities described in the ATEX Directive. Applicants will be required to demonstrate the capability fully to undertake the functions defined by a particular module or activity for the relevant types of equipment, protective systems, devices or components (this requirement does not preclude the possibility of sub-contracting).

4.5 In the context of the ATEX Directive (as implemented) and the conformity assessment modules referred to in Article 8 (regulation 10), manufacturers of some categories of equipment, protective systems, devices and components have a choice between a combination of EC type-examination (module B) with conformity to type (module C), quality assurance systems (modules D and E) or product verification (module F); there is also a procedure for internal control of production (module A). An alternative to all of these is unit verification (module G). See paragraph 6.4 below for more detailed information on the modular approach to conformity assessment.

4.6 EN45004 or EN45011 will be the basic standards for assessing the suitability of applicants wishing to operate under the type-examination and unit verification modules of the ATEX Directive (modules B and G). Those standards will also be applicable to applicants seeking to operate under the conformity to type module of the ATEX Directive (module C) as will EN45001 supplemented to cover the applicants ability to decide on conformity.

4.7 EN45012 will be the basic standard for assessing applicants wishing to operate under the quality assurance modules of the ATEX Directive (modules D and E).

4.8 EN45001, EN45004 or EN45011 will be the basic standards for assessing those applicants wishing to operate under the product verification module of the ATEX Directive (module F)

4.9 Bodies that are accredited to or assessed against EN45012 would be required to meet further criteria, based on EN45001 and EN45004, if they wished 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 quality assurance modules of the ATEX Directive would need to satisfy additional criteria based on EN45012.

4.10 Organisations seeking to become Notified Bodies will be assessed by UKAS against the appropriate criteria listed above and related to the essential health and safety requirements listed in Schedule 3 to the Regulations (Annex II of the Directive). Applicants should therefore state for which conformity assessment modules they wish to be appointed. The Secretary of State will, after the applicant has been assessed and a report has been made to him, consider whether the applicant is suitable for appointment and whether it should be appointed. If the Secretary of State is satisfied that the applicant should be appointed a letter of appointment will be issued. The applicant is then required to return to the Department a copy of the letter, duly signed by an authorised representative of the applicant. The Department will then inform the Commission of the applicant's appointment as a Notified Body. The applicant can also apply to UKAS for accreditation at the time of applying for Notified Body status (although accreditation to the standards referred to above is not a prerequisite for appointment).

5. APPOINTMENT

5.1 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 play a full 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 applicant's will undergo an initial surveillance after 6 months); and
- 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.

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

5.3 For the purposes of understanding the conformity assessment modules referred to above, applicants for Notified Body status should refer to Annexes III to IX of the Directive, and to the provisions in the Regulations (regulation 10 and Schedules 6 to 12).

6 CONFORMITY ASSESSMENT

6.1 Under the appropriate conformity assessment procedures it will be the duty of the Notified Body to assess accurately the conformity of equipment, protective systems, devices and components with the provisions of the ATEX Directive (as implemented by 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.

6.2 Applicants for Notified Body status should thoroughly familiarise themselves with the Regulations and ATEX Directive and, in particular, with the EHSRs laid down in Schedule 3 of the Regulations and the conformity assessment procedures in respect of which they seek appointment.

6.3 As provided for in Article 14 (3) of the Directive, which has been implemented in regulation 12(6) of the Regulations, the Notified Body shall take account of the results of tests and verifications already carried out **for the assessment of the conformity of electrical equipment placed on the market before 1 July 2003**, in respect of the harmonised standards which are applicable under:

- a) Council Directive 76/117/EEC and Council Directive 79/196/EEC (as adapted to technical progress and amended), or
- b) Council Directive 82/130/EEC (as adapted to technical progress),

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

6.4 The conformity assessment system under the ATEX Directive 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 Annexes III to IX of the ATEX Directive (together with all the relevant provisions of the ATEX Directive but with particular reference to Article 8). In summary (see Appendix 3) the procedures are:

For equipment in Group I, category M1 or in Group II, category 1; for autonomous protective systems; for safety devices for such equipment or systems; and for components for such equipment, systems or devices, the options are either:

(a) EC type-examination (see Annex III), followed either by:
- production quality assurance (see Annex IV); or

- product verification (see Annex V); or

(b) Unit verification (see Annex IX).

For equipment in Group I, category M2 or in Group II, category 2; for safety devices for such equipment or systems; and for components of such equipment, systems or devices, the options are either:

For electrical equipment and internal combustion engines:

(a) EC type-examination (see Annex III), followed either by:

- conformity to type (see Annex VI); or

- product quality assurance (see Annex VII); or

(b) Unit verification (see Annex IX); and

For other equipment in Group I, category M2 or Group II, category 2:

(a) Internal control of production (see Annex VIII) and communicate the technical dossier specified in paragraph 3 of Annex VIII with a Notified Body which shall acknowledge receipt and retain it; or

(b) Unit verification (see Annex IX).

For equipment in Group II, category 3; for safety devices for such equipment or systems; and for components for such equipment, systems and devices, the options are either:

(a) Internal control of production (see Annex VIII); or

(b) Unit verification (see Annex IX).

The criteria determining the classification of equipment groups into categories is given in Annex I of the ATEX Directive (implemented in Schedule 4 to the Regulations).

6.5 The Notified Body is required to have documented procedures relating to all the conformity assessment procedures (as specified in the Annexes on conformity assessment modules) which it is undertaking. Complementary documented staff instructions should be listed in the quality manual referred to in section 7 of EN45004 or section 12 of EN45011 and EN45012. These instructions should be of sufficient detail for their essential features to be identified. The applicant will be assessed on the adequacy of the internal organisation and the procedures adopted to give confidence in the quality of the applicant's services.

6.6 The basis of conformity assessment certification given should be clearly defined in the scope quoted on each certificate (see paragraph 3.2 above). Where judgements or interpretation of a standard or requirement are implicit or explicit in a decision to grant or withhold a certificate of EC type-examination, the Notified Body is required to have procedures for achieving common standards in such matters in its own operations. Guidance for achieving wider national and international agreement on interpretation and application of the Directive will be provided by the European Commission in 1999.

6.7 In the case of EC type-examination procedures (Annex III/Schedule 6), the applicant is required to inform the Notified Body of any modifications made, or planned to be made, to equipment, protective systems, devices and components. 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 certificate pursuant to paragraph 6 of Annex III.

6.8 The Notified Body must presume a quality assurance system's compliance with the provisions of paragraph 3.2 of Annex IV (Schedule 7 of the Regulations) if the former implement EN ISO 9001(≡ module H) or EN ISO 9002 (≡ module D). Similarly there is a duty to presume that a quality assurance system complies with the requirements referred to in paragraph 3.2 of Annex VII (Schedule 10 to the Regulations) if it implements EN ISO 9003 (≡ module E).

6.9 The presumption of conformity of a quality assurance system implementing EN ISO 9001, EN ISO 9002 or EN ISO 9003 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 evidence that it does, indeed, implement EN ISO 9001, EN ISO 9002 or EN ISO 9003 covering the scope of the equipment, protective systems, devices or components manufactured. In deciding how much evidence to take into account it should place progressively greater measures of confidence in the quality assurance system dependent upon whether the manufacturer:

- (i) makes an uncertified claim to have a quality assurance system which meets the requirements of either EN ISO 9001, EN ISO 9002 or EN ISO 9003;
- (ii) has a quality assurance system certified to either EN ISO 9001, EN ISO 9002 or EN ISO 9003 by an unaccredited certification body;
- (iii) has a quality assurance system certified to either EN ISO 9001, EN ISO 9002 or EN ISO 9003 by an accredited certification body.

6.10 In the case of production quality assurance procedures (Annex IV/Schedule 7), the applicant is required to inform the Notified Body of any changes made, or planned to be made, to the quality assurance system. The Notified Body will then be required to assess the acceptability of the changes (see paragraph 3.4 of that Annex/Schedule).

7. TESTING/INSPECTION FACILITIES AND SUB-CONTRACTING

7.1 If the Notified Body operates its own testing facilities, these facilities, and the associated activities, shall conform to the European Standard EN45001 (General criteria for the operation of testing laboratories). Where testing is performed on its behalf by external bodies, the Notified Body shall ensure that these bodies conform to EN45001.

7.2 Where the Notified Body operates its own inspection activity, this should conform to the requirements stated in section 4 above. Where inspection is carried out on its behalf by external bodies, the Notified Body should ensure that these bodies conform to EN45004.

7.3 When the Notified Body uses the services of an external body, a properly documented agreement covering the arrangements, including confidentiality (see paragraph 9.1 below), shall be drawn up.

7.4 Where testing is performed by an external body, the quality manual (paragraph 8.1 below) should describe the procedures adopted by the Notified Body to comply with these requirements. A list of the external bodies used shall be retained by the Notified Body.

7.5 Whenever an external body is used to perform any function, other than the certification assessment, on behalf of a Notified Body, the Notified Body should possess documented evidence to demonstrate that the external body is competent to do so. Documented procedures for assessing and monitoring an external body's competence should therefore be kept available for reference. The quality manual may include them or should state where they are to be found. Wherever a Notified Body assesses and monitors an external body's competence, the members of the assessment team must demonstrate evidence of relevant training in assessment procedures and the team must include at least one person who is experienced in the activity being sub-contracted.

7.6 A register of all external bodies used by the Notified Body should be maintained; the quality manual may include it or should state where it is to be found. The register should include:

- a) the name of the external body;
- b) its legal status and details of any relationship with a parent company, group of companies, or any other organisation of which the external body is a part;
- c) names and qualifications of all staff engaged in technical work sub-contracted by the Notified Body;
- d) functions performed by the external body;

- e) results of any assessment performed to check compliance with the requirements of EN45001 or EN45004.

The agreements (see paragraph 7.3 above) and the register should be available for scrutiny by the Secretary of State or such other person as may be appointed by the Secretary of State.

7.7 The responsibility for undertaking the conformity assessment in accordance with the requirements of the Regulations and liability for failure to do so always rests with the Notified Body itself, irrespective of whether it makes use of the services of consultants, external inspection bodies or anyone else.

8. QUALITY MANUAL

8.1 The Notified Body shall have a quality manual and associated documented operational procedures appropriate to the conformity assessment modules and categories of equipment, protective systems, devices or components which it wishes to undertake. The quality system set out in the documentation should ensure that all the requirements of the relevant standard(s) in the EN45000 series are met and criteria for appointment and operation as a Notified Body. The quality documentation should contain policies and procedures to include:

- a) a statement on the training of staff engaged in the conformity assessment process;
- b) details of the documented procedures for assessing initial and audit product testing;
- c) a general statement on the range of testing facilities appropriate to its activities;
- d) details of documented procedures for the surveillance of a manufacturer's quality system;
- e) a list of sub-contractors and details of the documented procedures for assessing and monitoring their competence;
- f) details of appeals procedures and the procedure for ensuring that complaints to a Notified Body are investigated to ensure that any shortcomings of the certification activities are revealed;
- g) a list of staff members responsible for investigating complaints and those having the authority to take remedial action;
- h) a copy of instructions to staff on confidentiality;
- i) a copy of the written undertaking by staff not to divulge any information gained about the client to a third party;

- j) a copy of the provisions in all sub-contracts to maintain confidentiality;
- k) documented procedures for the withdrawal and cancellation of certificates and conformity numbers.

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

9. CONFIDENTIALITY

9.1 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 certification 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.

10. DOCUMENTS TO BE RETAINED BY THE NOTIFIED BODY

10.1 The Notified Body is required to maintain an up to date record of any type-examination, conformity to type, quality assurance, product verification or unit verification certificate which has been issued, to whom it has been issued and for what equipment, protective systems, devices and components. 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.

11. INTERNAL AUDIT AND PERIODIC REVIEW

11.1 The Notified Body shall undertake internal audits and management reviews as required by the particular EN45000 standard to which it is working. Audits and reviews shall include checking compliance with the criteria for appointment as a Notified Body and checking that the certification process is correctly and effectively implemented.

12. MISUSE OF CERTIFICATES AND IDENTIFICATION NUMBERS

12.1 The quality manual should state the Notified Body's policy and procedure for controlling the use of its 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.

12.2 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. The Notified Body should not allow its number to be used without its express permission on any form of documentation issued by the manufacturer unless, in addition to satisfying other regulations governing the use of the number, either:

- a) each item of equipment, protective systems, devices and components has been inspected or tested by the Notified Body and found to be in compliance with all the relevant provisions of the ATEX Regulations/Directive; or
- b) equipment, protective systems, devices and components of the same type have been tested initially and subsequent manufacture is subjected to periodic surveillance and in each case found to be in compliance with all the relevant provisions of the ATEX Regulations/Directive. In this case it is a further condition that each marked piece of equipment, protective system, device or component should be produced under the same quality system for producing the tested or inspected items, the quality system concerned having been certified by a body notified for that function.

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

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

Applications:

Peter Howick
Department of Trade & Industry
Standards & Technical Regulations Directorate 4
323 Red Zone
151 Buckingham Palace road
London SW1W 9SS

Tel: 0171 215 1595

Fax: 0171 215 1529

Assessment/Accreditation:

David Evans
United Kingdom Accreditation Service
21-47 High St
Feltham
Middlesex TW13 4UN

Tel: 0181 917 8436

Fax: 0181 917 8499

Availability of texts:

The complete text of the ATEX Directive has been published in the *Official Journal of the European Communities* (No L100 of 19.4.94, pages 1-29). Copies of this text are generally available from the European Information Centres and European Documentation Centres.

The Regulations are available from:

The Stationery Office
PO Box 276
London
SW8 5DT

Tel: 0171 873 9090

Fax: 0171 873 8200

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 tests shall not be the designer, manufacturer, supplier or installer of equipment, protective systems or devices referred to in Article 1 (2) which they inspect, nor the authorised representative of any of these parties. They shall become involved neither directly nor as authorised representatives in the design, construction, marketing or maintenance of the equipment, protective systems or devices referred to in Article 1 (2) in question. This does not preclude the possibility of exchanges of technical information between the manufacturer and the body.
2. The body and its inspection staff shall carry out the verification tests 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 the inspection, especially from persons or groups of persons with an interest in the result of verifications.
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 verification; it shall also have access to the equipment required for special verification.
4. The staff responsible for inspection shall have:
 - sound technical and professional training;
 - 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 shall be 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 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 ATEX Directive 94/9/EC

BASES OF ASSESSMENT FOR APPOINTMENT OF NOTIFIED BODIES FOR THE PURPOSE OF THE 'ATEX' DIRECTIVE 94/9/EC

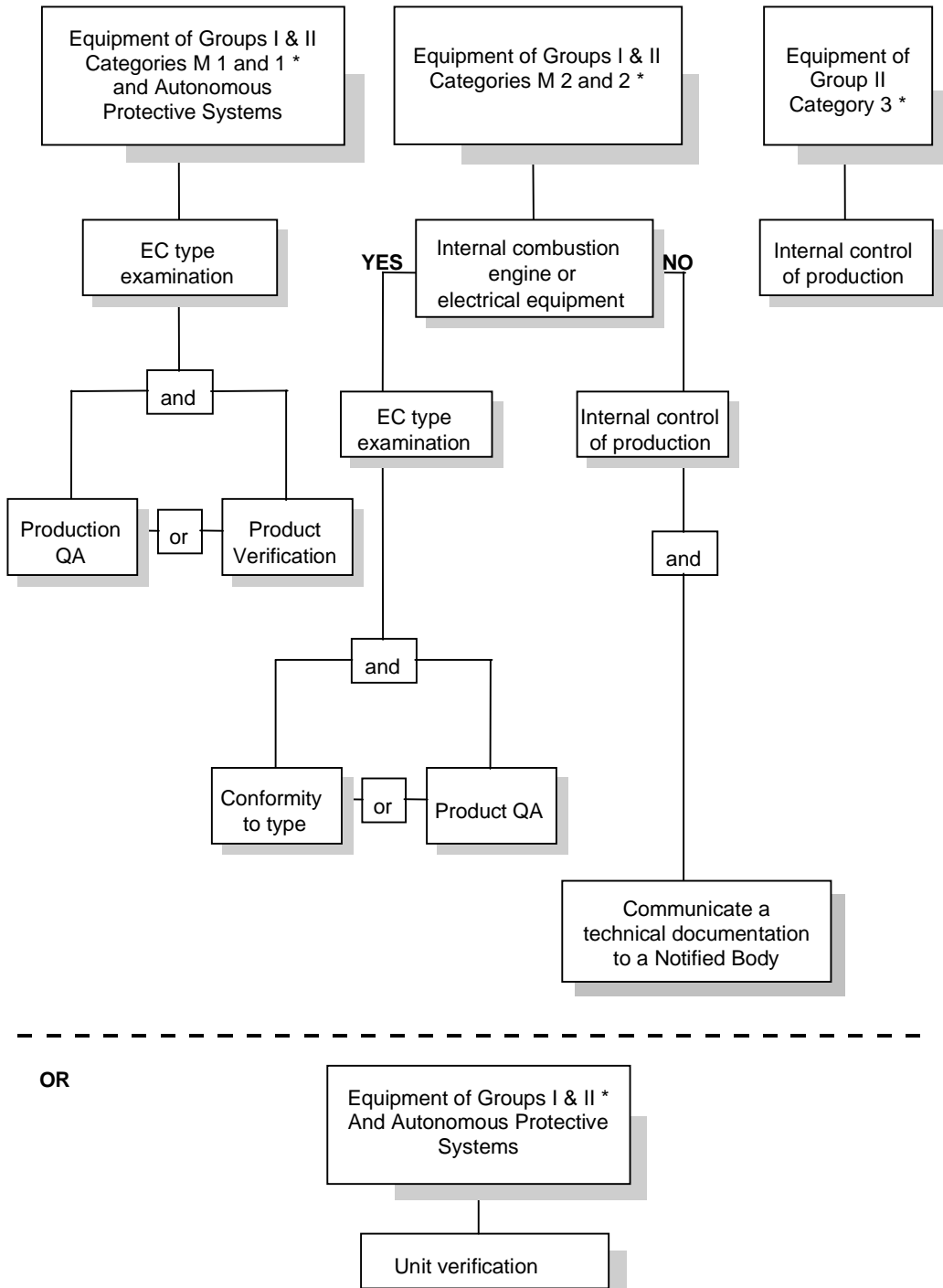
	FUNCTION					
	EC type examination (Annex III)	Conformity to type (Annex VI)	Production quality assurance (Annex IV)	Product quality assurance Annex VII)	Product verification (Annex V)	Unit verification (Annex IX)
Equipment, protective systems and devices. Components	EN45004 or EN45011 (observe relevant requirements in EN45001 and/or EN45004 for testing)	EN45001 (+ ability to decide on conformity) or EN45004 or EN45011	EN45012 (+ product knowledge)	EN45012 (+ product knowledge)	EN45001 or EN45004 or EN45011	EN45004 and/or EN45011

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

APPENDIX 3

Conformity Assessment Procedures

Conformity Assessment Procedures



(*) and their components if separately certified