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**The Equipment and
Protective Systems
intended for use in
Potentially Explosive
Atmospheres Regulations
1996**

**Interim 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**

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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) as amended ("the Regulations"). The Regulations, which were made under the European Communities Act 1972, came into force on 1 March 1996 and were amended in December 2001, S.I. 2001 No 3766, and became mandatory as from 1 July 2003. 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 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 under the Regulations. Any appointment of Notified Bodies in Northern Ireland (NI) will be effected under the relevant provisions in the NI legislation.

1.3 The purpose of these guidelines

The Secretary of State for Trade and Industry is responsible for the appointment, or designation, of notified bodies to undertake duties as set out in the Regulations. An organisation wishing to be appointed as a notified body in Great Britain will need to meet the criteria in the Directive and the requirements in these guidelines. These guidelines also provide information on how the relevant conformity assessment body standards are used to assess the applicant body.

2. APPLICATION AND APPOINTMENT

2.1 Eligibility and legal entity

To be eligible for appointment as a notified body for the Regulations in Great Britain, the applicant body shall be a legal entity established in the United Kingdom. It must carry out its assessment functions within the jurisdiction of the United Kingdom and only issue certificates from an establishment in the United Kingdom. It may have staff located outside the UK and it may conduct assessments of quality management systems, or product tests and inspections, or have them conducted on its behalf, outside the UK.

Note 1. To be eligible, a body must have a legal identity but does not have to be formed according to UK law. It must be established in the UK and thus come under its jurisdiction.

2.2 Application to UKAS, copy application to DTI

An application should be made in the first instance to the United Kingdom Accreditation Service (UKAS) for assessment using the general UKAS Application Form and Form AC 6. Further information on the UKAS application and assessment processes is given in UKAS document P-16. At the same time as it submits its application to UKAS, the applicant body shall send copies of both forms to the Department and this will be taken to be the formal application to the Secretary of State. (Please see Annex 2 for the addresses of UKAS and the Department and Annex 3 for downloadable document references.)

2.3 Overall process of assessment by UKAS

UKAS will then carry out an assessment of the applicant body on behalf of the Secretary of State against the requirements set out in these guidelines, and provide a report and recommendation to the Secretary of State.

2.4 Agreement on the use of subcontracted UKAS assessors

UKAS will use suitably qualified assessors or assessment teams to undertake the assessment and make clear to applicant bodies when sub-contracted assessors or technical experts are to be used. Applicant bodies will have the right to object to specific assessors and experts, where there are concerns about potential conflicts of interest. UKAS has established procedures to handle complaints or appeals associated with its assessment activities.

2.5 UKAS scale of charges

UKAS will quote and charge applicant bodies against its own standard scale of charges for its assessment activities carried out under these guidelines.

2.6 Insurance (please also see paragraph 6.8 for details)

The applicant body shall provide evidence of its insurance cover to UKAS and to the Department before any appointment is made. After any appointment, the notified body shall provide evidence of continued appropriate insurance cover to UKAS at each annual surveillance exercise.

2.7 Secretary of State's decision

The Secretary of State will make a decision based on the recommendation and accompanying assessment from UKAS and any other relevant information. It should be noted that appointment is at the discretion of the Secretary of State and it should not be assumed that, if an applicant body meets all the criteria then an appointment will automatically follow.

If the Secretary of State is minded not to appoint an applicant body, then the applicant body will be informed in writing of the reasons for being so minded and given the opportunity of making further representations within a period of

28 days of notice of this information. Such representations will be further considered before a final decision is made

However if the Secretary of State is satisfied that the applicant body is suitable, and should be appointed, a letter of appointment will be issued to the applicant body.

2.8 The letter of appointment

The precise terms and conditions of appointment will be set out in the individual letters of appointment, but it will be a standard condition that the applicant body agrees:

- to surveillance annually or at whatever intervals are thought appropriate by the Secretary of State (newly appointed bodies will undergo an initial surveillance after 6 months); and
- to a full reassessment every four years or at whatever intervals are thought appropriate by the Secretary of State; and
- to take part in notified body co-ordination activities at the national and European level (please also see section 7.6); and
- to notify the Secretary of State of any changes which, in any way, may have a bearing on its status as a notified body or its ability to perform the duties and functions in its scope of appointment.

2.9 Notification of the appointment to the European Commission and other Member States

When the applicant body has signed and returned the letter of appointment, the Department will notify the appointment to the European Commission and other Member States. (The appointment is said to have taken place when the signed letter is received by the Department.) If the applicant body has not previously been assigned an identification number according to another EC Directive, the Department will ask the Commission to assign such a number prior to notification. The appointed body may begin working when the appointment has taken place but it shall not issue any certificates until the identification number has been assigned and it has received confirmation from the Department of its notification. (Other Member States are only obliged to provide free circulation to products, which are subject to conformity assessment procedures requiring the involvement of a notified body, if they have received information about the notification of any notified body involved.)

2.10 Reassessment and surveillance of notified bodies by UKAS

UKAS will carry out reassessment and surveillance of the notified body according to the conditions in that body's letter of appointment and send a report to the Secretary of State. The information in the report will relate only to the notified body's activities as a notified body and will not include any other activity that is not relevant to the appointment. Reassessment and surveillance may also be carried out by the Secretary of State. UKAS will advise the Department if it believes that a notified body no longer complies with the terms of that body's letter of appointment, including compliance with the requirements in these guidelines.

2.11 Co-ordination of action between the Department and UKAS on suspension or withdrawal of accreditation and withdrawal of appointment

If the appointment of a notified body is based on accreditation to the conformity assessment body standards, UKAS will advise the Department if that accreditation is suspended, withdrawn, or is reduced in scope in a way that is relevant to the appointment. When an appropriate appeals procedure has been completed (if requested by the notified body) UKAS will advise the Department if it can no longer support its recommendation for appointment. UKAS will inform the Department when an accreditation that supports notification is re-instated following suspension, withdrawal, or a reduction in scope. In turn, the Department will advise UKAS if a notified body has been instructed to suspend its activities or when an appointment and notification has been withdrawn or terminated.

3 THE SCOPE OF APPOINTMENT

3.1 The scope of a directive defines the range of products, or hazards related to a product, or to a phenomenon, to which the related requirements in the directive apply ("the product scope"). The "scope of appointment" of a notified body for a directive sets out its entitlement to carry out certain tasks in relation to the product scope and includes the conformity assessment procedures for which it has been appointed.

- a) Conformity assessment procedures (modules)¹
 - i) EC type examination, Schedule 6, Annex III, module B
 - ii) Production quality assurance, Schedule 7, Annex VI, module D
 - iii) Product verification, Schedule 8, Annex V, module F
 - iv) Conformity to type, Schedule 9, Annex VI, module C
 - v) Product quality assurance, Schedule 10, Annex VII, module E
 - vi) Unit Verification, Schedule 12, Annex IX, module G

¹ "Schedule" relates to the Regulations and "Annex" to the Directive.

- b) Product risk types
- i) Equipment Group I, Categories M1 and M2
 - ii) Equipment Group 2, Categories 1, 2 and 3², Classes G and D
 - iii) Protective systems
 - iv) Safety related devices
 - v) components
- c) Technology used in products and their manufacture relating to explosion prevention and protection methods (concepts)
(list relevant standards where required)
- i) Electrical equipment
 - q, p, o, d, e, i, n, m
 - Dust
 - ii) Non-electrical equipment
 - fr, d, g, c, b, p, k
 - iii) Protective systems
 - Venting
 - Suppression
 - Flame arresters
 - Decoupling
 - Explosion resistant enclosure
 - iv) Safety related devices Schedule 3 (Annex II) Clause 1.5

3.2 A notified body is not required to include all of the elements listed in 3.1 in its application for appointment and a body can apply for those elements as it chooses; in addition, the Secretary of State may decide to limit any scope of appointment. However, it is not possible for a notified body to be appointed for part of a conformity assessment module, or to subdivide a product risk type or the explosion prevention and protection methods (concepts). Nevertheless, where a body is unable, or does not wish to undertake work in a particular and significant product area, this may be shown as an exclusion in its scope of appointment e.g. 'Excluding high voltage equipment'.

² Equipment Group II Category 3 products are normally dealt with through Internal Control of Production with no notified body involvement. However, manufacturers may choose to use the Unit Verification module which does involve a Notified Body.

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

The following text has been reproduced from Annex XI of the Directive and it will be referred to as 'The minimum criteria'. Member States are required to ensure that all notified bodies that they notify meet the minimum criteria and continue to do so while the appointment is valid.

“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.”

5. MEETING THE MINIMUM CRITERIA AND THE CONFORMITY ASSESSMENT BODY STANDARDS

5.1 The minimum criteria for the appointment of notified bodies

The applicant body shall demonstrate to UKAS that it meets the minimum criteria set out in the Directive (and reproduced in Section 4) and the additional requirements in these guidelines.

5.2 The ISO/IEC 17000 series and the EN 45000 series of standards

The Council Decision 93/465/EEC¹ among other things, set out the general framework for the assessment of notified bodies and the policy that Member States should use standards in the EN 45000 series as the basis for the assessment of an applicant body against the minimum criteria. These standards are being replaced progressively by standards in the ISO/IEC17000 series and the standards that are relevant for these guidelines are listed below. They are referred to collectively as the 'conformity assessment body standards'.

The accreditation standards cover different types of body but in general terms they have a similar structure, consisting of parts dealing with the organisation and management of a body, and parts dealing with the technical requirements relating to the operation of the body in the areas of testing, inspection, product certification and management systems assessment. However, the Department will require compliance with these standards only in so far as they relate to a notified body's activities with regard to the conformity assessment procedures and products in its scope of appointment.

BS EN ISO/IEC 17025:2000 *General requirements for the competence of testing and calibration laboratories* (The contents of this standard differ considerably from BS EN 45000:1989 that it has superseded.)

BS EN ISO/IEC 17020:2004 *General criteria for the operation of various types of bodies performing inspection* (This standard has superseded BS EN 45004:1995 but the contents are identical.)

BS EN 45011:1998 *General requirements for bodies operating product certification systems*

BS EN 45012:1998 *General requirements for bodies operating assessment and certification/registration of quality systems.* (This standard will be superseded by ISO/IEC 17021.)

Note 1 Official Journal L220 30 August 1993. 93/465/EEC Council Decision of 22 July 1991 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing of the CE Marking, which are intended to be used in the technical harmonisation directives. ("The Modules Decision")

5.3 The conformity assessment procedures in the Directive and the conformity assessment body standards

The basic correspondence between the conformity assessment procedures and the conformity assessment body standards is shown in the table below. Where more than one accreditation standard is provided as an option for a particular procedure, the applicant body will have the choice of deciding which standard to use.

Annex/Module	Conformity assessment body standards applicable
EC type-examination (Annex III), Module B	ISO/IEC 17020 (ISO/IEC 17025 to be observed for testing required), or EN 45011 (ISO/IEC 17025 to be observed of testing required)
Conformity to type (Annex VI), Module C	ISO/IEC 17025 (including the ability to evaluate and decide on conformity), or ISO/IEC 17020 (ISO/IEC 17025 to be observed for testing required), or EN 45011 (ISO/IEC 17025 to be observed for testing required)
Production quality assurance (Annex IV), Module D	EN 45012 (+ product related knowledge)
Product quality assurance (Annex VII), Module E	EN 45012 (+ product related knowledge)
Product verification (Annex V), Module F	ISO/IEC 17025 (including the ability to evaluate and decide on conformity), or ISO/IEC 17020 (ISO/IEC 17025 to be observed for testing required), or EN 45011 (ISO/IEC 17025 to be observed for testing required)
Unit verification (Annex IX), Module G	ISO/IEC 17020 (ISO/IEC 17025 to be observed for testing required), or EN 45011 (ISO/IEC 17025 to be observed for testing required)

5.4 Managing the assessment if more than one conformity assessment standard is used

Where the applicant body's proposed scope of appointment requires operation in accordance with the requirements of more than one conformity assessment standard, it may choose to base its systems on one selected core standard and deal with the relevant requirements of the other standards as additions to its base system. The parts of the standards covering technical competence requirements however, such as facilities and equipment, training and qualification of personnel, should be carried out on the basis of the requirements of each standard.

5.5 Policy on accreditation

The Council Decision 93/465/EEC concerning the modules, established that accreditation to a relevant standard in the EN45000 series provided a presumption of conformity to the minimum criteria in relevant directives. However, this statement needs to be qualified in two ways:

1. The requirements in the standards must be related to the specific tasks to be performed according to the relevant Directive;
2. All the standards include requirements on independence but they do not deal with the issues in the same way.

Further clarification is therefore provided in these guidelines to ensure that these points are dealt with in a consistent fashion.

If an applicant body is already accredited by UKAS to one of the conformity assessment body standards, for an appropriate scope, then any subsequent application for appointment as a notified body for a directive with a similar scope, will involve the minimum of additional work for the UKAS assessment.

Notwithstanding its importance, accreditation to any of the standards is not mandatory. However, if an applicant body does not wish to be accredited as part of the UKAS notified body assessment, the assessment will still be based on the relevant standard, but in this case only those requirements that are relevant to the Regulations will be assessed by UKAS.

6.0 MEETING THE MINIMUM CRITERIA USING THE CONFORMITY ASSESSMENT BODY STANDARDS

6.1 Additional specific information

This section sets out additional specific information to assist with the interpretation of the minimum criteria and the application of the conformity assessment body standards in the context of the Regulations.

6.2 Independence and impartiality

The first criterion in Section 4 prohibits the notified body from being any of the types of economic operators listed, or from being directly involved in any of the activities listed. The second criterion refers to the notified body being “...free from all pressures and inducements, particularly financial that might influence their judgements or the results of the inspection.....”.

In this respect, applicant bodies will be required to meet clause 4.2.1 (Type A) of EN 45004 (ISO/IEC 17020) “General criteria for the operation of various types of bodies performing inspection.” In addition, the EA Guidance to clause 4.2.1 shall be applied and has been included for reference in Annex 4.

(These requirements only apply in respect of products within the same technical scope area as that of the appointment.)

6.3 Technical competence of the notified body

The capability of a notified body to conduct its work depends on the collective competence of its staff as well as how the staff are organised and managed. The applicant body shall demonstrate with respect to the scope of appointment for which it has applied:

- a thorough technical understanding of the products concerned;
- the ability to undertake the duties of a notified body as set out in the conformity assessment procedures in the Regulations;
- a thorough knowledge of the Directive and the Regulations;
- a thorough working knowledge of the relevant essential requirements and the harmonised standards (please see section 6.6).

6.4 Identifying and assessing the technical competence of the applicant body on the basis of the Essential Health & Safety Requirements (EHSRs)

Under the appropriate conformity assessment procedure, the applicant body must be able to make an assessment directly to the EHSRs of the Regulations. The EHSRs will therefore form the basis of identifying and assessing the technical competence of an applicant body.

6.5 Permanent staff and staff under contract

The applicant body shall have under its control (i.e. as employees or by defined contractual access) the staff that between them have the range of individual competencies required for the full scope of its appointment. The applicant body may employ experts in particular fields through various forms of service contract, but the experts shall operate under the applicant body's quality management system in the same way as a member of its staff. The competence of experts shall be assessed and recorded in the same manner as for the body's permanent staff. The work carried out by experts for the applicant body shall be covered by the applicant body's professional indemnity and public liability insurance. There shall be a sufficient number of permanent staff to enable effective selection, management and review of expert staff under contract. Where the applicant body sub-contracts work expert staff under contract may be used to assist in the selection and monitoring of the work of sub-contractors.

6.6 Competence of individual staff involved in conformity assessment

The following requirements are intended to provide a common framework of terms and relationships that can be used by an applicant body to demonstrate to UKAS how it manages the assignment of different types of work to staff.

6.6.1 Competence categories

Each member of staff that is involved in conformity assessment shall be assigned one of the following competence categories:

- Competence category 1: carrying out work that involves the exercise of engineering judgement where only broad parameters and principles are defined e.g. EHSRs;
- Competence category 2: carrying out work that involves the exercise of engineering judgement within a field defined by written specifications, e.g. harmonised standards;
- Competence category 3: carrying out work in accordance with written technical specifications and instructions, e.g. testing and inspection procedures;
- Competence category 4: carrying out simple inspections or tests against specified numerical limits or visual standards.

6.6.2 Competence requirements

a) Education and professional qualifications

The following qualifications are intended as indicative rather than obligatory hard and fast requirements. Equivalent qualifications will be acceptable. It is

up to the notified body to satisfy itself and UKAS that the qualification criteria that it specifies in its quality management system are appropriate to the work and the conditions under which it is carried out.

- Competence category 1: Chartered Engineer in a relevant discipline.
- Competence category 2: BSc in a relevant engineering subject.
- Competence category 3: HNC or City & Guilds in a relevant engineering subject.
- Competence category 4: No technical qualifications are specified.

b) Knowledge

The applicant body shall possess the full range of technical, legal and procedural knowledge for the scope of work for which the body is notified. Individual staff should have a practical working knowledge of the source material such as; directives, relevant legislation (including implementing Regulations) standards, notified body group clarification sheets, and how and where they should be applied. In particular, staff in competence category 1 will need to understand the significance of deviations found with regard to products and manufacturing processes.

c) Experience

In the context of these guidelines, experience is taken to mean a history of carrying out work and applying knowledge that subsequently enables a person to demonstrate the competence to carry out work for the notified body. For work carried out under the constant supervision of a competent person, no specific experience is required. If work is to be carried out under the occasional supervision of a competent person, the following experience is recommended. (Please see 6.6.4 for 'degree of supervision'.) These periods are indicative and a shorter period may be acceptable if there is objective evidence of the achievement of the appropriate level of competence.

Competence category 1: 5 years

Competence category 2: 2 years

Competence categories 3 and 4: 1 year

For competence categories 1 and 2, experience gained by a person while working in the same, or a directly related field, at the next lower competence category can reduce the terms in the following way.

Two years or more at competence category 2, could reduce the period shown for competence category 1, from 5 years to 3.

One year or more at competence category 3, could reduce the period shown for competence category 2, from 2 years to 1.

(This is not intended to imply that a member of staff joining at category 3 or 4 would be expected to progress up to category 1, but experience gained at one level should be taken into account on promotion to the next level.)

6.6.3 Assessment of competence

The quality management system of the applicant body (see section 6.10) shall:

- Define the process for assessing and recording competence at the designated levels;
- Specify how work is allocated to people according to their designated competence;
- Define the degree of supervision that is required by people according to their designated competence.

6.6.4 Degree of supervision

Supervision may range from 'constant' for people new to an area of work to 'occasional' for people who have been designated as competent for the work they are undertaking. The quality management system should provide for circumstances where a person finds that the work is beyond their designated competence and needs to refer it to a person having the appropriate competence.

The degrees of supervision are defined as:

- Constant – direct daily contact with Supervisor at site of operation. Authoritative technical support from Competence category 1 or 2 personnel to be readily available.
- Occasional – direct contact with Supervisor at least monthly. Authoritative technical support from Competence category 1 or 2 personnel to be available as required.

6.7 Harmonised standards

The Regulations also define the role of harmonised European standards produced in response to a mandate from the European Commission. Products that comply with national standards transposing harmonised standards, the reference numbers of which have been published in the Official Journal of the European Communities, are presumed to comply with the corresponding essential health and safety requirements. A notified body shall be familiar with the harmonised standards and their application. However, it is important to note that this does not reduce the priority given to the essential health and safety requirements as the basis for assessing the technical competence of a notified body.

6.8 Insurance

A notified body's activities under the directive, must be covered by public liability and professional indemnity insurance. An explanation of these terms has been included to be helpful but they shall not be taken to be legal advice. It is the responsibility of the notified body to ensure that the policies are properly integrated to avoid disputes in the event of borderline claims and that the arrangements are adequate for its requirements in terms of scope and level.

6.8.1 Public liability insurance

Covers the legal liability of the notified body to members of the public (i.e. third parties not employed by the notified body or its clients) in respect of accidental bodily injury to any person or accidental loss of or damage to property happening in connection with its business as a notified body. The notified body will not necessarily be in a contractual or any direct relationship with the third party. The territorial limits of the public liability insurance must include all countries in the European Economic Area (EEA) and in addition those countries listed in Annex 1 covered by inter-country agreements. If the notified body has been appointed to work under Mutual Recognition Agreements then it shall comply with the insurance requirements of the country of destination.

6.8.2 Professional indemnity insurance

Indemnifies the notified body against any claim for damages for breach of professional duty due to any negligent act or omission, to those to whom the notified body is under contract, or to others to whom it has provided professional advice and owes a duty of care. The policy shall provide this cover wherever the clients of the notified body are located. The policy may however include a restriction on jurisdiction that limits any claims for damages to a specified court.

6.8.3 Provision of information on insurance to the Department and UKAS

The applicant body shall send summary written evidence of its public liability and professional indemnity insurance policies provided by its insurance broker to the Department and UKAS, prior to any appointment as a notified body. The summaries shall include the scope, applicable conditions, the amount of cover, the territorial limits, jurisdiction and period of application. They may be submitted when the organisation makes an application or, at the latest, when UKAS has completed its assessment with a recommendation that the applicant body should be appointed. If the former, it may be necessary to ensure that the insurance arrangements are still in place at the time of any appointment. Thereafter, as one of the conditions of appointment, the notified body shall provide UKAS with a summary of current insurance cover at each annual surveillance visit.

6.8.4 Responsibility for insurance

The Secretary of State will not under any circumstances cover any liability of the notified body (except for the Secretary of State's liability (if any) if appointed as a notified body). The provision of evidence of insurance to either UKAS or the Department should not be construed as either party's confirmation of the adequacy of such insurance, as this is the responsibility of the notified body. The Department or UKAS may however ask the applicant body to explain the basis on which the amount of insurance has been determined, the Department reserves the right to refuse or withdraw the appointment if the issue cannot be resolved to the Department's satisfaction.

6.9 Testing and inspection facilities

Where the notified body operates its own testing, or inspection facilities these facilities and their associated activities, shall conform to the relevant requirements of BS EN ISO/IEC 17025:2000 or BS EN 45004:1995, respectively, though accreditation is not mandatory. Where the notified body's certifications are dependent wholly or in part on test or inspection facilities or results provided by another party, (e.g. a manufacturer), the notified body shall satisfy itself that the tests and inspections are carried out to its satisfaction in accordance with the requirements of the relevant conformity assessment standards.

6.10 Quality management system of the applicant body

The notified body shall operate a quality management system as described in the relevant accreditation standard, that is appropriate to its scope of appointment. The quality policy of the notified body shall include a commitment that it shall meet all the requirements in these guidelines when carrying out its duties as a notified body. The quality management system will be documented in relevant manuals, procedures and work instructions as appropriate that will form the basis for control of the applicant body by its management. Where an applicant wishes to undertake work that falls within the scope of more than one conformity assessment body standard, the management system will identify the base standard, the additional standards and ensure that the relevant requirements not covered within the base standard are met.

6.11 Subcontracting

Where tasks relating to conformity assessment are carried out on behalf of a notified body by subcontractors, the notified body shall ensure that such subcontractors and their personnel conform to all the requirements of the regulations and these guidelines, that would apply had the task been performed by its own personnel.

6.11.1 Assessment by UKAS

The procedures of the applicant body in relation to its subcontractors will be a part of the UKAS assessment of the body

6.11.2 Limits on the activities that can be subcontracted

The notified body shall not subcontract the responsibility for making its conformity assessment decisions. Subcontracting shall be limited to defined, discrete supporting activities, on the basis of which the notified body shall make assessments and judgments in relation to the requirements of the regulations.

6.11.3 Documented agreement between the notified body and its subcontractors

A documented agreement shall be drawn up between the notified body and its subcontractors reflecting these requirements, including that of confidentiality. This agreement shall also prohibit subcontractors from further subcontracting their duties.

6.11.4 Documented procedures used by subcontractors

The notified body shall ensure that the subcontracted activities are carried out according to detailed documented procedures that are the same as, or judged by the notified body to be equivalent to, those followed by the notified body itself in the context of conformity assessment.

6.11.5 Competence of the notified body to assess subcontracted work

The notified body shall have staff with the necessary expertise to monitor the performance and assess the work of subcontractors.

6.11.6 The register of subcontractors

The notified body shall keep an up to date register of all its subcontractors and include the following information:

- the name and address of all the subcontract organisations;
- the tasks to be carried out by the subcontractors
- documented evidence of the technical competence and facilities of the subcontractors to carry out the tasks.

6.11.7 Availability of the register

The register shall be available for scrutiny at any reasonable time on request by UKAS, the Secretary of State or such other person as may be appointed by the Secretary of State.

6.11.8 Subcontracting to organizations located outside the UK

The conditions on subcontracting in these guidelines apply irrespective of whether the subcontractor is located in the UK, the Community or a third country.

7. DUTIES OF A NOTIFIED BODY

7.1 Access to the services of a notified body and equal treatment

The notified body shall ensure that it does not unreasonably restrict access to its services or place undue financial or other conditions upon manufacturers (or any others) seeking their services under relevant conformity assessment procedures. The procedures under which a notified body operates must be administered in a non-discriminatory manner.

7.2 Conformity assessment

The notified body shall carry out conformity assessment on products, or quality management systems, as specified in its scope of appointment, according to the conformity assessment procedures in the Regulations.

7.3 Procedures to ensure consistency

Where judgements or interpretation of a standard or requirement are implicit or explicit in a decision to grant or withhold certification, the notified body is required to have procedures for achieving consistency in such matters.

7.4 The assessment of a manufacturer's quality management system

The notified body must assess the quality management system to determine whether it satisfies the requirements in the appropriate module (D or E), or annex (IV or VII). Compliance to BS EN ISO 9001:2000, as the relevant harmonized standard, gives a presumption of conformity to the requirements of modules D or E, provided the quality management system is implemented to ensure that the product meets the essential requirements referred to in the module. In the case of modules D and E it is permissible to exclude certain specific requirements from BS EN ISO 9001:2000 whilst retaining the presumption of conformity. These specific requirements relating to New Approach Directives and CE Marking are set out in the foreword to BS EN ISO 9001:2000. It should be noted however that notwithstanding compliance with the directive, if a manufacturer excludes more than can be justified by clause 1.2 (Application) of BS EN ISO 9001:2000 then it will not be possible to claim compliance with the standard.

If an accredited certification body, with a scope included in the scope of the Regulations, has certified that the manufacturer's quality management system meets the requirements of BS EN ISO 9001:2000, the notified body should take this into account during its assessment and avoid unnecessary duplication. The notified body may reduce the extent and frequency of assessment and surveillance, provided it is satisfied that the audits and surveillance carried out by the certification body ensure that the product meets the essential requirements referred to in the module.

7.5 Documentation to be retained

A notified body is required to maintain an up to date record of all certification that it has issued, to whom it has been issued and to what it applies. These records shall be retained by the notified body and made available on request to the Secretary of State, or such other person as may be authorised by the Secretary of State, subject to the usual provisions relating to confidentiality. A list of the relevant technical documentation must be annexed to the certificate and a copy kept by the notified body. Where the Regulations do not explicitly require a notified body to retain copies of the technical documentation for a certain period of time, this is a matter of agreement between the notified body and its client. It is suggested however, that the technical documentation relating to the certification issued should be retained until the certificate is no longer valid or required either as a matter of contract or to comply with requests from the enforcement authorities.

7.6 Participation in co-ordination activities

Notified bodies are required to participate in the notified body co-ordination activities at the national and European level. Notified bodies should demonstrate active participation by a record of frequent attendance at UK meetings and they should also show that they have an effective means of providing input and making themselves aware of the outcome of co-ordination at the European level. The notified body shall take account of notified body co-ordination decisions at the European level. The Department will be responsible for monitoring the level of participation at UK meetings, and UKAS will be responsible for checking that the notified body participates, in the way described, at the European level.

7.7 Circumstances in which a notified body shall contact the Department

The notified body shall inform the Department of the occurrence of the following events:

- a) the withdrawal of an EC type examination certificate by the notified body (including the reasons for doing so);

b) any changes which, in any way, have a bearing upon its status as a notified body, or its ability to perform the duties and functions in its scope of appointment;

c) details of any defective harmonised standard and, if relevant, an inappropriate application of harmonised standards. (Defective standards are those which do not fulfil the mandate issued to the European Standards organisations by the Directive 98/34/EC Article 5 committee, and/or do not fully address the essential health and safety requirements of the Regulations).

For point (b) the notified body shall also inform UKAS.

7.8 Confidentiality

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.

7.9 Policy and procedures for the control of its identification number

The notified body's documentation shall state its 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. 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 in the quality manual and the reference numbers of the documentation listed.

7.10 Involvement of a notified body in conformity assessment at the request of a manufacturer that is not covered by the Regulations

A manufacturer may ask a notified body to become involved in a conformity assessment procedure that is not required by the Regulations (e.g. carrying out testing as part of module A). In such circumstances the notified body shall have procedures to ensure that any marking on the product, or certification provided by the notified body, shall be distinguishable from marking on the product or certification that relates to the requirements in the Regulations.

8. MUTUAL RECOGNITION AGREEMENTS

Applicants should note that the European Community has established 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. 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. So far, for ATEX an MRA has only been agreed with Switzerland, and all EU Notified Bodies appointed for the specific sectors covered by the MRA will automatically be included in the relevant lists of Notified Bodies.

ANNEX 1

CONTRACTING PARTIES TO THE EUROPEAN ECONOMIC AREA AGREEMENT

Products meeting the requirements of the Regulations have free circulation throughout the European Economic Area which consists of EU member states and the EFTA countries.

EU MEMBER STATES

Austria	France	Lithuania	Slovenia
Belgium	Germany	Luxembourg	Spain
Cyprus	Greece	Malta	Sweden
Czech Republic	Hungary	Netherlands	United Kingdom
Denmark	Ireland	Poland	
Estonia	Italy	Portugal	
Finland	Latvia	Slovakia	

EEA EFTA MEMBER STATES

Iceland	Norway	Liechtenstein
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Candidate Countries

- Bulgaria
- Romania
- Turkey
- Croatia

The position of the candidate countries will evolve and the current situation can be checked via the following link:

<http://trade-info.cec.eu.int/tbt/index.cfm>

ANNEX 2

CONTACT INFORMATION

- **The applications for appointment described in Annex 3, (UKAS publications) should be sent to:**

United Kingdom Accreditation Service
21-47 High Street
Feltham
Middlesex
TW13 4UN

Tel: 0208 917 8400
Fax: 0208 917 8500
Email: info@ukas.com
Web site: www.ukas.com

And be copied to:

Mrs R.A.Wasserberg
Department of Trade and Industry
Standards and Technical Regulations Directorate 4
Bay 322
151 Buckingham Palace Road
London SW1W 9SS

Tel: 020 7215 1427
Fax: 020721501529
Email: rosemary.wasserberg@dti.gsi.gov.uk

- **UK Notified body forum for the Directive:**
Please contact one of the listed Notified Bodies for information, or the contact at DTI

ANNEX 3

SOURCES OF INFORMATION AND RELEVANT DOCUMENTS

- **The Directive**

The complete text of the Directive has been published in the Official Journal of the European Communities No. L100 19 April 1994. Copies of this text may be obtained from:

The Stationery Office
Norwich
NR3 1GN

Tel : 0870 600 5522
Fax: 0870 600 5533

{The Eur-lex website <http://europa.eu.int/eur-lex/en/index.html> has the Official Journal from 1998 onwards on-line. It is possible to download copies of Directives published prior to 1998 from this site using the Directive reference number but it is in HTML format and graphics are not reproduced. This problem does not occur with the corresponding Regulations downloaded from HMSO below.}

- **The UK Regulations**

The {Regulations S.I.1996 No. 192 amended by S.I. 2001 No.3766} may be obtained from The Stationery Office (please see above.)

Or by direct download from:

Web: <http://www.hmso.gov.uk/stat.htm>

- **European and national standards**

Copies and information on the relevant standards in the EN 45000 and ISO/IEC 17000 series are available from:

BSI
389 Chiswick Road
London
W4 4AL

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

DTI

<http://www.dti.gov.uk/strdpubs.html>

- Guidelines on the “Equipment and Protective Systems for Use in Potentially Explosive Atmospheres Regulations 1996”
- List of UK notified bodies for the Regulations

UKAS Publications

<http://www.ukas.com>

- Applications to UKAS for assessment as a notified body will require two forms (i) a general form and (ii) AC 6 Approved or notified body form. Both forms should be returned to UKAS and copied to the Department.

The following publications may also be of interest:

- LAB 3 The conduct of UKAS Laboratory Assessments;
- C1 General principles for the assessment of certification bodies for management certification;
- C2 General principles for the assessment of certification bodies for product certification;
- E1 General principles for the assessment of inspection bodies by the United Kingdom Accreditation Service.

European Commission

- ATEX Guidelines (first edition), published by the European Commission May 2000 and other relevant information concerning the ATEX Directive and its application are on:

<http://www.europa.eu.int/comm/enterprise/atex/guide.htm>

Notified bodies notified by the UK and other Member States are listed in:

- NANDO Information system

<http://europa.eu.int/comm/enterprise/nando-is/home/index.cfm>

Explanations of the terminology that is used in directives and further background information can be found in:

- The New Approach Guide

<http://europa.eu.int/comm/enterprise/newapproach/legislation/guide/legislation.htm>

European Accreditation (EA)

<http://www.european-accreditation.org/>

Tel: 020 8996 9001

Fax: 020 8996 7048

Web: www.bsi-global.com

UKAS Publications

<http://www.ukas.com>

- Applications to UKAS for assessment as a notified body will require two forms (i) a general form and (ii) AC 6 Approved or notified body form. Both forms should be returned to UKAS and copied to the Department.

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ANNEX 4

Extract from EA 5/01 “Guidance on the application of EN 45004 (ISO/IEC 17020)”

G4.5 A Type A Inspection Body, to claim to be independent of the parties involved, shall demonstrate that it is not linked to a party directly involved in design, manufacturer, supply, installation, purchase, ownership, use or maintenance of the items inspected or similar competitive items by

- common ownership (except where the owners have no ability to influence the outcome of an inspection), *Note 1*;
- common ownership appointees on the boards (or equivalent) of the organisations except where these have functions that have no influence on the outcome of an inspection) *Note 2*;
- directly reporting to the same higher level of management;
- contractual arrangements, informal understandings or other means that may have an ability to influence the outcome of an inspection.

In addition to the above, an Inspection Body shall not become a Type A Inspection Body if another part of the same organisation is directly involved in design, manufacture, supply, installation, purchase, ownership, use or maintenance of the items inspected or similar competitive items, when such other parts of the organisation do not have a separate legal identity.

The Chief Executive of the legal entity of which the Inspection Body is a part shall define and document its policy for maintaining Type A status of the Inspection Body. The Accreditation Body will examine the evidence of implementation of this policy in respect of ownership interests, constitution of board of directors, means of financing, decision making methods and other such factors that may have an influence on the impartiality, independence and integrity of a Type A Inspection Body

Note 1 An example of this is a co-operative type of structure where there are a large numbers of stakeholders but they individually or as a group have no formal means of influencing the policies, strategies or operation of the inspection body.

Note 2 An example of this is where a Bank financing a company may insist on an appointee to the board to overview how the company is manage but will not be involved in any decision making.

END